# Evaluating the GPhC's approach to regulating community pharmacies

**Final Report to the General Pharmaceutical Council**

**ICF Consulting Services**

**20 August 2015**

# Document Control

| Document Title | Evaluating the GPhC's approach to regulating community pharmacies |
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# Contents

# Glossary – terms and definitions

## C

**Community pharmacy**: in the context of this report, a registered pharmacy serving patients and users of pharmacy services, often on the high street.

**Community pharmacy professionals**: registered pharmacists and pharmacy technicians who work in a community pharmacy located in England, Scotland or Wales.

**Community pharmacist (see also: "pharmacist")**: a registered pharmacist who works in a community pharmacy.

## I

**Independent(s) (or independent pharmacy)**: a community pharmacy business with five or fewer pharmacies.

**Inspected pharmacy**: although registered pharmacies were previously inspected by the GPhC and its predecessor body, in the context of this report, an inspected pharmacy is one that has been inspected since the introduction of the GPhC's new approach on 4 November 2013.

## L

**Locum (or locum pharmacist)**: a pharmacist who fulfils the duties of the regular pharmacist on an ad hoc basis, typically under temporary contract or self-employed.

## M

**Multiple(s) (or multiple pharmacy)**: a community pharmacy business with six or more pharmacies, such as large high street chains, or in-store supermarket pharmacies.

## N

**Non-community pharmacy professionals**: in the context of this report, pharmacists and pharmacy technicians working in settings other than community pharmacy, such as hospitals, primary care, industry and research.

## O

**Owner**: may be an individual pharmacist (sole trader); a pharmacist partnership; a partnership in Scotland where only one partner must be a pharmacist; a body corporate that owns a retail pharmacy business; or a representative of the aforementioned in the event of death or bankruptcy. An owner is responsible for ensuring their pharmacy meets the GPhC's standards.

## P

**Patients and users of pharmacy services**: any individuals or groups, patients, customers and clients who use or need pharmacy services, advice or other services provided by pharmacy professionals.

**Pharmacist**: a healthcare professional registered with the GPhC to practise in Great Britain. Only a registered pharmacist can act as a responsible pharmacist or superintendent pharmacist. (See also: "responsible pharmacist", "superintendent pharmacist", "owner").

**Pharmacy services**: the activities, advice, products, treatment or care that is provided at or from a registered pharmacy.

**Pharmacy technician**: a healthcare professional registered with the GPhC to practise in Great Britain. In a community pharmacy, a pharmacy technician will typically work under the supervision of a registered pharmacist.

## R

**Registered pharmacy**: a retail pharmacy business that consists of or includes the retail sale of medicinal products, including medicines classed as GSL (general sale list), pharmacy only (P) medicines or prescription only medicines (POM) against a prescription. Registered pharmacies in Great Britain are regulated by the GPhC.

**Responsible pharmacist**: to conduct a retail pharmacy business lawfully, a registered pharmacist must be in charge as the responsible pharmacist, to ensure the safe and effective operation of the pharmacy. The name of the responsible pharmacist is recorded in the pharmacy record and displayed in the registered pharmacy.

## S

**Superintendent pharmacist**: a pharmacist who is a superintendent of a retail pharmacy business owned by a body corporate, with responsibilities detailed in the Medicines Act 1968.  A superintendent is responsible for ensuring their company's pharmacies meet the GPhC's standards.

# Headline summary

This document constitutes the Final Report for a study to evaluate the new approach to regulating community pharmacies in Great Britain introduced by the General Pharmaceutical Council (GPhC) in November 2013.

The aim is to provide the GPhC with a better understanding of how well the new regulatory approach is working in practice and the extent of its impact. Evidence from primary and secondary research (community and non-community pharmacy professionals, GPhC inspectors and stakeholder organisations) has been gathered and analysed to reach conclusions that will inform the GPhC's ongoing regulatory reforms and further improve the effectiveness of the new interventions.

## Summary of key findings

### To assess whether the new approach is consistent with the GPhC's ambitions, objectives and goals

The new GPhC framework is assessed to be working well. Those working in community pharmacies, GPhC inspectors and stakeholder organisations all agree that the new approach is operating satisfactorily and is an improvement on the previous approach. Standards are generally well-understood by community pharmacy professionals and the current framework encourages community pharmacy professionals to act on their own initiative when meeting the regulatory standards.

### To test whether the new interventions are working well

The four interventions introduced under the new approach (i.e. standard setting, inspections, action planning, reporting and rating) are each assessed to be working as intended, and are helping to deliver better outcomes to patients and users of pharmacy services:

- **The principles and standards** underpinning the new approach are clear to pharmacy professionals. A few concerns were raised regarding the lack of clarity in the wording of some standards, and the level of duplication among certain standards.

- **Inspections** are a key intervention tool – they are working well and there is evidence that inspections are increasingly helping to promote awareness of the standards in the community pharmacy sector. They are also seen as an opportunity to further "educate" pharmacy teams. The study found that there is an appetite for more frequent visits and post-inspection follow-ups.

- **Actions plans** are generally well-received by community pharmacy professionals as an efficient and effective way to address the most serious failings and to improve areas most relevant to patient safety. The study identified a preference to extend the time window for implementing actions plans, where resources are stretched.

- **Inspection reports and ratings** are valuable when designing and implementing improvements in quality and performance as well as ensuring continued focus on the needs of patients and users of pharmacy services. Pharmacy professionals and GPhC inspectors raised concerns about the lack of clarity and differentiation between ratings. Publication of inspection reports and ratings is expected to improve sector performance and increase accountability of pharmacies when meeting the standards. Most study participants supported the GPhC's proposals to publish the reports and ratings.

### To assess whether the outcomes targeted under new approach are being achieved

There is evidence that the culture is gradually shifting away from the previous rules-based approach to compliance towards a focus on patient outcomes and continuous improvement. Multiples were more likely (although the difference is small) than independents to consider their services to be patient-focused as a result of the new standards. There is no clear-cut evidence as to whether the new approach is helping sustain improvements in community pharmacies. The new approach is still in its early days and further rounds of inspections are required to provide a more complete picture of its achievements.

# Executive summary

## Introduction

This document constitutes the Final Report for a study to evaluate the new approach to regulating community pharmacies in Great Britain introduced by the General Pharmaceutical Council (GPhC) in November 2013. Putting patients first is core to this new approach, alongside legal compliance and standard operating procedures that were the focus of the previous regime.

## Objective of this study

The aim of this study is to provide the GPhC with a better understanding of how well the new regulatory approach is working in practice and the success of its objectives. An intervention logic model was used as a framework to assess the direct impacts of the new regulatory interventions (such as improved awareness, increased compliance) and how they translate into changes in pharmacy and patient outcomes (such as safer premises, improved pharmacist-patient interactions). These have been tested and evidenced through data gathered as part of a literature review exercise and primary research with community pharmacy professionals, GPhC inspectors and stakeholder organisations[1]. Evidence from these various sources has been triangulated to reach conclusions that will inform the GPhC's ongoing regulatory reforms and further improve the effectiveness of newly-introduced interventions in the community pharmacy sector.

**Figure 1 Consolidated logic model of the GPhC's new approach to regulation**



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## Methodology

The collection of primary evidence during this study involved three main elements:

1. An online census was designed to draw on community pharmacists and pharmacy technicians' experience of the new regulatory approach. 5,350 responses were received and analysed.
2. Qualitative semi-structured interviews were designed to provide a more detailed understanding of the new regulatory approach, particularly around the new standards for registered pharmacies[2], inspections and action plans. The interviewees were selected by the GPhC. In total 18 qualitative interviews were conducted with GPhC inspectors and stakeholder organisations.
3. Qualitative semi-structured depth interviews were designed to unpack individual responses to the online questionnaire and explore in depth the issues of relevance to the study. 20 interviews were conducted in total.

To inform primary data collection tools and facilitate discussion, existing research and information was also gathered and reviewed.

## Summary of key findings

### To assess whether the new approach to regulation is consistent with the GPhC's ambitions, wider objectives and goals

The new GPhC framework seems to be working well according to those working in community pharmacies, GPhC inspectors and stakeholder organisations. Standards are generally well-understood by community pharmacy professionals because they set out clearly what is expected to meet the standards. Further, there is evidence that the current framework encourages community pharmacy professionals to act on their own initiative when meeting the regulatory standards.

However, some community pharmacy professionals still practise a compliance approach (so-called tick-box approach) to regulation, focused on achieving a narrow set of targets, rather than adopting a more systematic approach to improvement which requires an understanding of the drivers of continuous improvement. This is considered an issue of cultural adjustment, which will diminish over time. The following aspects of the framework seem not be working very well, as stressed by study participants:

■ There is a request for more guidance from inspectors on how to rate pharmacies, i.e. focusing on practical examples that would help link pharmacy evidence to the inspection framework.

■ There is not enough information regarding the evidence and measures pharmacies need to prepare to achieve a certain rating.

### To test whether the new interventions are working well

Most of the evidence gathered as part of this research indicates that the GPhC's new regulatory approach is working well. The four interventions introduced under the new approach (i.e. standard setting, inspections, action planning, reporting and rating) are largely working as intended, and helping to deliver better outcomes to patients and users of pharmacy services. A clear link between outcomes and impacts of the intervention tools is established in all cases, as presented by the logic model in Figure 1 above.

**The principles and standards** underpinning the new approach are clear for pharmacy professionals. However, there were some differences between online census respondents regarding pharmacy professionals' experience of the standards:

■ Pharmacy technicians displayed a slightly higher level of understanding than pharmacists, reflecting the increasing role pharmacy technicians play during inspections. This is in line with the new approach to regulation, which encourages the involvement of the whole pharmacy team in the inspection process.

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[2] Available at: https://www.pharmacyregulation.org/standards/standards-registered-pharmacies

- Community pharmacy professionals operating in multiples indicated a higher level of understanding of all five principles underlying the new GPhC standards compared to those working in independent pharmacies. These differences are potentially due to more training, guidance and knowledge sharing provided to staff in multiples, more difficult to offer and achieve in independent pharmacies.

- Community pharmacy professionals based in England and Scotland seem to have a slightly higher level of awareness of the standards than those based in Wales.

**Inspections** are working well and there is evidence that inspections increasingly help to promote awareness of the standards in the community pharmacy sector. Indeed, those working in recently inspected pharmacies were more likely to say that they clearly understood the principles and fully implemented relevant standards (particularly regarding governance arrangements and staff empowerment) than those working in pharmacies awaiting inspection.

Inspections are seen as an opportunity to further "educate" pharmacy teams. Most interviewees and online survey respondents felt that engaging with the whole pharmacy team during the inspections is crucial to driving better compliance and achieving consumer-focused outcomes. This aspect of inspections is more important to pharmacy technicians than to pharmacists, reflecting their increasing role under the new approach and "buy-in" this is intended to generate.

**Actions plans** are generally well-received by community pharmacy professionals as an effective way to address the most serious failings and to improve areas most relevant to patient safety. Action plans target specific areas deemed lacking by the inspector, allowing respondents to define priorities for improvements and assign responsibilities within the pharmacy team to rectify failings as effectively and quickly as possible. However, there is some evidence that action plans provide insufficient time for pharmacies to implement remedial action.

**Inspection reports** are a valuable tool when considering and implementing improvements in quality and performance, as well as ensuring continued focus on the needs of patients and users of pharmacy services. Inspected pharmacies supported this opinion more than those not yet inspected. While GPhC inspectors and stakeholder organisations generally recognised that ratings incentivise pharmacies to focus on the standards, the general opinion was that certain ratings, in particular the "satisfactory" rating, are misleading and often demotivating for pharmacies. Additionally, some expressed concern that the "satisfactory" rating has potentially significant knock-on effects, such as undermining patients' trust and confidence in services provided by community pharmacy.

### Whether outcomes targeted under the new approach are being achieved

There is evidence that the culture is gradually shifting from one that previously focused primarily on rules and compliance, towards a focus on patient outcomes and improvement – this has been achieved thanks to the introduction of new regulatory interventions such as standards and inspections.

Standards encourage the pharmacy team to understand the importance of their roles and responsibilities, and to see the "bigger picture". Most community pharmacy professionals increased patient focus by working closely with the standards embedded in daily work practices and training policies. In particular, the whole pharmacy team is encouraged to be fully involved in the day-to-day activities of the pharmacy and to acquire first-hand knowledge of the new GPhC intervention tools. Multiples were more likely than independents (although the difference is small) to consider their services to be patient-focused as a result of standards (86 per cent compared to 81 per cent), potentially by more regularly reviewing and monitoring the safety and quality of their pharmacy services.

Inspections are key to maintaining good levels of practice. They help community pharmacy professionals focus more on their patients and users of pharmacy, and encourage them to enhance the services they offer to them, for example, providing additional services to patients and pharmacy users, such as emergency services and home visits. Also, the new approach to regulation encourages community pharmacy professionals to promote better interactions between patients and users of pharmacy services and the pharmacy team.

While there is evidence of a shift in culture, there is little information yet to suggest that the new approach leads to sustained improvements. This is to be expected given the short time since the implementation of the new approach. How far the different interventions, in particular inspections and action-planning, encourage continued focus on improvement is also difficult to assess – inspections have historically been carried out every three years on average, and there is little post-inspection data available yet.

Where an action plan is implemented, it leads to improvement, but it is not clear whether the new GPhC interventions generate *continued* improvement. Further, there is only limited evidence that inspection reports and ratings result in sustained improvements in outcomes. While reports and ratings tend to act as a "wake-up call," pushing pharmacies towards greater compliance, some GPhC inspectors felt that such changes are not maintained long-term, partly because these reports are not yet publicly available. Reputation and competition with neighbouring pharmacies could be a significant driver of improvement if these reports were published. However, a few GPhC inspectors and stakeholder organisations pointed out that the new rating system might discourage pharmacies as the term "satisfactory" is perceived negatively and the wide definition of "satisfactory" might discourage pharmacies from actively pursuing further improvement.

### Whether there is any scope for improving the newly-introduced regulatory interventions, as suggested by study participants

Overall, the evidence gathered and analysed during the course of this study shows that the experience of the process and outcomes of the GPhC's new approach to regulating pharmacies has generally been positive, although the work has identified areas for improvement which would benefit from the GPhC's consideration.

Suggested improvements include simplifying the wording of some of the standards and avoiding unnecessary duplication, reducing uncertainties over the evidence and measures required to achieve them. The majority of GPhC inspectors interviewed suggested that standards that overlap (for example around governance) should merge to provide more clarity and time to focus on the areas of most concern during inspections.

Inspections are a key intervention tool (supported by action plans) – they drive the standards and promote good practice. The study analysis shows that some community pharmacy professionals want regular visits from the inspectors which, in their opinion, would help maintain a continued focus on standards and improvement. Receiving feedback from inspectors is among key suggestions put forward by pharmacists to improve the inspection process.

There is a need for greater clarity and differentiation between ratings. Some GPhC inspectors reported that additional guidance on how to rate pharmacies under the standards would be useful. There is also a perceived lack of information for community pharmacy professionals regarding the evidence and measures needed to achieve a certain rating.

Regarding the publication of reports and ratings, there is evidence that making them public could help improve sector performance, increase accountability of pharmacy owners, and increase patients and users of pharmacy's trust in pharmacy care.

## Concluding remarks

The new GPhC approach to regulating pharmacies is generally well-received by the pharmacy sector as the new intervention tools increase sector performance and help deliver better outcomes to patients and users of pharmacy services. While there is evidence of a shift in culture, there is little information yet to suggest that the new approach leads to sustained improvements. This is to be expected given the short time since the implementation of the new approach. How far the different interventions, in particular inspections and action-planning, encourage continued focus on improvement is, to some extent, also difficult to assess – inspections have historically been carried out once every three years on average, and there is little post-inspection data available yet. Finally, the GPhC has signalled its intention to publish inspection reports and ratings, and this study supports this approach.

# 1      Introduction

This Final Report has been prepared by ICF Consulting Ltd (ICF) for the General Pharmaceutical Council (GPhC) to evaluate its approach to regulating community pharmacies in Great Britain. This report describes the role of the research, the study methodology and the findings from the research, its conclusions and recommendations.
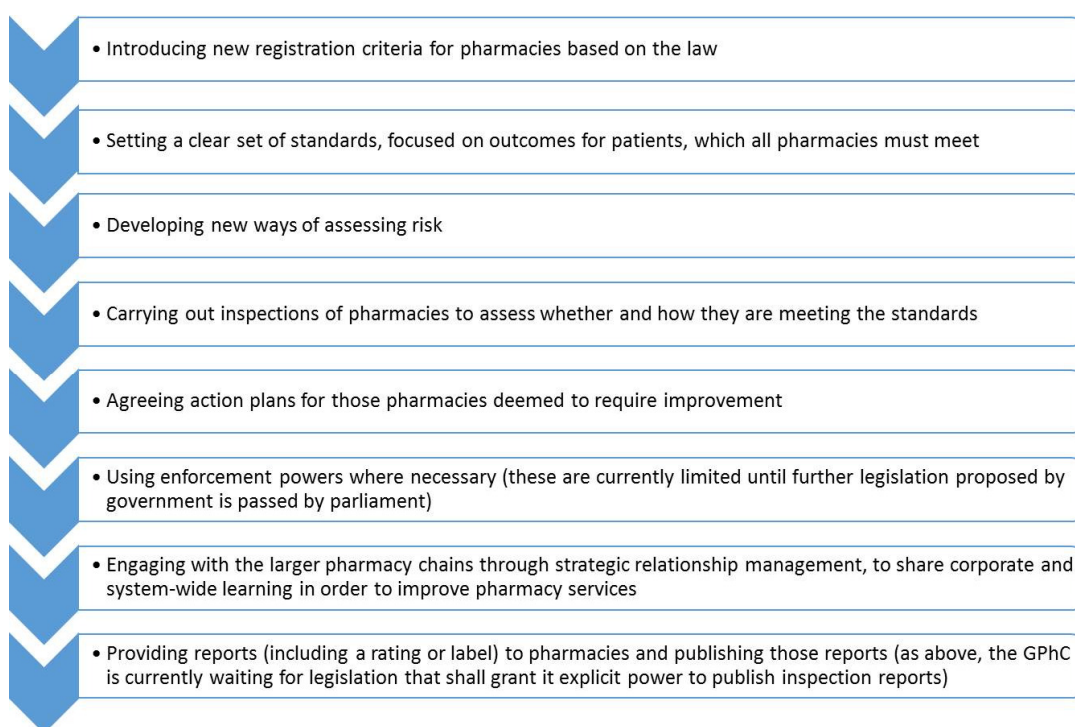
## 1.1      Background to study

The GPhC is the independent regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain. The GPhC seeks to protect, promote and maintain the health, safety and wellbeing of members of the public (by upholding standards and public trust in pharmacy), while ensuring strong community pharmacy service development without unnecessary regulatory burdens[3].  Pharmacy counter assistants and support staff are not regulated by the GPhC.

*A new approach to regulating community pharmacies*

In November 2013, the GPhC introduced a new approach to regulating community pharmacies in Great Britain. Putting patients first is core to this new approach alongside legal compliance and standard operating procedures that were the focus of the previous regime. Figure 1.1 describes the key elements of this new regulatory approach.

**Figure 1.1      Key elements of the GPhC's new approach to regulating community pharmacies**

- Introducing new registration criteria for pharmacies based on the law
- Setting a clear set of standards, focused on outcomes for patients, which all pharmacies must meet
- Developing new ways of assessing risk
- Carrying out inspections of pharmacies to assess whether and how they are meeting the standards
- Agreeing action plans for those pharmacies deemed to require improvement
- Using enforcement powers where necessary (these are currently limited until further legislation proposed by government is passed by parliament)
- Engaging with the larger pharmacy chains through strategic relationship management, to share corporate and system-wide learning in order to improve pharmacy services
- Providing reports (including a rating or label) to pharmacies and publishing those reports (as above, the GPhC is currently waiting for legislation that shall grant it explicit power to publish inspection reports)

*Source: GPhC website*

*Anticipated impacts*

Key to the new approach is a move away from prescriptive rules to a system that focuses on better outcomes for patients. This should encourage patient-centred professionalism in community pharmacies by placing a clear responsibility on pharmacy owners and

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[3] GPhC website http://www.pharmacyregulation.org/about-us.

superintendents to ensure that pharmacy professionals are empowered to uphold high standards and deliver improved pharmacy and patient outcomes.

In the consolidated logic model (Figure 1.2), each aspect of the GPhC's new regulatory approach is shown as separate inputs. However, each input plays an equally important role in contributing to the delivery of a common set of outcomes and impacts, such as: enabling safer pharmacy premises; more empowered and competent pharmacy staff, and the provision of better information, advice and treatment for patients.

## 1.2    Purpose of the study

The aim of this study is to provide the GPhC with a better understanding of how well the new regulatory approach is working in practice and the extent to which the desired impacts are being achieved. The evidence gathered as part of this study will help inform the GPhC's ongoing regulatory reforms and further improve the effectiveness of newly-introduced interventions in the community pharmacy sector.

An intervention logic model provides an effective framework to explore and set out the nature and extent of the relationships between the direct impacts of the new regulatory interventions (such as improved awareness, increased compliance, etc.) and how they translate into changes in pharmacy and patient outcomes (such as safer premises, improved pharmacist-patient interactions, etc.). Where possible, these relationships have been tested and evidenced using data gathered from of a literature review and primary research with affected stakeholders.

Figure 1.2 (overleaf) depicts a high-level logic model for evaluating the GPhC's current approach to regulating community pharmacies. The model captures process and impact evaluation elements (including potential unintended consequences). The logic model also provides a basis against which to measure the progress achieved by the new approach and the extent to which it has met the GPhC's desired objectives and wider goals, contributing to the intended outcomes.

The GPhC's new approach to regulating pharmacies has been introduced only recently. Consequently, there is limited evidence to support the impact evaluation, partly because the impacts could not be captured at this stage (for example, due to lack of data).  As a minimum the report does provide guidance for future impact evaluation.

**Figure 1.2    Detailed intervention logic model underpinning the pathway from intervention to outcome for the GPhC's recent regulatory interventions**
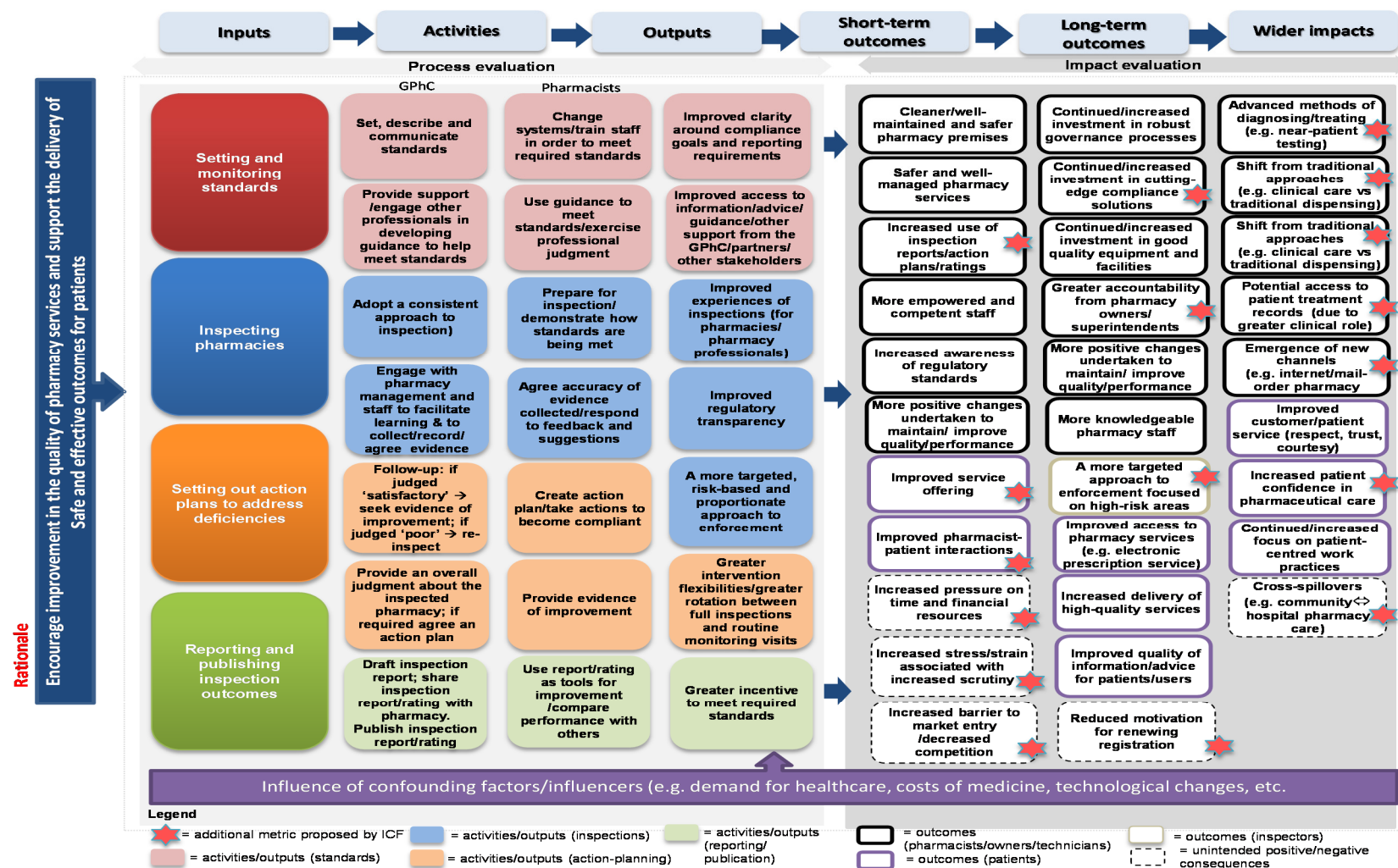
The logic model provided a framework for this study, identifying the evidence needed to inform this evaluation, notably in the following areas:

- **Whether the new approach to regulation is consistent with the GPhC's ambitions, wider objectives and goals**, i.e.

    – whether the GPhC's new approach, when applied in practice, is consistent with its wider ambitions to regulate community pharmacies and the outcomes it is seeking to encourage;

    – whether GPhC inspectors are translating the GPhC's stated intentions and ambitions into a consistent, risk-based and outcomes-focused approach to regulation, and

    – whether community pharmacies and their customers are experiencing the outcomes that the GPhC has been seeking to incentivise and encourage.

- **Whether the new interventions and the overall regulatory approach are effective**, i.e.

    – whether each newly-introduced intervention works in practice as intended;

    – whether each of the new elements supports the "pharmacy journey" to help deliver better outcomes for patients and users of pharmacy services, and

    – whether any barriers are undermining the success of the new approach and how these can be removed to drive better compliance with standards and outcomes for patients and users of pharmacy services.

- **Whether there are any additional developments the GPhC should consider to improve the newly-introduced regulatory interventions**, i.e.

    – whether the current regulatory approach could be improved to drive greater compliance with standards, and

    – whether there are any barriers to address to ensure the new approach is applied more consistently across England, Scotland and Wales.

## 1.3 Evaluation framework and understanding of new regulatory measures

This study focuses on four types of regulatory interventions:

- standard setting;
- inspection;
- action planning, and
- reporting, rating and publication.

Table 1.1 summarises the evaluation questions (as set out in the proposal stage of the project) and indicates where each is addressed to help the reader navigate this document.

**Table 1.1     The project evaluation questions and the response location in this report**

| Evaluation question | Location of response in the report |
|---|---|
| **Standard setting** | |
| Do the current standards set out clearly what a pharmacy needs to do to deliver effective patient care? | Sections 2 & 5 |
| What are the levels of awareness of the standards amongst pharmacies, and does this level of awareness change as a result of inspection? | Section 3 |
| Do pharmacies actively engage in trying to meet the standards, or are they merely seen as a reference tool for inspections? | Section 4 |
| Do the standards encourage pharmacies to focus on patients and users of their services? | Section 4 |
| Have the standards helped change a culture that previously focused primarily on rules and compliance, towards outcomes, innovation and improvement? | Section 4 |
| **Inspection** | |
| To what extent is the GPhC achieving its goal to create an approach to inspection that focuses on outcomes, drives improvement and is applied consistently by inspectors? | Sections 4 & 5 |
| How do pharmacies prepare for inspection? | Section 3 |
| Is advance notification helpful, and do pharmacies use the GPhC's standards and other information available on its website, or consult information provided, for example, by the Royal Pharmaceutical Society or National Pharmacy Association? | Section 3 |
| How do pharmacies experience inspection? In particular, which elements of an inspection – involvement of the whole pharmacy team, facilitating learning and good practice, collecting and agreeing evidence – seem most important in supporting pharmacies to meet the standards and to improve? | Section 3 |
| What is the impact on pharmacies after inspection, particularly for those without action plans? Does it provide a continuing focus for improvement? | Section 4 |
| **Action planning** | |
| Is action planning an effective intervention leading to sustained improvement? | Section 4 |
| the right areas being addressed within action plans to ensure a focus on roving quality, including safety? | Section 3 |
| **Reporting and publication** | |
| Does the provision of inspection reports and ratings provide an incentive for continued focus on quality provision of pharmacy services and improvement? | Sections 4 & 5 |
| What is the opinion of stakeholders concerning the GPhC's intention to publish inspection reports and ratings? How can the policy move forward? | Section 5 |

## 1.4     The market for Community Pharmacies in Great Britain

There were 14,361 community pharmacies in Great Britain in 2014. There are two types of pharmacies:

■ **Independents** (one to five branches): 4,201 independent owners operate 5,590 pharmacies (39 per cent).

■ **Multiples** (more than six branches, including six large entities - Boots, Lloyds, Rowlands, Well Pharmacy[4], Day Lewis and Superdrug): 14 multiple owners operate just fewer than 7,890 pharmacies (55 per cent). Boots owns 2,300 pharmacies (16 per cent) and Lloyds has 1,600 (11 per cent). This category also includes supermarkets (in-store pharmacies in ASDA, Tesco, Sainsbury's and Morrison's): these four retailers have more than 880 pharmacies in the UK (6 per cent)[5].

In England, the share of independents has decreased over time from 41 per cent in 2006-07 to 39 per cent in 2012-13, while the total number of community pharmacies has increased from 10,133 to 11,495 over the same period[6]. In Wales, the decline of independents is more pronounced, decreasing from 43 per cent of all community pharmacies in 2006-07 to 35 per cent in 2013-14[7].

The vast majority of the UK population (96 per cent) can access a pharmacy within 20 minutes on foot or using public transport. There is a higher density of pharmacies in deprived areas where public health needs are greater. For example, per 100,000 population there are around 26 pharmacies in the North West and North East England compared to 18 pharmacies in South East Coast and South Central regions. The greatest share of independents is found in London (61 per cent), see Table 1.2. In contrast, the share of independents in the South West is the lowest at 24 per cent. There are also a small number of private pharmacies regulated by the GPhC, but not contracted by the NHS excluded from the table below.

**Table 1.2     Number of community pharmacies in Great Britain by region and ownership**

| | Community pharmacies (total) | Independents (5 or less pharmacies) | Multiple (6 or more pharmacies) |
|---|---|---|---|
| North East | 606 | 34% | 66% |
| North West | 1,812 | 34% | 66% |
| Yorkshire and Humber | 1,206 | 33% | 67% |
| East Midlands | 919 | 35% | 65% |
| West Midlands | 1,297 | 40% | 60% |
| East of England | 1,148 | 44% | 56% |
| London | 1,846 | 61% | 39% |
| South East Coast | 857 | 31% | 69% |
| South Central | 756 | 28% | 72% |
| South West | 1,048 | 24% | 76% |
| **England (total)** | **11,495** | **39%** | **61%** |

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[4] Previously known as Cooperative Pharmacy.

[5] The Pharmaceutical Journal, 9/16 August 2014, Vol 293, No 7822/3, online | URI: 20066074

[6] GPS (2014): General Pharmaceutical Services in England: 2003-04 to 2012-13, available at: http://www.hscic.gov.uk/catalogue/PUB12683/gen-pharm-eng-200304-201213-rep.pdf

[7] StatsWales (2014): Community pharmacy services in Wales, 2013-14, available at: http://gov.wales/docs/statistics/2014/141112-community-pharmacy-services-2013-14-en.pdf

| | Community pharmacies (total) | Independents (5 or less pharmacies) | Multiple (6 or more pharmacies) |
|---|---|---|---|
| **Scotland** | **1,273** | **37%** | **63%** |
| **Wales** | **714** | **35%** | **65%** |

*Source: England: NHS Prescription Services part of Business Services Authority, 2012-2013; Scotland: GPhC register of pharmacies, 2015; Wales: National Statistics, for Wales, 2013-2014*

According to the National Pharmacy Association, there are 1.6 million visits to a pharmacy every day, and 84 per cent of adults visit a pharmacy every year. The main activity of UK pharmacies is providing NHS services (about 90 per cent of the whole business). It is estimated that pharmacies process about 2 billion prescriptions each year, and resolve around 44,000 incidents that could cause serious harm relating to instructions on dose (15 per cent of all incidents), quantity (13 per cent) or strength (8 per cent[8]). Pharmacies affect the choice of treatment given to the patient, in addition to administering prescriptions where the choice is made by another health professional. Pharmacies in the Great Britain also have other roles, such as treating minor ailments, providing healthy lifestyle advice and supporting people affected by substance abuse and alcohol misuse.

Verdict Research estimated the pharmacy market in Great Britain to be worth £14bn in 2011, growing 1.4 per cent from 2010. More recent research shows that the market grew at 2.1 per cent in 2014, its fastest rate of growth from since 2010[9]. This is largely driven by over-the-counter (OTC) sales which grew nearly 4 per cent, while NHS receipts have grown at a slower pace. NHS dispensing fees have increased from £612mn in 2003-04 to £934mn in 2012-13 (52 per cent increase), while the number of prescriptions dispensed has increased from 597mn to 914mn over the same period (53 per cent). Due to decreasing margins on generic treatments and increasing pressure on NHS expenditure in the longer term, growth in NHS prescription revenue is likely to remain subdued for some time.

There are several characteristics of the pharmacy market and drivers for change relevant to this study affecting the ability of community pharmacies to improve the consumer experience and standard of care. They are:

■ **Pressure on healthcare budgets and pharmacy margins:** Forecasts estimate a 4.7 per cent average annual growth in dispensing volumes over the next three years[10] as the population ages and more pharmaceutical solutions are licensed and available to consumers. There is expectation that the Department of Health (England) will seek efficiency and pharmacy productivity improvements over the same period in the region of 25 per cent according to the same study, placing increased pressure on margins. The bulk of current prescriptions is for generics with the lowest margins for pharmacies.

■ **Entry and exit**: Community pharmacies can only dispense NHS prescriptions under contract. The rules for acquiring an NHS dispensing contract in England were relaxed in 2005 resulting in initial large scale entry by independents and multiples alike before stabilising. Entry has since been limited, requiring a local pharmaceutical needs assessment (PNA) to be completed before an NHS dispensing contract is issued.

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[8] Pharmacy Voice (2012): Local pharmacies intervene on two million prescriptions every year, available at: http://www.pharmacyvoice.com/press/local-pharmacies-intervene-on-two-million-prescriptions-every-year

[9] Data Monitor (2015): Pharmacy Retailing in the UK | Verdict Sector Report, available at: http://www.datamonitor.com/store/Product/?productid=CM00279-014

[10] AT Kearney (2012): The Future of Community Pharmacy in England, available at: http://www.atkearney.co.uk/documents/10192/649132/The+Future+of+Community+Pharmacy.pdf/1838dede-b95a-4989-8600-6b435bd00171

Together with slow consolidation within the market, entry by providers in the traditional pharmacy market is constrained. Obtaining distance selling contracts that permit Internet and mail order services have been the focus for entry[11]. Despite this, there are more than 1,000 openings, closures or change of ownership of pharmacies every year[12], with the number of independents exiting the market expected to increase as competition intensifies.

■ **Intensification of competition:** Changes to market entry conditions, reduced margins, pressure on NHS budgets, and the emergence of alternative channels for consumers have all contributed to more intense competition. Larger players (including supermarkets) are better positioned to respond to these challenges by offering a greater range of products, developing alternative sources of revenue from non-pharmaceutical sales to supplement prescription sales, and offering multichannel sales. Multiples also tend to be located in prime retail locations (i.e. rail stations and high streets) with the highest consumer footfall. Internet sales currently represent 1 per cent of sales but are increasing and offer the greatest opportunity for growth. Experience in Germany indicates the potential in the UK for this segment. Independents by comparison rely on local knowledge, convenience and customer loyalty to attract and maintain custom. They are consequently more susceptible to market entry in the future, particularly where consumers are price sensitive as they do not benefit from scale economies in distribution or buyer power. Analysis by consultants A.T. Kearney estimates that these combined pressures could result in 900 community pharmacy closures in England by 2016, many of which will be independent[13].

■ **Expanding role of pharmacies:** Pharmacies have started developing alternative revenue streams to dispensing to maximise revenues. Healthcare policy has also driven this change resulting in pharmacies becoming the first point of call for a wide range of health services, driven by national policy and local priorities. It has also driven changes to the business model (i.e. extending opening hours, changes to supply chain and the move online). The implication is that many community pharmacies must make significant up-front investments to achieve these changes, with multiples best placed to benefit from scale economies and the lessons learnt in related retail markets. Specialist investment adviser Christie + Co highlights the expectation of buyers of pharmacy businesses in terms of what is needed to meet the GPhC standards[14]:

> [Pharmacy] Buyers now expect to have a dedicated consultation room and will make provision to provide one if necessary. This does not need to be expensive but will be seen as a basic requirement in the future. It is also believed that the layout of a typical community pharmacy will alter with more thought to how and where the pharmacist and patient interact. At present, if a patient wants a private

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[11] The Pharmaceutical Journal (2014): Community Pharmacy - Corporate operators set to become acquisitive in 2014 in pharmacy market, available at: http://www.pharmaceutical-journal.com/publications/supplements/focus-community-pharmacy/corporate-operators-set-to-become-acquisitive-in-2014-in-pharmacy-market/11134167.article

[12] The Miles Group (2015): Pharmacy coverage, available at: http://www.milesgroup.co.uk/pharmacy-coverage.php.

[13] AT Kearney (2012): The Future of Community Pharmacy in England, available at: http://www.atkearney.co.uk/documents/10192/649132/The+Future+of+Community+Pharmacy.pdf/1838dede-b95a-4989-8600-6b435bd00171

[14] The Pharmaceutical Journal (2014): Community Pharmacy - Corporate operators set to become acquisitive in 2014 in pharmacy market, available at: http://www.pharmaceutical-journal.com/publications/supplements/focus-community-pharmacy/corporate-operators-set-to-become-acquisitive-in-2014-in-pharmacy-market/11134167.article

discussion with the pharmacist, he or she either has to go into the consultation room or talk across the counter, often within earshot of other patients. The more forward-thinking contractors will increasingly offer a private area one side of the counter where the pharmacist can discuss medication with patients without the formality of the consultation room (The Pharmaceutical Journal 2014).

This would clearly have cost implications for small independents with limited floor space to alter their business or find the financial means to invest up-front in new property.

## 1.5    Study methodology

The collection of primary evidence during this study involved three main exercises: (1) an online census; (2) qualitative interviews with selected stakeholders, and (3) qualitative interviews with a sample of respondents to the online census. To help inform primary data collection, existing research and information from the literature was also reviewed.

### 1.5.1    Online census of pharmacy professionals working in or responsible for community pharmacy

The online census was designed to draw on community pharmacy professionals' experience of the new regulatory approach.  The census included questions relating to each regulatory intervention, newly-introduced as part of the new approach. These questions explored community pharmacy professionals' attitudes towards the new interventions and the overall approach, the range of influences that motivate them to meet the standards and/or go beyond the requirements and their perceived impacts of the new approach on pharmacy and patient outcomes.

#### 1.5.1.1    *Sample design*

The population for the online census comprised all community pharmacy professionals who feature on the GPhC's register. Pharmacists and pharmacy technicians practising in England, Scotland and Wales were invited to take part.

The whole population of pharmacists and pharmacy technicians was included in the online census as it was difficult to distinguish between pharmacists and pharmacy technicians working in different settings (i.e. community, hospital, primary care, etc.). This enabled the census to reach a greater proportion of the target audience (i.e. community pharmacy professionals).

Contacts were sourced from the GPhC's register of pharmacists and pharmacy technicians. Initial contact was made by the GPhC to gauge interest. Pharmacy professionals who opted out were excluded from the target population and did not receive an invitation to participate.

#### 1.5.1.2    *Data collection method*

A total of 62,982 contacts were identified for the pilot and main stage online fieldwork. Automated email invitations were sent to potential respondents using Snap WebHost.

The online questionnaire was piloted before full roll-out (Annex 3 contains the census questionnaire and question routing can be found in Annex 4). The first pilot involved 100 participants (selected at random) and was conducted between the 1st and 7th May 2015. Due to a low response rate to the first pilot, a second pilot was run between 11th and 17th May 2015. The second pilot involved 3,144 participants[15]. 73 responses were received to the second pilot. Following analysis of the results of the second pilot, further changes were

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[15] 5 per cent of the population of community pharmacy professionals who had not been contacted as part of the first pilot

made to the online questionnaire. The main fieldwork commenced on 18th May and continued until 12th June 2015.

### 1.5.1.3    Response rates

In total, 5,350 responses were received, representing 8.5 per cent of the 62,982 contacts approached during the fieldwork. Of these responses, 70 per cent (n = 3,747) were from community pharmacy professionals.

The overall response rate from community pharmacy professionals was 6 per cent of the total contacts approached during the fieldwork. However, it could be considered slightly higher if measured only against the number of community pharmacy professionals registered with the GPhC. The latest registration statistics from the GPhC indicate that, as of March 2015, there were 48,226 pharmacy professionals registered in Great Britain working in community pharmacies as their only or main job[16]. On the basis of this figure, the response rate to the online census is around 8 per cent. Table 1.3 provides a summary of outcomes and response rates.

**Table 1.3    Summary of online fieldwork outcomes**

| Outcome | n= | % of all |
|---|---|---|
| Target audience | 3,747 | 6.0% |
| Other[17] | 1,603 | 2.5% |
| **Completed (total)** | **5,350** | **8.5%** |
| Refused[18] | 544 | * |
| Partial completion / quit[19] | 384 | * |
| **Refused to participate/ partial completion / quit (total)** | **928** | **1.5%** |
| **Email delivery failure** | **1,391** | **2.2%** |
| **No response (target and non-target audience)** | **55,313** | **87.8%** |
| **Total number of invitations** | **62,982** | **100%** |

*[\*] denotes a percentage close to 0%.*

### 1.5.1.4    Data weighting and robustness of results

The possibility for weighting responses from the census was examined. It was concluded that this was not necessary as the achieved sample was broadly representative of region and type of pharmacy (independent versus multiples)[20]. Although at the point the study was commissioned a higher proportion of community pharmacies had not yet been inspected

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[16] Community pharmacists: about 36,153; community pharmacy technicians: about 12,073. Source: GPhC 2015. *Annual fitness to practise report Annual accounts 2014/15.*

[17] "Other" includes hospital pharmacists and pharmacy technicians, pharmacy professionals working in primary care and elsewhere in the NHS and the pharmaceutical industry

[18] "Refused" relates to participants who notified the survey team that they would not participate for various reasons: not eligible; busy schedule; not interested; etc.

[19] "Partial completion / quit" relates to participants who started to fill in the online questionnaire but did not submit a full response. They were not included in the base used for the analysis

[20] No one group is under-represented.

under the new approach (about 80 per cent)[21], the number of inspected pharmacies has increased, not therefore creating significant sampling imbalances. Among the overall sample of respondents, the proportion of community pharmacy professionals working in inspected pharmacies (38 per cent) was not significantly different from the proportion of community pharmacy professionals working in pharmacies not yet  inspected (34 per cent) under the new approach. This reduced the possibility of some groups being under-represented or over-represented.

A margin of error of 1.57 per cent at the 95 per cent confidence level[22] was achieved for the sample of 3,747 community pharmacy responses indicating the accuracy and reliability of the fieldwork results[23]. Finally, differences are reported only where they are found to be statistically significant.[24]

### 1.5.1.5  *Census outputs*

During the data cleaning process, a number of edit checks were identified and carried out on the data. Once the data set had been cleaned and checked, data tables and charts were produced to facilitate descriptive analysis. The percentages reported for some of the survey questions may not add up to 100 per cent as respondents were allowed to choose more than one category of response. The bases also change between questions as responses were not mandatory.

Two-way cross-tabulations were also produced against the appropriate analytical variables to report differences (if any) between:

- pharmacy types (i.e. multiples versus independents);
- pharmacy professionals' roles (i.e. pharmacists versus pharmacy technicians);
- pharmacies inspected under the new approach and those not;
- across geographic location (i.e. England, Scotland and Wales), and
- hospital and community pharmacies.

### 1.5.2  Qualitative depth interviews with GPhC inspectors and stakeholder organisations

The interviews were designed to provide a more detailed understanding of the new regulatory approach, particularly around the new standards, inspections and action plans. These interviews were carried out over three weeks. They were undertaken in conjunction with the community pharmacies online census, and were conducted between 13th and 29th May 2015.

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[21] According to the GPhC, 2,800 of the 14,300 community pharmacies have been inspected under the new approach.

[22] The finite population margin of error (FPMOE) was calculated in excel using the following standard formula:

FPMOE = Margin of Error * Finite Population Correction Factor = $(0.98)\sqrt{1/n} * \sqrt{(N-n)/(N-1)}$ where *sqrt* is the square root function; *N* is the number of subjects in the population; and *n* is the number of subjects in the sample.

[23] The margin of error determines how reliable a survey is or how reliable the results of the survey are. The lower the margin of error, the higher the accuracy and reliability of the results. A 1.57% margin of error at the 95% confidence level means that in 95% of the time, the exact **population** value or result lies in the following range: (estimated value – 1.57%) and (estimated value + 1.57%), i.e. the sample result is very close to the true population value.

[24] In statistics, "significance" refers to the extent to which a research finding is true, i.e. how close the sample estimate is to the real population value.

The qualitative interviews were conducted by telephone and lasted between 45 minutes and one hour on average. In total, the study team performed 18 qualitative interviews with inspectors and stakeholder organisations pre-selected by the GPhC.

Annex 3 provides a copy of the topic guide used for the interviews.

### 1.5.2.1 Profile of stakeholders interviewed

Depth interviews were arranged with 18 key stakeholders identified during the inception stage. These interviews aimed at supplementing the evidence gathered as part of the desk research and the online survey. The following interviews were conducted:

- 10 GPhC inspector interviews, and
- eight organisations actively involved in pharmacy or the wider health sector: Community Pharmacy Scotland, Community Pharmacy Wales, Department of Health (England), National Pharmacy Association, NHS England, Pharmacy Voice, Royal Pharmaceutical Society, Welsh Government.

### 1.5.3 Qualitative depth interviews with community pharmacy professionals

Qualitative semi-structured depth interviews were designed to unpack individual responses to the online questionnaire and explore in more detail some of the issues of relevance to the study. These included:

- general experiences of inspections (including those who have been inspected under the new approach and those not yet inspected);
- attitudes towards the different interventions, focussing on inspections, action plans and inspection reports and ratings[25];
- perceived impacts of the new interventions and the overall approach, particularly in terms of driving improvement in the community setting and shifting the focus on patients and users of pharmacy services.

The interviews commenced one week after closing the online census and took about two weeks to complete. They were conducted by telephone and lasted between 25 and 30 minutes on average.

### 1.5.3.1 Profile of community pharmacy professionals

A total of 20 interviews were carried out with responsible pharmacists and superintendent pharmacists. These pharmacy professionals were considered the most authoritative to discuss the issues affecting the pharmacy and the pharmacy professionals it employs.

Interviewees were selected for qualitative semi-structured interviews on the basis of criteria agreed with the GPhC. The criteria relate to specific characteristics of the pharmacy in which pharmacy professionals work. The selected sample included:

- pharmacies that have been inspected under the new approach;
- pharmacies that have not yet been inspected under the new approach;
- pharmacies that have received an action plan (sub-set of those whose have been inspected);
- multiple pharmacies;
- independent pharmacies, and
- pharmacies located in each of the three countries (England, Scotland and Wales).

Table 1.4 provides a summary description of the sample.

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[25] Less emphasis was given to standard setting based on census responses

**Table 1.4    Summary of interviews with pharmacists**

| Profile of pharmacies interviewed | | | Number of interviews completed |
|---|---|---|---|
| England | Inspected | Independents | 3 |
| England | Inspected | Multiples | 2 |
| England | Not inspected | Independents | 4 |
| England | Not inspected | Multiples | 1 |
| Scotland | Inspected | Independents | 1* |
| Scotland | Inspected | Multiples | 1 |
| Scotland | Not inspected | Independents | 1 |
| Scotland | Not inspected | Multiples | 1 |
| Wales | Inspected | Independents | 2 |
| Wales | Inspected | Multiples | 2 |
| Wales | Not inspected | Independents | 1 |
| Wales | Not inspected | Multiples | 1 |
| **Total** | | | **20** |

*\* Inspected under the old approach*

### 1.5.4    Secondary research

A total of 20 documents were reviewed, many of which were identified through desk research. Additionally, the GPhC provided a list of sources to review, supplementing the evidence gathered from the desk research. The full list of data sources reviewed is provided in Annex 1.

The sources reviewed mainly provided information relating to:

- the general context of the community pharmacy sector in Great Britain;
- the GPhC's new approach to regulating community pharmacies, and
- initial views and experiences of inspections and other aspects of the new regime.

## 1.6    Profile of community pharmacy professionals surveyed

The community pharmacy professionals surveyed included pharmacists and pharmacy technicians who work in community pharmacies.

### 1.6.1    Geographic location

Of the 3,747 responses received from community pharmacy professionals, most were from people working in community pharmacies based in England (85 per cent). The remaining 15 per cent of responses were from community pharmacy professionals based in pharmacies in Scotland (9 per cent) and Wales (6 per cent). The sample excluded those pharmacy professionals working in community pharmacies in Northern Ireland[26].

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[26] Northern Ireland does not fall within the remit of the GPhC.

**Figure 1.3    Profile of respondents, by region**



*Base: community pharmacy professionals: 3,747.*

### 1.6.1.2    Type of pharmacy

Two-thirds of the respondents are based in independent pharmacies (67 per cent) while the rest consists of multiple pharmacies (33 per cent).

**Figure 1.4    Proportion of independent pharmacies versus multiples**
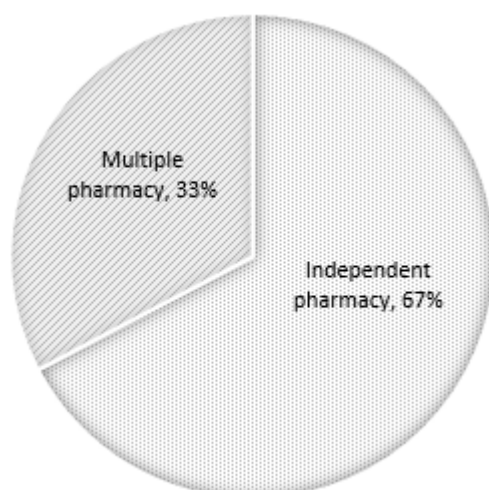


*Base: community pharmacy professionals: 3,716*

### 1.6.1.3    Current role of respondents

Almost three-quarters (74 per cent) of respondents were pharmacists while 25 per cent were pharmacy technicians. Respondents from Wales were more likely to be technicians (35 per

cent against 24 and 29 per cent in England and Scotland respectively). Responsible pharmacists accounted for a large proportion of the achieved sample (45 per cent). 39 per cent of the sample consisted of employees, followed by locum staff (20 per cent), superintendents (10 per cent), and business owners (8 per cent). The remaining four per cent were classified as "other".

**Figure 1.5    Respondents' current role in their respective pharmacies**
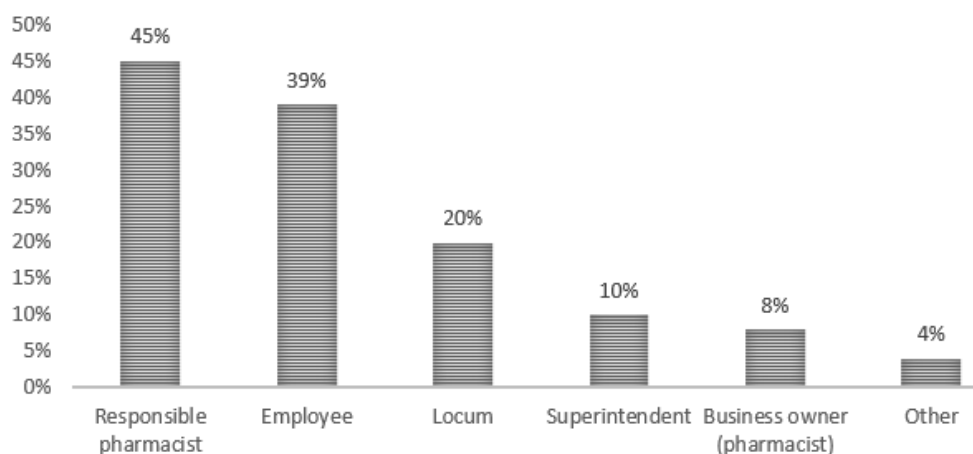


*Base: community pharmacy professionals: 3,746. Please note that the percentages may not add up to 100% as respondents may have chosen more than one category to describe their role.*

Some differences exist between England, Scotland and Wales: only 12 per cent of respondents worked as locums in Wales, compared to 22 per cent in England. English respondents were less likely to say they were employees of a community pharmacy (38 per cent) than Scottish or Welsh respondents (46 and 47 per cent respectively).

## 1.7    Research challenges and problems addressed

The study team encountered minor challenges in the piloting phase. The first pilot, involving 100 randomly-selected potential respondents, achieved a very low response rate. This prompted the study team to organise a second pilot, whereby the online questionnaire was "pre-tested" on a larger number of subjects from the target audience. The second pilot involved 3,144 potential respondents. 73 pharmacists responded. This allowed the study team to follow-up with a sufficient sample of participants to check the design of the questionnaire and ease of completion in practice, to identify and amend problematic questions and to further refine the questionnaire.

## 1.8    Report structure

The remainder of this report is structured as follows:

- Section 2 presents evidence on the level of consistency in applying the new regulatory approach and alignment with the GPhC's wider objectives;

- Section 3 presents findings relating to the effectiveness of the new regulatory regime, especially on various aspects of intervention delivery;

- Section 4 presents findings relating to 'early' impacts of the new approach;

- Section 5 sets out improvements suggested by study participants; and

■ Section 6 provides an overview of the results and draws final conclusions and recommendations relating to the new approach.

Detailed survey findings, including cross-tabulation where relevant, are available to download in excel format from the GPhC's website.

Technical annexes are provided in a separate document entitled: "Evaluating the GPhC's Approach to Regulating Community Pharmacies: Detailed Annexes:

■ Annex 1 - Bibliography

■ Annex 2 - Linking the evaluation questions, and the sources of evidence and analysis

■ Annex 3 - Survey questionnaire and interview guides

■ Annex 4 - Survey routings

■ Annex 5 - Notes of depth interviews with stakeholders organisations

■ Annex 6 - Notes of depth interviews with GPhC inspectors

■ Annex 7 - Notes of depth interviews with community pharmacy professionals

■ Annex 8 - Profile of non-community respondents

■ Annex 9 - Other regulators' approaches to rating

# 2 Consistency in regulatory approach and alignment with the GPhC's wider objectives

This section reports on the views of the respondents to the online survey as well as the depth interviews with GPhC inspectors, stakeholder organisations and community pharmacy professionals regarding their views and experience as to whether the new approach to regulation is consistent with the GPhC's ambitions and goals.

## 2.1 Key messages

- The new framework seems to be working well as perceived by those working in community pharmacies, inspectors and stakeholder organisations. Standards are generally well-understood by community pharmacy professionals because they set out clearly what is expected to meet the standards.

- The general view from interviews with GPhC inspectors and stakeholder organisations is that although the new approach covers similar standards, it has moved away from the old tick-box approach to regulation.

- There is evidence from GPhC inspectors and stakeholder organisations that the current framework encourages community pharmacy professionals to act on their own initiative when meeting the regulatory standards. However, some community pharmacy professionals still practise a traditional tick-box approach to regulation, suggesting the shift towards the new approach will take time.

- A few GPhC inspectors reported lack of guidance for inspectors on how to rate pharmacies. In particular, they highlighted a lack of information relating to practical examples which would link pharmacy evidence to the inspection framework.

- Similarly, a few community pharmacy professionals argued a lack of information regarding what evidence and measures pharmacies need to prepare to achieve a certain rating. They suggested that this may be the reasons that too many pharmacies are rated "satisfactory" while very few achieve a "good" or "excellent" grade[27].

- A few GPhC inspectors pointed to the inflexibility of the current decision-making framework for the purpose of collecting evidence and writing inspection reports. Specifically, there were a few instances reported where the situation in the pharmacy made collecting evidence under the new framework difficult.

- A few GPhC inspectors and stakeholder organisations reported a lack of uniformity in the reporting process inspectors follow after the inspections. In particular, there is inconsistency in the follow-up phase, for example pharmacies have reported experiencing delays in receiving reports.

**In summary, the evidence indicates that the new regulatory regime is generally well-understood. The framework seems to be working well. However, there is some evidence (albeit small) around the current lack of clarity and consistency in the guidance and information available around collection of evidence, and the guidance around the assignment of ratings.**

## 2.2 General overview of the reported views and experience of the new regulatory approach

The majority of inspectors and stakeholder organisations interviewed as well as survey respondents **consider that the new standards provide a very good framework for**

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[27] So far only one pharmacy has achieved an "excellent" grade.

**community pharmacy professionals.** Specifically, the new approach is clear and explicit on what is expected of community pharmacy professionals to meet the standards:

> The structure of the standards is fine. The five principles and what they include is clearly set out (GPhC inspector, 2015).

> […] standards can more easily be achieved as pharmacists have a clearer understanding of what the standards are and how to demonstrate they comply with these standards (Stakeholder organisation, 2015).

> Standards are clear and staff do their best for care of patients (Online survey respondent, 2015).

In comparison to the GPhC's previous approach to regulating pharmacies, **the general view from interviews with GPhC inspectors and stakeholder organisations is that the new approach covers similar standards, but these are less prescriptive by nature.** Indeed, the guidance developed under the framework (for instance, information provided on the GPhC website) encourages pharmacists to act on their own initiative as opposed to adhering to strict rules and directions. The new inspection model has led to a gradual shift from the old tick-box approach towards a more partnership-based regulatory approach, whereby inspectors are encouraged to engage with pharmacists and share examples of best practice to help pharmacies understand how to achieve the best outcomes for patients and users of pharmacy services.

> The style of inspections has moved away from just looking at paperwork. I think that talking and engaging with pharmacists actually makes them see why they should be doing things in a certain way and what they should do to improve (GPhC inspector, 2015).

> It's better than the old tick-box exercise – it's more involving, encourages pharmacies to provide evidence to show what they are doing (Stakeholder organisation, 2015).

At the same time, **some community pharmacy professionals considered that,** although formally less prescriptive, **the new standards still engender a traditional tick-box approach to regulation. Many community pharmacy professionals are still inclined to use the standards as a "check-list" to ensure they comply and demonstrate to inspectors that they adhere to all standards. The evidence suggests that the change in attitudes and behaviours in community pharmacy practice is slow – pharmacy professionals are generally more focused on following the rules than making sustained changes to achieve improved patient outcomes in the short- and long-term.**

> The new approach could end the current tick-box format, but at the moment I don't think so. We're still stuck on the "do you do that? yes? that's great.", and "do you do that? no? Oh no, that's a big cross!  It's a shame because we should be looking much more at how, as a whole, the pharmacy makes its services safe (Online survey respondent, 2015).

Furthermore, one representative from a stakeholder organisation recognised that some types of pharmacy might be more adaptive to the new regulatory regime than others:

> Those who see and continue to see inspections as a tick-box exercise are the most likely to be "shocked," especially due to the action plans that come out of these inspections. The more proactive pharmacies will take time to digest the information and understand the standards and the desired focus on patients, quality and safety (Stakeholder organisation, 2015).

This is consistent with the findings that community pharmacy professionals operating in multiples indicate a higher level of understanding and awareness of standards than those

### 2.3 Concerns regarding the GPhC approach and its decision-making framework

**A few concerns were raised across all types of respondents in relation to the new approach and decision-making framework.** For example, some GPhC inspectors reported a **lack of guidance** for inspectors on how to rate pharmacies, resulting in the majority of pharmacies being rated "satisfactory"[28]. The guidance documents for inspectors are written in such a "high-level" way that most inspectors find it difficult to relate them to practical examples experienced in the pharmacy.

> The way the framework is worded makes it difficult to match evidence [from pharmacy] with what is provided in the framework (GPhC inspector, 2015).

Similarly, there is lack of guidance for community pharmacy professionals regarding what evidence and measures are needed to achieve a certain rating – a few of the community pharmacy professionals explained that the rating process is a "subjective assessment" which creates inconsistencies in how pharmacies are rated across Great Britain. Although pharmacists may have read guidance documents around the decision-making framework, they find it too vague and too conceptual since the documents currently provide unclear direction regarding the outcome-focused examples needed to be demonstrated to achieve good ratings.

> While the statements are quite clear, it's not always clear exactly what it would mean in practice. Some real life examples might help to demonstrate what would fail to meet the standards and what would be required to achieve a grade of satisfactory, good or excellent (Online survey respondent, 2015).

**Also, many GPhC inspectors and some stakeholder organisations pointed to the inflexibility of the current decision-making framework for the purpose of collecting evidence and writing inspection reports** – on various occasions, inspectors explained that the evidence the decision-making framework stipulates should be collected during inspections does not always reflect the practical situation in the pharmacy. One example provided related to a situation where the GPhC inspector gathered evidence on training from the pharmacy technician who, as a new employee, did not know about training arrangements of the inspected pharmacy. This suggests that inspectors should advise a minimal amount of preparation prior to an inspection. Pharmacy owners or superintendents could be advised to brief all pharmacy staff (including temporary staff and locum pharmacist) so that all necessary evidence is produced on the day of the inspection. To some extent, inspectors could provide guidance as regards the type of evidence they will seek to gather during the inspection. One inspector explained that, presently, pharmacy teams tend to rely heavily on the inspection decision-making framework when deciding what evidence to gather and produce on the day of the inspection.

> A growing problem is that contractors are using the inspection decision-making framework as a check-list. They tend to even paraphrase certain areas or parts of the decision-making framework that have been classified as "good" or "excellent"

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[28] One GPhC inspector reported:

The decision-making framework is not useful at all. It has contributed to the polarisation of most of the pharmacies which are mostly rated as 'satisfactory' (GPhC inspector, 2015).

and claim to produce the necessary evidence and should be rated at these levels (GPhC inspector, 2015).

However, the inspector warned that the inspection decision-making framework was established before the roll-out of the new inspection model and should therefore not be used as the sole reference for evidence-gathering.

> The key problem is that the framework was developed before the prototype model was rolled out. Since then, it has not really evolved. Things have changed! (GPhC inspector, 2015).

These findings suggest that the new inspection model and the decision-making framework ought to be better aligned to improve consistency among inspectors, particularly regarding the evidence they require to inform their assessment of the services offered by the pharmacy being inspected, as well as within the community pharmacy sector by assisting pharmacy professionals in their preparation for inspections.

In the same vein, a few GPhC inspectors and stakeholder organisations reported a lack of uniformity in the process following inspection. For example one inspector reported delays in report production, while others quoted lack of consistency in evidence gathering described above.

> […] there […] does not seem to be much consistency in the follow-up phase. I've received a couple of emails […] saying that they have not received a report from the inspector despite having had an inspection six weeks before. Pharmacists should in principle receive an inspection report within five working days (GPhC inspector, 2015).

# 3 Effectiveness of the new interventions – process evaluation

This section reports the evidence on the process of implementing the GPhC's new regulatory regime in terms of how processes work. In particular, it assesses the effectiveness of the sets of measures introduced to support the new principles and standards, inspections, action planning, reporting and rating (the process evaluation part of the intervention logic presented earlier in Figure 1.2).

The findings focus on various aspects of intervention delivery, and provide evidence of the extent to which each of the four newly-introduced interventions have been implemented and how they interact as part of the "pharmacy journey", and work as intended.

## 3.1 Key messages

**Standards**

- The vast majority of community pharmacy professionals considered the underpinning principles and the required standards to be clear, i.e. they fully understood what needed to be achieved, and have fully implemented all five principles.

- Pharmacy technicians generally showed a slightly higher level of understanding than pharmacists as regards the knowledge and experience of the standards. This reflects the increasingly higher profile role that pharmacy technicians play during inspections, as the new approach to regulation encourages the involvement of the whole pharmacy team.

- Community pharmacy professionals operating in multiples indicated a higher level of understanding of all five principles underlying the new GPhC standards as opposed to those working in independent pharmacies. Qualitative evidence from the interviews with inspectors suggests that these differences are mainly due to "more training and guidance" provided to staff in multiples than in independent pharmacies.

- Those working in inspected pharmacies were more likely to say they clearly understood the principles and fully implemented relevant standards than those working in pharmacies not yet inspected, particularly regarding specific GPhC principles, notably Principles 1 and 2 on governance arrangements and staff empowerment and competence respectively.

- Community pharmacy professionals based in England and Scotland seem to have a slightly higher level of awareness of the standards than those based in Wales.

- According to the majority of community pharmacy professionals the level of awareness around the new standards is generally high. Interviewed inspectors and stakeholder organisations considered the levels of awareness of the new standards to be slightly more variable – while the majority thought that these levels were "good", a few recognised that some community pharmacy professionals fall behind others.

- The evidence gathered from inspectors and online survey respondents suggests that some pharmacies (particularly multiples) have been more actively involved than others in promoting the standards internally to staff. This has generally been achieved through internal training sessions and regular attendance at events focussing on the new standards.

- Inspectors further recognised that active promotion of the standards (either internally or by third parties) has raised awareness of the standards and the GPhC's new inspection model.

**Inspections**

- There is no clear-cut evidence as to the amount of time pharmacies spend on inspections (inclusive of the amount of time required to prepare) but information provided by both pharmacy professionals and inspectors suggests that the actual inspection can last up to three hours:

  - in comparison to the length of inspections conducted by other regulatory bodies, the current GPhC inspections are considerably shorter; and

- qualitative evidence from interviews with community pharmacy professionals indicates that inspections under the new regime are not much longer in comparison to the GPhC's previous approach. At the same time, a few GPhC inspectors pointed out that the inspections might last slightly longer under the new approach, owing to more rigorous evidence-gathering that is undertaken by the inspector on the day of the inspection.

■ The majority of community pharmacy professionals have indicated that they rely on various sources to prepare for inspections. The majority of inspectors and stakeholder organisations agreed that guidance currently available is useful, and that pharmacies do take advantage of it. The guidance available on the GPhC's, NPA's and RPS's websites, as well as advance notifications from the GPhC have proven useful.

■ There is evidence that inspections are increasingly helping to promote awareness of the standards in the community pharmacy sector. They are seen as an opportunity to further "educate" pharmacy teams.

■ Most interviewees and online survey respondents felt that engaging with the whole pharmacy team during the inspections is crucial to driving better compliance and achieving patient-focused outcomes. This aspect of inspections is of greater importance to pharmacy technicians than pharmacists. Indeed, greater involvement of the pharmacy team is regarded as a means to obtaining "the whole team's buy-in".

■ The majority of community pharmacy professionals have pointed to the importance of GPhC inspector's feedback during the inspection process. This is further described in Section 4.

**Action plans**

■ 18 per cent of survey respondents who had experienced an inspection also had an action plan in place. This compares with the GPhC figures from November 2014 which show that 21 per cent of inspected pharmacies had developed an action plan[29].

■ Remedial action was most commonly required in the areas of governance arrangements (35 per cent of online survey respondents); staff competence (34 per cent); and the environment and condition of the premises (33 per cent).

■ Almost all study participants said that action plans have proved effective in helping pharmacies improve compliance with the standards. Particularly defining priorities for improvements, assessing how well standards were met and reflecting on the inspector's findings proved effective in helping to achieve standards.

■ Four in five online census respondents indicated that follow-up evidence is helpful and has proved effective in helping them improve and become compliant.

■ Pharmacy technicians were more likely than pharmacists to find these elements of action planning very helpful, particularly "assigning responsibilities" (79 per cent of pharmacy technicians and only 51 per cent of pharmacists), "providing follow up evidence to the GPhC" (78 per cent of pharmacy technicians and only 51 per cent of pharmacists) and "being re-inspected" (68 per cent of pharmacy technicians and only 42 per cent of pharmacists).

■ A few stakeholder organisations, however, have stressed that action plans could provide more time to pharmacies to take remedial action.

**Reporting and ratings**

■ 89 per cent of the respondents to the census recognised that inspection reports are a valuable tool when thinking about and implementing improvements in quality and performance while an additional 84 per cent of respondents acknowledged that inspection reports help them focus on areas of most relevance to patients and customers.

■ Multiples and inspected pharmacies were more likely to be of an opinion that reporting is valuable and helps focus efforts on the areas of most relevance to patients safety, than

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[29] GPhC. November 2014. Meeting of the Council, available at:
http://www.pharmacyregulation.org/sites/default/files/2014_11_13gphc_council_papers_2.pdf.

independents and not inspected pharmacies. Further, pharmacy technicians were more likely to find reporting valuable than pharmacists.

■ While GPhC inspectors and stakeholder organisations generally recognised that ratings incentivise pharmacies to focus on the standards and improve, the general opinion was that certain ratings, in particular the "satisfactory" rating, are misleading and often demotivating for pharmacies.

**The following conclusions are based on the evidence gathered:**

**1. The new GPhC standards are generally well-understood and have been fully implemented. Pharmacy technicians, those working in multiples or inspected pharmacies, or those based in England and Scotland are more likely to show understanding of the standards in general. More active promotion of the standards would be helpful in furthering awareness and understanding of the standards and anticipated outcomes. This would particularly benefit independent pharmacies where opportunities for training and knowledge-sharing are less common;**

**2. The new inspections are well-perceived among study participants, particularly the emphasis on involving the whole pharmacy team, the information available and the time spent. The majority of community pharmacy professionals have pointed to the importance feedback from GPhC inspectors during the inspection process;**

**3. Action plans have been judged useful, particularly for targeting improvement in high-risk areas observed during the inspection and allowing changes to be implemented efficiently. Pharmacy technicians were more likely than pharmacists to find these elements of action planning very helpful. A few stakeholder organisations, however, have stressed that action plans ought to be fair by providing enough time for pharmacies to take remedial action;**

**4. Inspection reports are a valuable tool when considering and implementing improvements in quality and performance, with inspected pharmacies, multiples and pharmacy technicians generally being more likely to consider reporting useful. While stakeholders generally recognised that ratings incentivise pharmacies to focus on the standards and improve, the general consensus was that certain ratings, in particular the "satisfactory" rating, are misleading and often demotivating for pharmacies.**

## 3.2 Standards

### 3.2.1 Understanding of regulatory principles and standards by community pharmacy professionals

**Most online survey respondents indicated that they understand and have fully implemented all the GPhC's governing principles and associated standards** – at least 70 per cent of community pharmacy professionals surveyed have clearly understood and fully implemented all five principles (as indicated in Table 3.1 below)[30]. A very small number of pharmacy professionals report that they have fully implemented the principles but without fully understanding them (one or two per cent of online respondents for each principle), which raises concern that at least in the cases reported, implementation may be inadequate.

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[30] GPhC. "Registered pharmacy standards and inspection - The principles and standards." Available at: http://pharmacyregulation.org/pharmacystandardsguide/principles-and-standards.

**Table 3.1    Whether community pharmacy professionals understand and have implemented the standards**

| Level of clarity around the new standards | Principle 1 | Principle 2 | Principle 3 | Principle 4 | Principle 5 |
|---|---|---|---|---|---|
| Clearly understood and fully implemented | 77% | 70% | 71% | 78% | 74% |
| Clearly understood and partially implemented | 19% | 25% | 24% | 18% | 21% |
| Clearly understood and not implemented | 1% | 2% | 2% | 2% | 2% |
| Unclear and fully implemented | 2% | 1% | 1% | 1% | 1% |
| Unclear and partially implemented | 2% | 2% | 1% | 1% | 1% |

*Base: 3,720; 3,710; 3,714; 3,716; 3,710 respondents.*

**In particular, most community pharmacy professionals surveyed indicated that they have a clear understanding of specific standards focussed on delivering better patient care.** Figure 3.1 shows the extent to which specific, patient-focused outcomes are understood and the relevant standards are implemented. "Patients are treated with respect by the pharmacy staff" is the outcome which was clearly understood and fully implemented by 95 per cent of the community pharmacy professionals, followed by "Patients are asked questions by the pharmacy staff to make sure they are given the best advice" (83 per cent), and "Patients' privacy is maintained during their discussions with pharmacy staff" (81 per cent). Only 67 per cent of community pharmacy professionals thought that pharmacy staff are fully knowledgeable and experienced with the patient-focused standards, while 31 per cent admitted to be only partially knowledgeable and experienced about them.

**Figure 3.1    Whether outcomes are understood and the relevant standards are implemented**
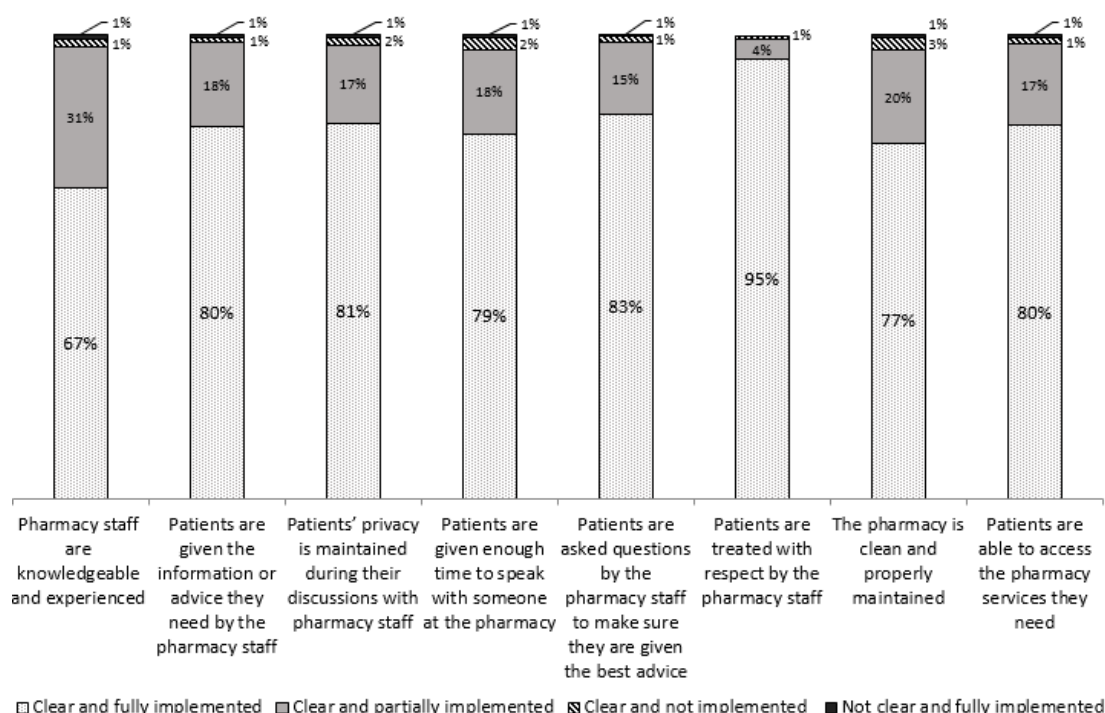


*Base: community pharmacy professionals: 3,720; 3,714; 3,717; 3,709; 3,717; 3,707; 3,712; 3,708 respondents.*

**Pharmacy technicians showed a slightly higher level of understanding than pharmacists as regards the outcomes intended by the newly-introduced standards.** This reflects the increasingly high profile role that pharmacy technicians play during inspections as the new approach to regulation encourages the involvement of the whole pharmacy team. Differences were particularly pronounced as regards pharmacy staff's knowledge and experience of the standards (81 per cent of technicians declared "clearly understood and fully implemented" while only 62 per cent of pharmacists did). Additionally, pharmacy technicians had higher understanding as regards outcomes "patients are given the information or advice they need" (89 per cent and 77 per cent respectively) and "patients' privacy is maintained during discussions" (87 per cent and 79 per cent respectively). Among pharmacists, levels of understanding were highest as regards outcomes "patients are asked questions by the pharmacy staff" (80 per cent of pharmacy technicians and 91 per cent of pharmacists) and "patients are treated with respect" (92 per cent and 97 per cent respectively). On cleanliness, both groups indicated an equal level of understanding as to the outcome to be achieved.

**Those working in inspected pharmacies were more likely to say they clearly understood principles and fully implemented relevant standards than those working in pharmacies not yet inspected**, particularly for Principle 1 (81 and 72 per cent respectively) and Principle 2 (76 and 63 per cent respectively). This suggests that the experience of inspections is likely to result in higher understanding of the GPhC's new approach to regulation – indeed, those not yet inspected under the new approach gain their knowledge from guidance and information available, and training.

**Figure 3.2    Percentage of respondents who clearly understood and fully implemented the principles underlying the new GPhC standards**
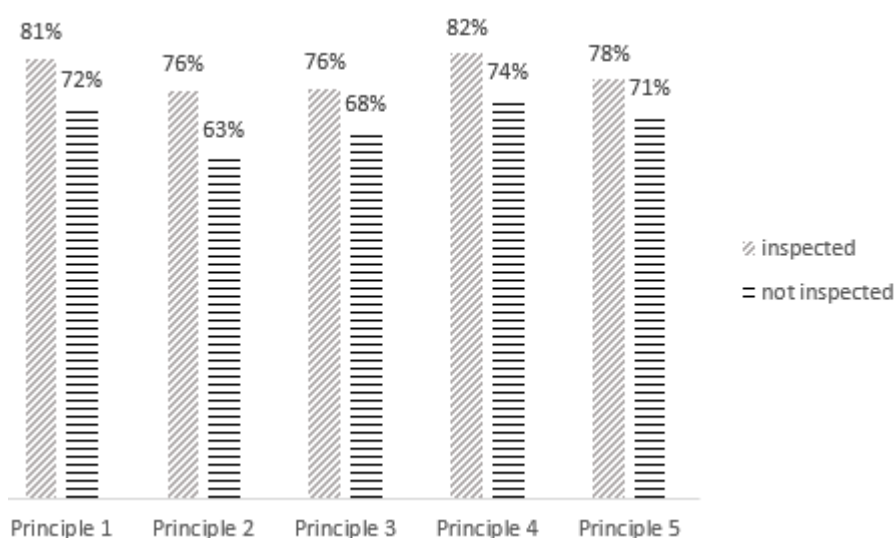


*Base: community pharmacy professionals working in inspected pharmacies: 1388; 1388; 1386; 1388; 1385; community pharmacy professionals working in pharmacies that have not yet inspected: 1239; 1233; 1237; 1239; 1236.*
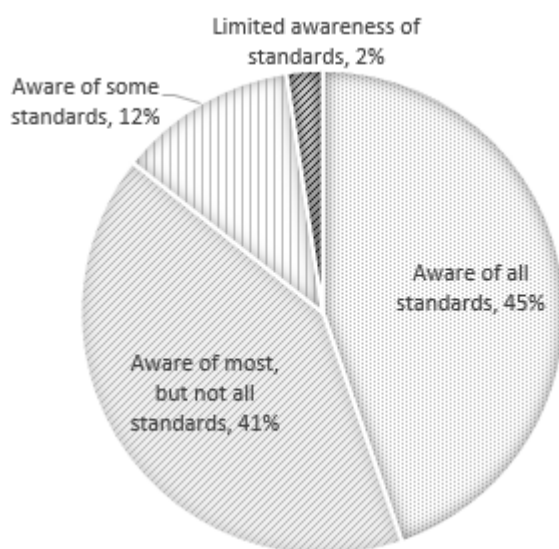
However, **community pharmacy professionals operating in multiples indicated a higher level of understanding** of all five principles underlying the new GPhC standards compared to independents. This was only statistically significant for Principle 1, where, most respondents based in multiples (81 per cent) felt particularly well-informed and have fully implemented the associated standards as opposed to 69 per cent of community pharmacy professionals based in independents. Qualitative evidence from the interviews with inspectors suggests that these differences are mainly due to "more training and guidance" provided to staff in multiples compared to independent settings (as explained in Section 3.2.2 below).

### 3.2.2    Level of awareness

**The level of awareness of the new standards is high, according to the online survey results.** As shown in Figure 3.3 below, more than 85 per cent of community pharmacy professionals surveyed reported that they were aware of the new standards, with 45 per cent being fully aware of all standards. The level of awareness of the new GPhC standards varies by location: respectively 50 and 45 per cent of the respondents based in Scotland and England said they were aware of all standards, while only 36 per cent of those based in Wales said the same. A greater proportion of pharmacists operating in multiples were aware of all standards compared to independent pharmacists (46 and 40 per cent respectively). This is potentially due to the fact that the multiples have a greater scope to provide their staff with more training and guidance (such as attendance of meetings and seminars) but also due to knowledge sharing among branches. Indeed, as one inspector notes:

> In larger organisations, awareness is very high (as the sharing of the knowledge is easier) and it varies amongst smaller ones. In general the level of awareness has increased over time. Generally, there is now fairly good awareness (GPhC inspector, 2015).

**Figure 3.3    Whether those working in community pharmacies are aware of the GPhC's Standards for Registered Pharmacies**



*Base: community pharmacy professionals: 3,741.*

Further, some community pharmacy professionals (particularly multiples) have sought to raise awareness of the standards among their staff, while others have been less active in that regard, resulting in potential barriers to effective implementation.

> Awareness of the standards is probably inconsistent. […] some pharmacists know about them, others are fairly familiar with them. There are also some who don't know much about the standards (GPhC inspector, 2015).

Indeed, inspectors recognised that active promotion of the standards – for example internally in pharmacies (by training or knowledge sharing) or by third parties (seminars organised by NHS organisations or stakeholder organisations) has helped further awareness of the standards and the GPhC's new inspection model.

> The large multiples, in particular, have done a lot of work in raising awareness among the teams by having training sessions. […]. But even among the independent pharmacies, some have always been proactive and keen to focus on patient safety. Consequently they were a lot more aware of the standards. […] (GPhC inspector, 2015).

**Compared to community pharmacy professionals who responded to the online survey, interviewed inspectors and stakeholder organisations considered the levels of awareness of the new standards to be slightly more variable.** The majority of interviewees thought that the level of awareness was "good", while they also stressed that it has increased over time as community pharmacy professionals experience inspections, and participate in training:

> I think it varies. But over time, it seems that pharmacists are becoming more aware of the standards and the new inspection model – they are attending more meetings and seminars that are helping to enhance their awareness. I feel that pharmacists better understand the standards and what sort of things they should be doing that would help them meet the standards (GPhC inspector, 2015).

 A few stated, however, that there are still some community pharmacy professionals whose awareness is limited compared to others.

## 3.3 Inspections

### 3.3.1 Preparation for inspections

Since implementation, 38 per cent of online survey respondents across Great Britain have experienced inspections under the new regulatory regime (as showed by figure 3.4 below). 34 per cent of respondents have not yet been inspected under the new regime while 24 per cent of the respondents did not know and 5 per cent preferred not to answer. The online census sample over-represents the UK population numbers - the GPhC figures from April 2015 show that around 20 per cent of the UK registered pharmacies had been inspected[31].

**Figure 3.4    Whether respondents' pharmacies have been inspected by the GPhC since 4 November 2013**
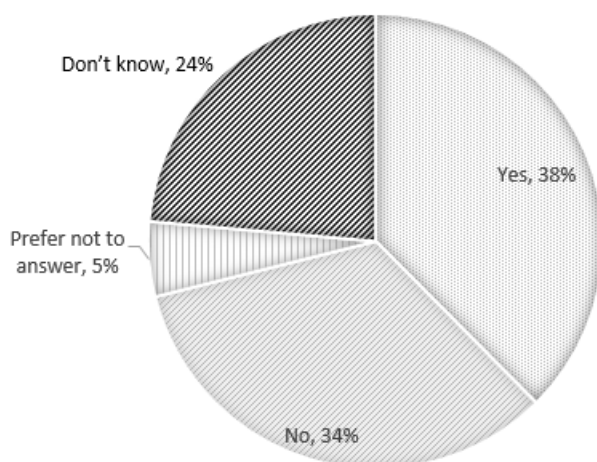


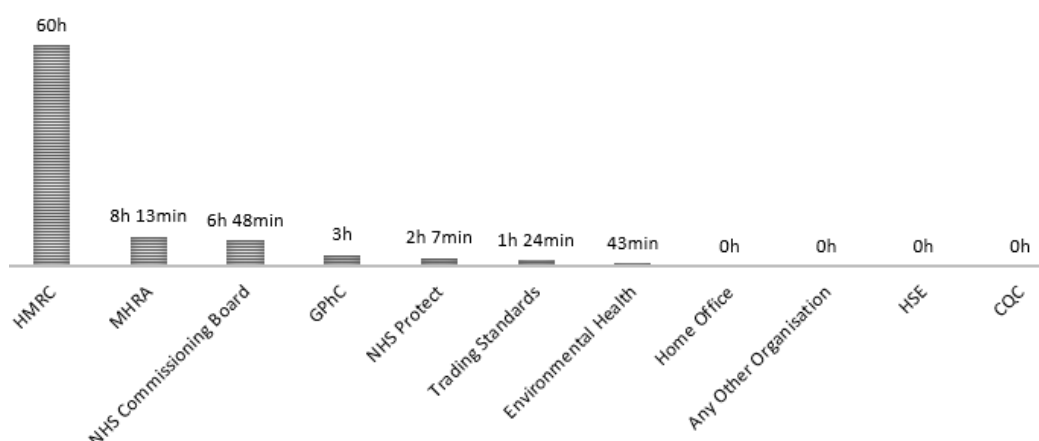*Base: community pharmacy professionals: 3,707.*

**There is no clear-cut evidence regarding the average amount of time pharmacies spend on inspections.** There were as many respondents to the online survey (20 per cent) who indicated having spent a few hours on inspections, as those who reported that inspections required a few days' work (20 per cent of online survey respondents). For a smaller proportion of respondents (9 per cent), the total time spent on inspections spanned more than a month. The estimates provided by a few inspectors indicated that inspections might take up to five hours, but on average last around three hours. These discrepancies most likely arise from the fact that some pharmacies take into account in their estimates the preparation time ahead of inspections.

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[31] GPhC. April 2015. Meeting of the Council, available at:
http://www.pharmacyregulation.org/sites/default/files/2015-06-11_gphc_council_papers_-_public3.pdf

**Figure 3.5     Amount of time spent in relation to inspections**
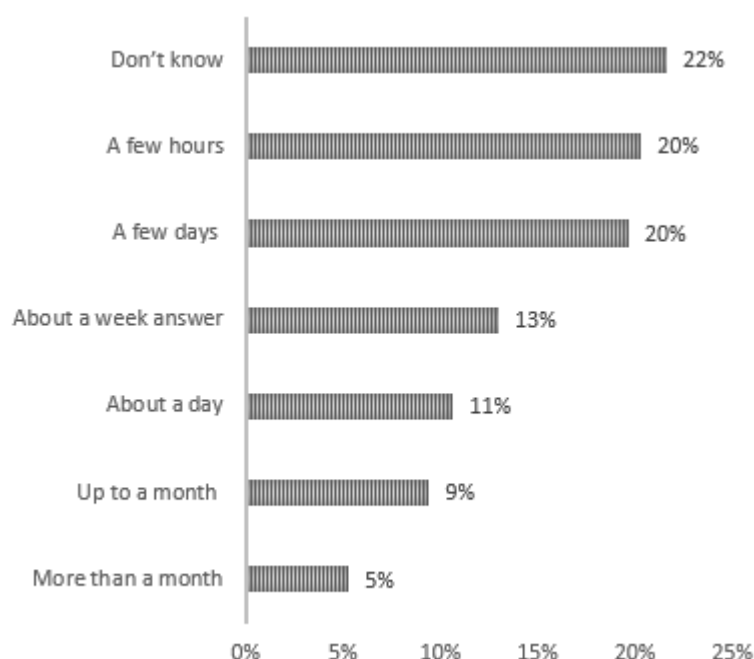


*Base: respondents inspected since 4 November 2013: 1,378.*

In comparison, inspections from other regulatory bodies appear to take longer than those under the new GPhC approach: the HMRC were reported to require, on average, two days of staff time (including preparation time); the MHRA eight hours; and the NHS Commissioning Board about seven hours (as showed in Figure 3.6 below).

**Figure 3.6     The average amount of inspection time, by inspecting organisation.**



*Source: Department of Health (2013).*

Qualitative evidence from interviews with community pharmacy professionals indicates that inspections under the new regime do not take much longer than inspections under the GPhC's previous approach:

> If you are up-to-date with everything, then there is no significant amount of time involved in preparing for inspections. We should be ready anyway. I do not foresee any significant differences in the amount of time involved under the old approach and the new approach (Online survey respondent, 2015).

However, a few inspectors pointed out that inspections might last slightly longer under the new approach, owing to more rigorous evidence-gathering undertaken by the inspector on the day of the inspection.

A few pharmacies also account for the time spent on monitoring internal procedures and processes. This is to ensure that the pharmacy team is "inspection-ready at all times", and impacts the ability to meet the standards (described in detail in Section 4 below):

> The general idea (…) is that we need to go through a checklist every month and then sign off a summary sheet. This takes us about 20 minutes to half an hour every month. Our superintendent expects us to be inspection-ready at all times (Online survey respondent, 2015).

**Most online survey respondents have indicated relying on various sources to prepare for inspections.** A majority (98 per cent) felt that the GPhC's standards themselves helped them prepare for inspections, followed by the advance notifications from the GPhC (93 per cent)[32], and the information and guidance relating to the new standards (92 per cent) available on the GPhC website. 87 per cent the respondents (48 per cent) also found additional advice and information offered by professional bodies (e.g. RPS) and industry associations (e.g. NPA) to be helpful in preparing for inspections.

**Figure 3.7    Whether information and guidance are helpful in helping community pharmacy professionals prepare for inspections**
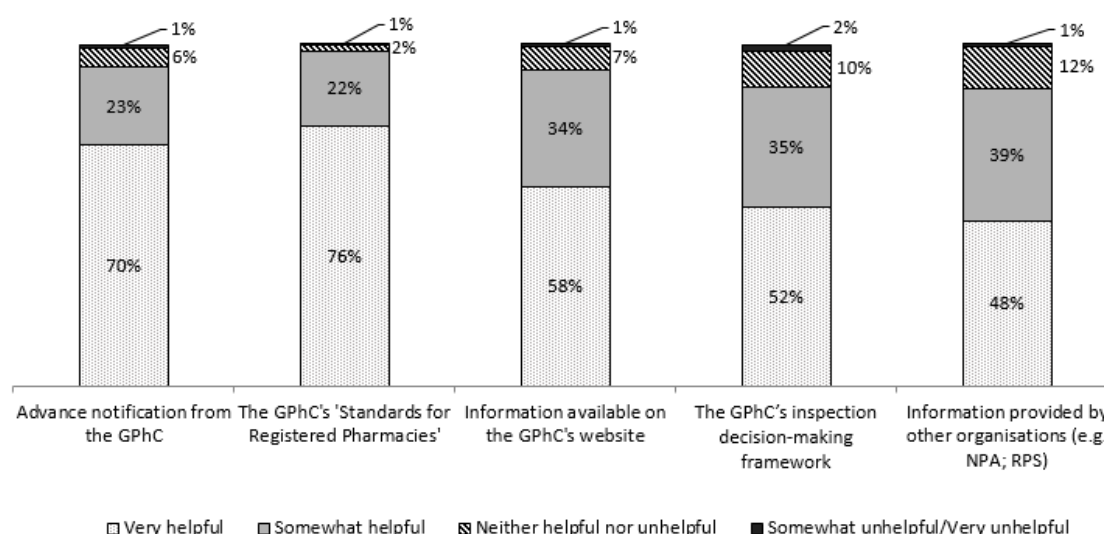


Base: respondents inspected since 4 November 2013: 1,384; 1,374; 1,371; 1,377; 1,378.

Many respondents also cited the following additional sources as useful for helping them prepare for upcoming inspections:

■ in-house advice, information and guidance (e.g. internal audits, inspections, internal guidelines and procedures, e-learning, internal "continuing professional development" (CPD) requirements, etc.);

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[32] In most cases inspectors will send a letter to the pharmacy premises notifying them that the pharmacy will be inspected in the next four to six weeks. Further information is available on the GPhC's website: http://www.pharmacyregulation.org/pharmacystandardsguide/how-often-pharmacies-will-be-inspected-notification-inspection.

- regular discussions with peers and colleagues (particularly those with first-hand experience of the new inspections);

- exchange forums and other industry-wide discussions and conferences (e.g. hosted by professional associations such as Pharmacy Voice or PSNC).

Some of the community pharmacy professionals interviewed further indicated that there are "checklists available from the GPhC" that they regularly consult to ensure they are operating in line with GPhC requirements.

The views of GPhC inspectors and stakeholder organisations validated the findings from the online survey. **The majority of GPhC inspectors and stakeholder organisations agreed that guidance currently available is useful and that pharmacies do take advantage of it.**

> I do see a lot more of people having gone to the website and they will have printed out the different documents that are available, with regard to the new inspection model and the new decision-making framework. However, some pharmacists are not aware of the existing material and say they will consult such information after the inspection (GPhC inspector, 2015).

However, a few inspectors noted that the degree to which pharmacists use such information varies:

> Yes, they do [use available information and guidance]. Mostly the information available on the websites of NPA and RPS. Also GPhC. The RPS website offers guidance documents, and they have support teams in place which pharmacies can call for help and advice (Stakeholder organisation, 2015).

### 3.3.2    Level of awareness

**A majority of the community pharmacy professionals (81 per cent) surveyed recognised that inspections carried out under the new regime have helped raise their awareness of the new standards.**

**Figure 3.8    Whether the level of awareness of the GPhC's standards has improved as a result of inspection**
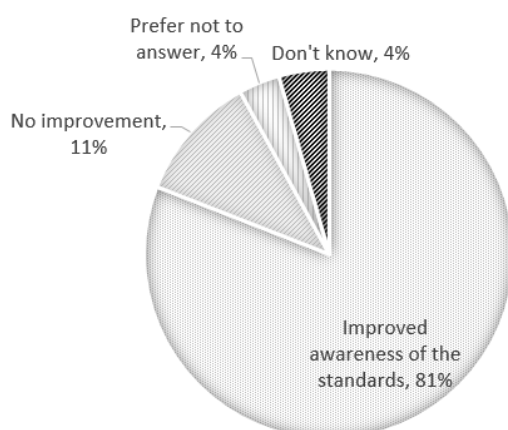


*Base: respondents inspected since 4 November 2013: 1390*

The majority of both stakeholder organisations and inspectors interviewed also stated that the level of awareness increases as a result of inspection:

> The level of awareness does increase as a result of the inspection. Before the inspection (once the pharmacist has received notice of the inspection) many

pharmacist will look at the standards and see what is required, which raises their awareness of the standards (GPhC inspector, 2015).

Similar findings were observed from interviews with community pharmacy professionals, whereby several interviewees praised inspections for their usefulness, particularly to "new trainees and employees" who "can listen to the inspector's recommendations and learn from them". This learning curve was also noted by one representative of a stakeholder organisation:
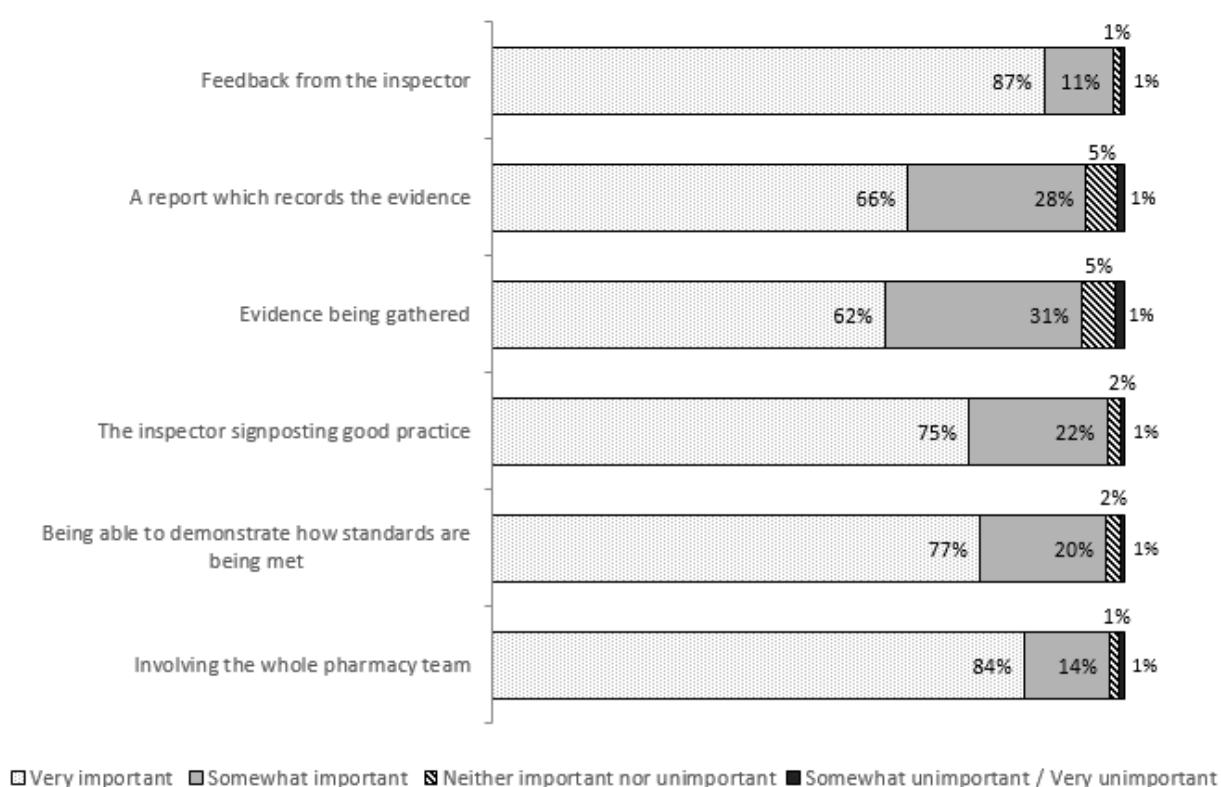
> The inspection is a real eye-opener with the inspection of areas that do not necessarily catch the pharmacy team's attention; […] I think that with subsequent rounds of inspection, pharmacists will further develop their understanding of the standards and targeted outcomes (Stakeholder organisation, 2015).

Overall, the evidence indicates that inspections constitute an indispensable tool towards assessing professional performance in community pharmacy and further improving the delivery of pharmacy services to patients.

### 3.3.3 Important aspects of the new inspection framework

**There are various aspects of the new inspection model which those working in community pharmacies reported to be very helpful in meeting the standards.** These mainly include: (1) receiving feedback from inspectors (87 per cent) which is analysed in detail in the following Section 4; (2) involving the whole pharmacy team (84 per cent); (3) being able to demonstrate how standards are being met (77 per cent); and being informed about good practices implemented by others in the sector (75 per cent) – see Figure 3.9 below.

**Figure 3.9     The elements of the new inspection model which were important to community pharmacy professionals for meeting and further improving standards**



☐ Very important   ▨ Somewhat important   ⊠ Neither important nor unimportant   ■ Somewhat unimportant / Very unimportant

*Base: respondents inspected since 4 November 2013: 1,377; 1,371; 1,367; 1,371; 1,374; 1,376 respondents.*

Greater involvement of the pharmacy team is regarded as a means to obtaining "the whole team's buy-in" and enhancing awareness around the importance of meeting the GPhC standards and the envisaged impacts on patients and users of pharmacy services. This is particularly true for pharmacy technicians who place greater importance than pharmacists on "involving the whole pharmacy team" aspect of inspections (91 and 82 per cent respectively).

> I think the most important aspect of the inspection is the involvement of the whole pharmacy team. Staff feel they are part of the process and feel they are contributing to painting the pharmacy in a good light. With the new inspections, staff definitely have a much greater role to play than 10 years ago (Online survey respondent, 2015).

**Most GPhC inspectors and stakeholder organisations also felt that engaging with the whole pharmacy team is crucial to meeting the standards.**

> […] getting the whole team's buy-in is important (GPhC inspector, 2015).

> The involvement of the whole pharmacy team is useful, as it helps to see if something has been implemented (Stakeholder organisation, 2015).

Finally, independent community pharmacy professionals were less likely than multiples to consider certain inspection elements important, particularly in terms of "evidence being gathered" (only 55 per cent of independent community pharmacies thought it was important while 67 per cent of multiples did). The table below illustrates other differences between their responses.

**Table 3.2** **Proportion of respondents thinking the elements of the new inspection model are important to community pharmacy professionals for meeting and further improving standards**

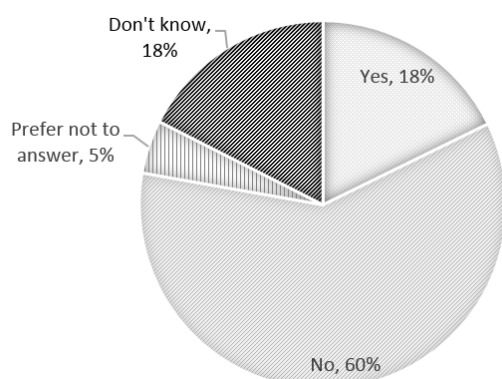| | Independent community pharmacy professionals | Those working in multiples |
|---|---|---|
| Feedback from the inspector | 82% | 89% |
| A report that records the evidence | 60% | 69% |
| Evidence being gathered | 55% | 76% |
| The inspector signposting good practice | 70% | 78% |
| Being able to demonstrate how standards are being met | 69% | 81% |
| Involving the whole pharmacy team | 80% | 87% |

*Base: independent pharmacies: 928; 923; 922; 922; 926; 926. Multiple pharmacies: 358; 357; 353; 358; 356; 358. Please note that the percentages may not add up to 100% as respondents may have rated more than one element of the new inspection model as important.*

## 3.4    Action-planning

Actions plans are generally well-received by community pharmacy professionals because they allow them to rectify the most serious failings and to improve in the areas most relevant to patient safety. Action plans target specific areas deemed lacking by the inspector, allowing respondents to define priorities for improvements and to assign responsibilities for rectifying failings as effectively as possible.

As shown in Figure 3.10, among the respondents inspected since 4 November 2013, 18 per cent needed to develop an action plan after failing to meet the required standards in certain areas.

**Figure 3.10    The need for community pharmacy professionals to develop an action plan**



*Base: respondents inspected since 4 November 2013: 1,386.*

**Among those community pharmacy professionals who needed to develop an action plan, remedial action was most commonly required in the following principles of the GPhC standards**: **governance arrangements** (35 per cent of online survey respondents); **staff competence** (34 per cent); and the **environment and condition of the premises** (33 per cent). Issues around **staff competence** were also raised during interviews with inspectors:

> Pharmacies may have a qualified team but then there is no additional training, feedback, support and encouragement given to them so that they can take on additional responsibility or grow in their role (GPhC inspector, 2015).

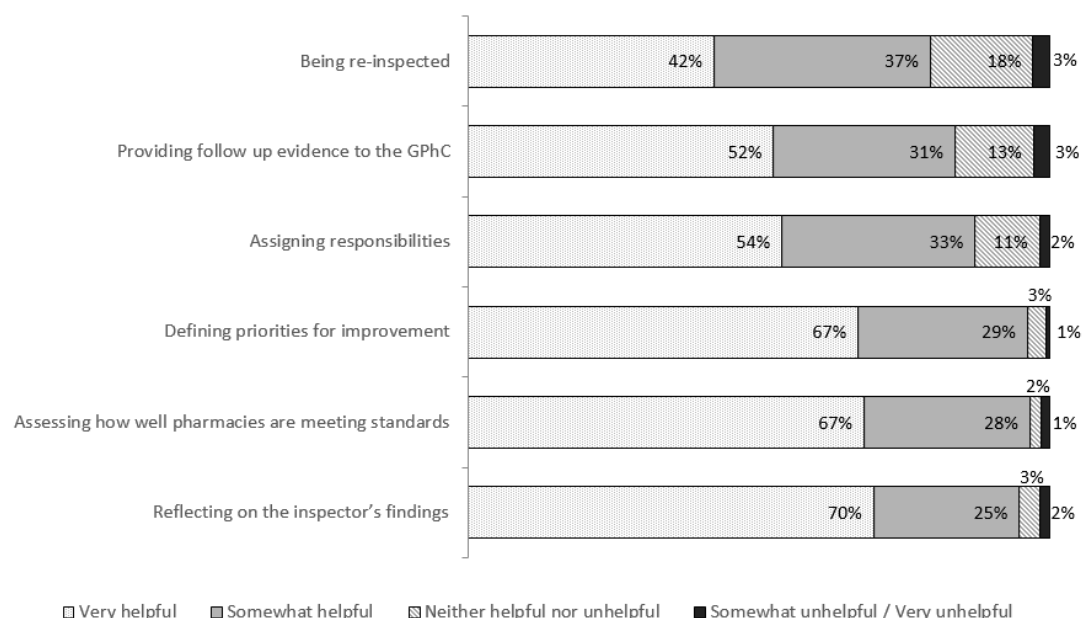**Figure 3.11    Main areas highlighted in action plans for remedial work**
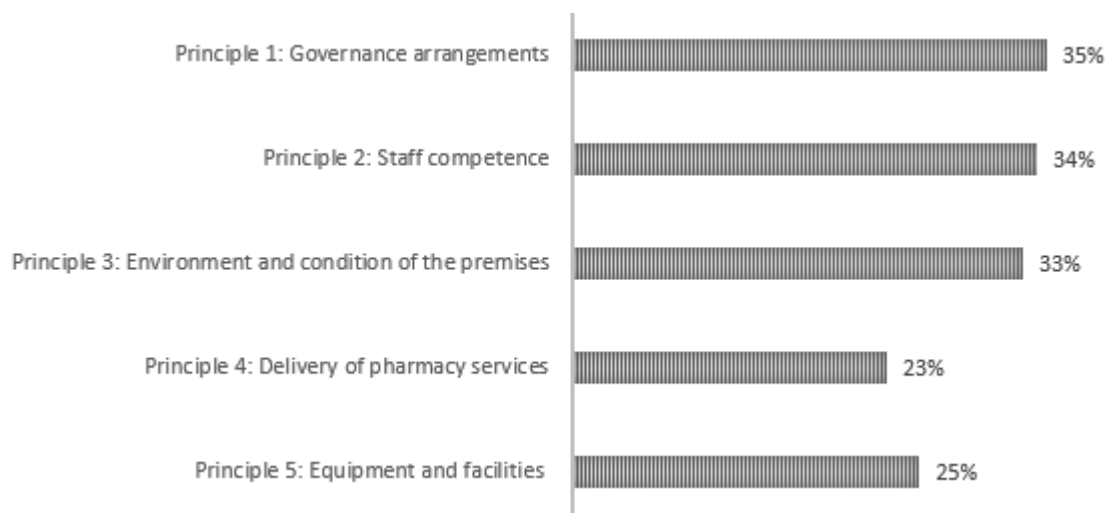


*Base: respondents required to develop an action plan by the GPhC: 292.*

As regards specific aspects of the action plan designed to improve patient care, almost all respondents indicated that particularly defining priorities for improvements, assessing how well standards were met and reflecting on the inspector's findings were very or somewhat helpful and proved effective in helping them improve compliance (Figure 3.12). Pharmacy technicians were more likely than pharmacists to find these elements of action planning very

helpful, particularly "assigning responsibilities" (79 per cent of technicians and only 51 per cent of pharmacists), "providing follow up evidence to the GPhC" (78 per cent of technicians and only 51 per cent of pharmacists) and "being re-inspected" (68 per cent of technicians and only 42 per cent of pharmacists).

**Figure 3.12    Whether elements of action planning were useful in improving standards of patient care**



Base: respondents required to develop an action plan by the GPhC: 277; 282; 280; 285; 286; 287

As regards specific aspects of the action plan, four in five online census respondents indicated that the guidance provided by GPhC inspectors in developing action plans as well as being able to provide follow-up evidence **are helpful and have proved effective in helping them improve and be compliant.** These views were equally supported by inspectors.

> Action plans focus the mind on the standards and the outcomes, leading to better working practices (GPhC inspector, 2015).

**The general consensus among stakeholder organisations is that where an action plan is implemented** (typically for the pharmacies with poor rating), **it leads to an improvement** of pharmacy processes. This change is particularly noticeable when pharmacies shift from "poor" to "satisfactory" rating but is also true for pharmacies with action plans rated "satisfactory":

> Most definitely, particularly among poorly-rated pharmacies. I have inspected pharmacies that were not performing as they should. But upon re-visiting and following-up after they've had time to make changes in accordance with the action plan, the pharmacy is a totally different place (GPhC inspector, 2015).

**A few stakeholder organisations**, however, **stressed that action plans ought to be fair** by providing **enough time** for pharmacies to take **remedial action**. This is due to the evidence provided by several community pharmacy professionals who argued that the action plan has not provided them with enough time to accomplish required tasks. One case referred to maintenance work around the pharmacy, which could not be accomplished due to bad weather. In another example, repairs to the "patient room" affected pharmacy customers because they could not use it.

Action plans should not penalise pharmacies […] they should have enough time […] rather than trying to fix something quickly and not getting any benefits out of it (Stakeholder organisation, 2015).

## 3.5 Reporting and rating

**The majority (89 per cent) of the respondents to the census recognised that inspection reports are a valuable tool** when considering and implementing improvements in quality and performance, while an additional 84 per cent of respondents acknowledged that inspection reports help them focus on areas most relevant to patients and customers (Figure 3.13). Conversely, only 70 per cent of respondents thought inspection reports were accurate and only 63 per cent thought they were sufficient to support final inspection judgments and ratings.

**Figure 3.13    Perceptions of inspection reports and ratings**
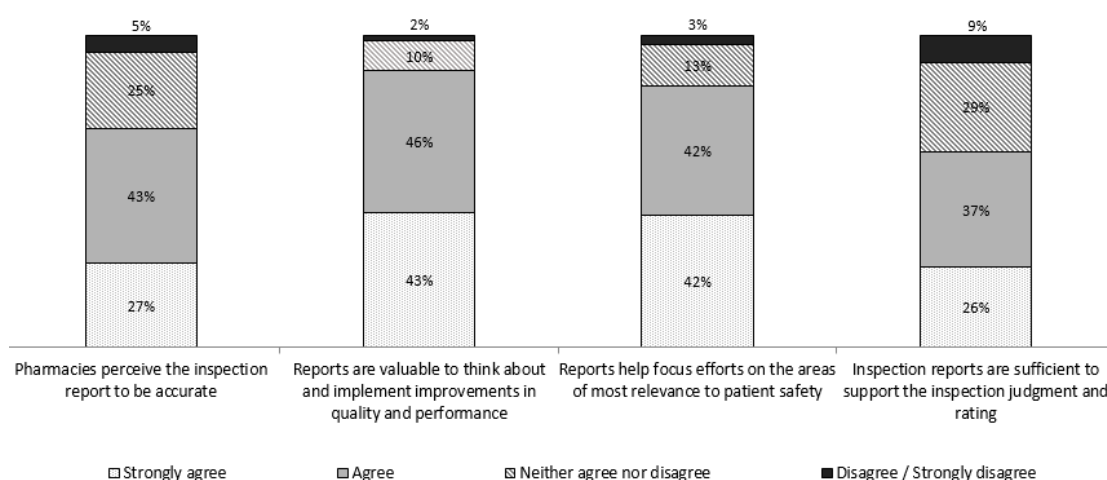


Base: community pharmacy professionals: 3693; 3693; 3691; 3687.

Multiple and inspected pharmacies were more likely to be of the opinion that reporting is valuable and helps focus efforts on the areas most relevant to patient safety than independents and not inspected pharmacies. Pharmacy technicians were also more likely to find reporting valuable than pharmacists (as showed in Figure 3.14 below).

**Figure 3.14    Percentage of respondents who strongly agreed with statements concerning reporting and rating**
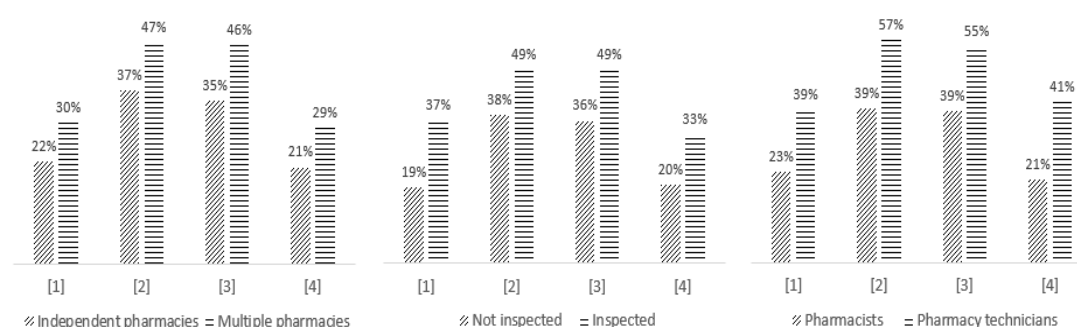


[1] Pharmacies perceive the inspection report to be accurate
[2] Reports are valuable to consider and implement improvements in quality and performance
[3] Reports help focus efforts on the area's most relevant to patient safety
[4] Inspection reports are sufficient to support the inspection judgment and rating

*Base: community pharmacy professionals. Independent pharmacies: 993; 1000; 1001; 999. Multiple pharmacies: 2459; 2460; 2458; 2455. Not yet inspected pharmacies: 1223; 1224; 1223; 1220. Inspected pharmacies: 1383; 1382; 1384; 1383. Pharmacists: 2526; 2525; 2526; 2520. Pharmacy technicians: 858; 857; 857; 856*

**The usefulness of inspection reports and ratings was reiterated during the in-depth interviews with community pharmacy professionals.** However, some community pharmacy professionals felt that ratings may not truly reflect how the pharmacy works in practice. Specifically, some expressed concern that ratings such as "satisfactory" could create uncertainty and undermine patients' confidence and trust. While GPhC inspectors and stakeholder organisations generally recognised that ratings incentivise pharmacies to focus on the standards and improve, **the general consensus was that certain ratings, in particular the "satisfactory" rating, are misleading and often demotivating for pharmacies**. Section 5 below analyses potential solutions to this problem.

> I think it is unfair to publish the report when you receive a "satisfactory" grade. It just gives the wrong impression (Online survey respondent, 2015).

> Ratings are controversial but I think it's more the wording […] "satisfactory" has a negative connotation in many people's minds (GPhC inspector, 2015).

# 4 Effectiveness of the new interventions – impact evaluation

The findings of this section relate to the changes that have occurred and how far these can be attributed to the GPhC's new approach to community pharmacy regulation. As the new approach is still in its early days, concrete evidence of its impact is limited. However, where available, the evidence presented in this section seeks to provide a better understanding of how far targeted outcomes are being achieved, specifically:

■ whether the culture is gradually shifting from one  previously focussed primarily on rules and compliance, towards one that focusses on outcomes and improvement, i.e. whereby pharmacies put patients and users of their services first;
■ whether pharmacies are actively engaged in achieving and sustaining compliance and improvement and, ultimately, quality and safety; and
■ how far the overall regulatory approach is effective in practice by driving better outcomes for pharmacies and their patients and users of pharmacy services.

## 4.1 Key messages

**Impact on patients**

■ The majority (74 per cent) of all survey respondents recognised that the new standards have helped them increase their focus on patients and users of their services, albeit a few GPhC inspectors have stressed that this cultural shift is a slow process. Most community pharmacy professionals increased patient focus by working in line with the standards embedded in their:

– daily work practices
– recruitment and training policies (in particular, the whole pharmacy team is encouraged to be fully involved in assisting in day-to-day activities and to acquire first-hand knowledge of the new GPhC intervention tools)
– promotion of better interaction between users of pharmacy services and the pharmacy team.

■ A higher proportion of pharmacy technicians said the new GPhC standards encourage them to increase their focus on patients (81 per cent), as compared to pharmacists (72 per cent).

85 per cent of respondents stated that inspections help them focus more on their patients and customers. They often achieve this by providing additional services to patients such as emergency services and home visits. Most GPhC inspectors also recognised that "inspections are key" in ensuring that good levels of practice are maintained.

■ Inspections appear to be very important to a higher proportion of pharmacy technicians (70 per cent) than pharmacists (47 per cent). Multiples were more likely (although the difference is marginal) than independents to consider their services to be patient-focused as a result of standards (86 per cent of as compared to 81 per cent respectively).  Multiples are potentially more likely to do so by more regularly reviewing and monitoring the safety and quality of their pharmacy services, and maintaining all necessary records for the safe provision of pharmacy services on their premises.

■ Community pharmacy professionals indicated that, as a result of the new approach to regulation, they promote better interactions between users of pharmacy services and pharmacy team – that community pharmacy professionals are generally keen to adopt a more proactive approach towards patients and users of pharmacy.

■ While the majority of interviewed GPhC inspectors agree that the new approach to regulation is changing the culture, a few have stated that this change is slow, and that not all pharmacies have succeeded in changing the focus to a more patient-centred culture.

■ Some stakeholder organisations thought that the standards allow the pharmacy team to realise the importance of their roles and responsibilities, while encouraging them to see the "bigger

picture". At the same time, a few GPhC inspectors raised concerns about there being too many standards, which decreased their understanding.

**Evidence of sustained improvement**

■ There is little evidence yet to suggest that the new approach leads to sustained improvements.

■ How far the different interventions, in particular inspections and action-planning, encourage continued focus on improvement is, to some extent, difficult to assess – inspections have historically been carried out every three years on average, and there is little post-inspection data available yet.

■ The general consensus among stakeholder organisations and GPhC inspectors is that where an action plan is implemented (typically for the pharmacies with poor rating), it leads to an improvement (partly due to greater involvement of pharmacy owners), but it is uncertain whether action planning results in continued improvement (mostly due to lack of post-action plan data).

■ GPhC inspectors and stakeholder organisations held mixed views regarding the relevance of inspection reports and ratings in sustaining improved outcomes. While reports and ratings tend to act as a "wake-up call," pushing pharmacies towards greater compliance, some inspectors felt that such changes are not maintained long-term, partly because they are not yet publicly available.

■ A few stakeholder pointed out that the new ratings system might discourage pharmacies because the rating term "satisfactory" is perceived negatively and the definition very wide. This might discourage pharmacies from embracing improvement. This is discussed in more detail in Section 5.

**In summary, the general consensus is that the new approach has increased the focus of pharmacies on patients and users of pharmacy. There is little evidence yet to conclude to what extent the new interventions lead to sustained improvement, and views are divided. While reports and ratings tend to push community pharmacy professionals towards greater compliance, some study participants suggested that the rating term "satisfactory" might discourage further improvement.**

## 4.2 Putting patients first

### 4.2.1 Evidence of a "cultural shift" towards a patient-centred service

**In particular, a majority (74 per cent) of all respondents recognised that the new standards have helped them increase their focus on patients and users of their services.** Only 10 per cent of respondents did not consider the use of new standards useful as a means to encourage patient-centred service. The remaining respondents did not know if new standards were useful or preferred not to answer. A higher proportion of pharmacy technicians said the new GPhC standards encourage them to increase their focus on patients (81 per cent) compared to pharmacists (72 per cent). Also, a higher proportion of multiples than independents (86 per cent as compared to 81 per cent respectively) recognised that the new GPhC standards increase their focus on patients and users of pharmacy. There were no statistically significant differences between respondents working in inspected or not yet inspected pharmacies.

**Figure 4.1    Standards are important to encourage pharmacies to increase focus on patients and users of their services**
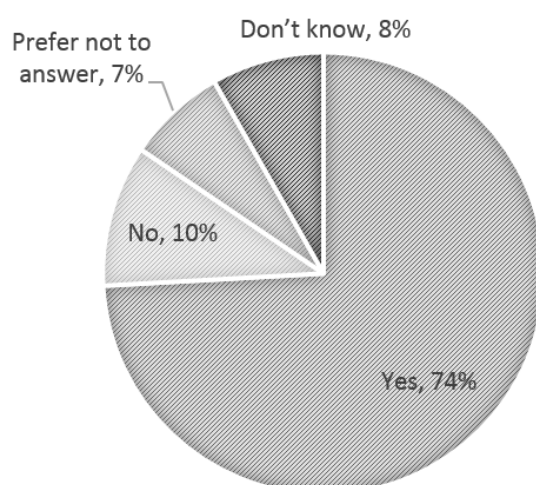


*Base: community pharmacy professionals: 3744.*

In particular, most respondents supported the view that the new standards encourage pharmacists and their teams to source equipment (75 per cent) and medicines and medical devices (78 per cent) from reputable sources to ensure they are safe and fit for purpose and to store and dispose of any equipment and medicines and medical devices securely.

Additionally, many respondents (69 per cent) felt that the standards encourage greater focus on protecting the privacy and confidentiality of patients and users of pharmacy services.

**Figure 4.2    Standards are important to encourage pharmacies to increase focus on patients and users of their services.  As a result of the standards…**
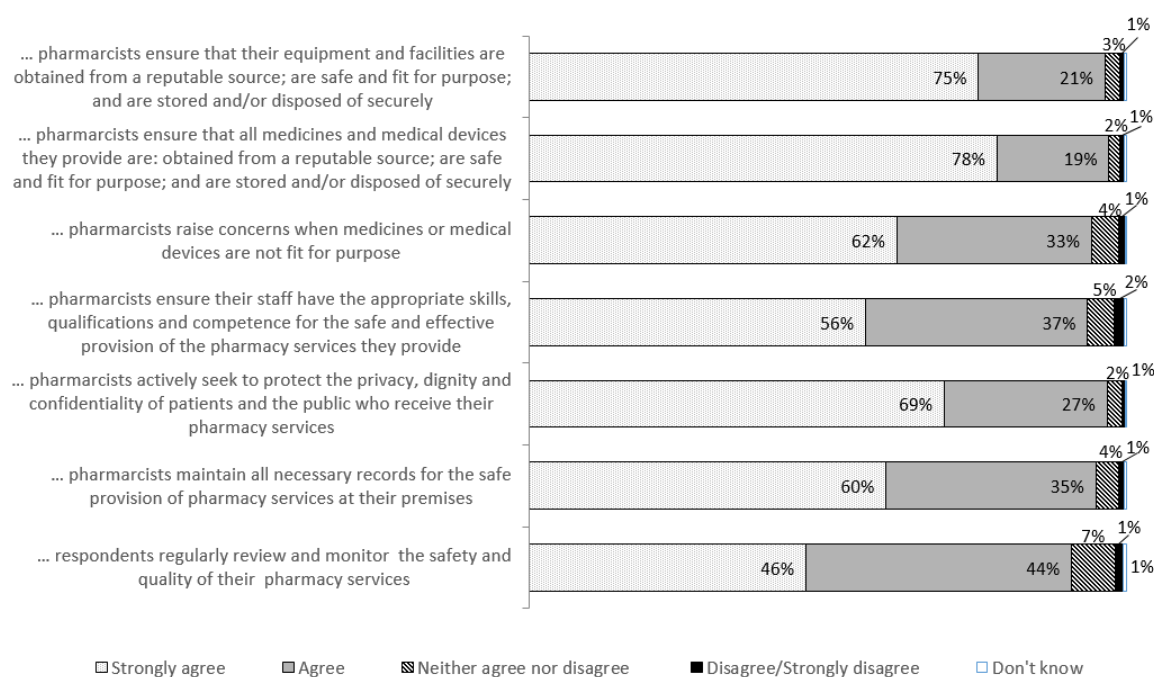
**The majority (85 per cent) of respondents who had inspections stated that they helped them focus more on their patients and customers.** This evidence reinforces findings reported previously around the usefulness of inspections to further patient focus in community pharmacy. More information and guidance around standards should therefore be maintained to ensure that pharmacy professionals understand the objectives of the new approach.

**Figure 4.3    Inspections are important for encouraging community pharmacy professionals to focus on patients and users of their services**
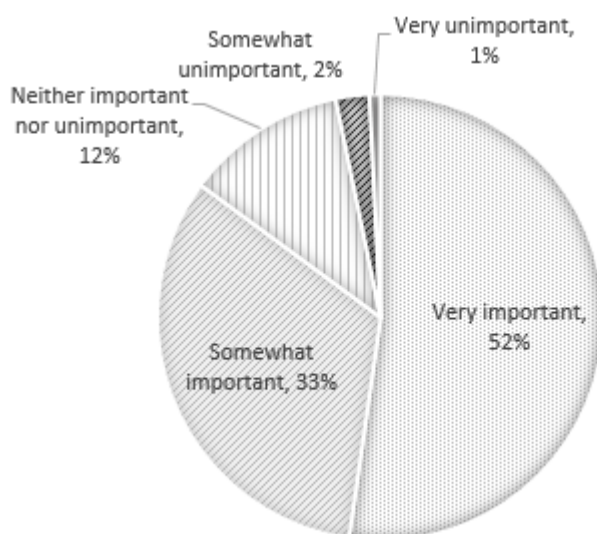


*Base: respondents inspected since 4 November 2013: 1389.*

Other than dispensing services, most pharmacists surveyed indicated that they provide a range of additional pharmacy services to their patients. These include:

■ emergency/on-call services (e.g. services typically required outside surgery opening times or as a result of a patient's condition deteriorating);

■ free and/or "after-hours" delivery services for the most vulnerable patients (e.g. house-bound patients, the elderly, etc.);

■ "home visits" for patients in palliative, terminal and/or end-of-life care (e.g. delivery of end-of-life medications outside of normal working hours, management/provision of dosette boxes);

> We operate a palliative care service that requires specialist input and out of hours support (Online survey respondent, 2015).

■ health checks, free of charge in many cases (e.g. glucose tests, blood pressure tests

■ travel health services (e.g. vaccinations travel health information and advice)

■ healthy lifestyle services (e.g. smoking cessation services, substance abuse and alcohol misuse services, allergy services, flu vaccination services)

> My branch has also signed up for private flu vaccination last year for first time. We will be looking to continue with this service this year as well (Online survey respondent, 2015).

Evidence provided by a large number of online census respondents indicates that community pharmacy professionals work in close partnership with doctors, nurses, carers and other healthcare professionals to improve the quality of care provided to patients and users of pharmacy services. Additionally, pharmacists work closely with patient's families and friends to ensure the "safe use of medication".

Further, community pharmacy professionals operating in multiples were more likely than independent pharmacists to strongly agree with the following statements:

- "as a result of the standards, we regularly review and monitor the safety and quality of our pharmacy services" (49 per cent of pharmacies in multiples strongly agreed compared to 41 per cent of independent pharmacists).
- "as a result of the standards, we maintain all necessary records for the safe provision of pharmacy services at our premises" (63 per cent of pharmacies in multiples strongly agreed compared to 54 per cent of independent pharmacists).

**Some stakeholder organisations thought that the standards focus on outcomes, particularly the patient experience.** The standards are not only about dispensing, but focus much more on providing the patient with a particular service. The standards also enable the pharmacy team to realise the importance of their roles and responsibilities, while encouraging them to see the "bigger picture":

> In a way it does, the better a pharmacy does in terms of being innovative, implementing good services in the pharmacy, the better service the patient will receive from the pharmacy and the better image pharmacy will have ( Stakeholder organisation, 2015).

**While the majority of interviewed GPhC inspectors agree that the new approach to regulation is changing the culture, a few have stated that change is slow**, and that not all pharmacies have succeeded in changing the focus to a more patient-centred culture:

> I don't think the standards have driven this culture yet. There are very few occasions, if any, where pharmacists will give me evidence which clearly demonstrate an outcome-focused approach. Their evidence is principally process-focused. They don't necessarily provide examples of the impact(s) of their services or the quality of their services on patients (GPhC inspector, 2015).

**A few GPhC inspectors also raised concerns about the "wording of the standards."**

> The word "services" appears a lot in the standards. I think if they were refined a bit more, it might be easier for pharmacists to understand that we are primarily inspecting on behalf of patients (GPhC inspector, 2015).

### 4.2.2 Enhancing patient care via the new standards

#### 4.2.2.1 Internal work practices and standards

**There is general support for the new standards and their aim to promote and enhance patient care** in the community pharmacy sector. Most community pharmacy professionals indicated that they work in line with the standards embedded in the internal work practices, notably:

- *With regards to maintaining safe and well-managed pharmacy premises and services –* nine in 10 respondents confirmed they regularly review and monitor the safety and quality of their pharmacy services.

■ *With regards to implementing and maintaining robust governance procedures and processes* – more than 90 per cent of respondents indicated that they strive to: (i) maintain all necessary records for the safe provision of pharmacy services at their premises (95 per cent); and (ii) ensure that all medicines and medical devices (97 per cent) as well as equipment and facilities (96 per cent) they provide are obtained from a reputable source, are safe and fit for purpose and are stored and/or disposed of securely.

> […] we regularly undergo spot checks and audits to ensure that GPhC standards are being maintained at all times (Online survey respondent, 2015).

The above statement corroborates evidence provided by many community pharmacy professionals who work in multiples. These respondents generally praised the robustness of internal governance arrangements which, in their opinion, help ensure delivery to the "highest standard". Many of these respondents also indicated that meetings regularly take place (at branch level) to discuss areas that require further improvement. These meetings often benefit from the input of all pharmacy staff.

The above finding reiterates the need for support in meeting the new standards. Investment in training and professional development is, however, limited in independent pharmacies, largely for financial reasons. Such opportunities could therefore be provided by third-party organisations in collaboration with the GPhC, to ensure that staff in independent pharmacies receive adequate training and are able to work in accordance with the standards. These would also ensure that internal procedures and systems are up to scratch.

#### 4.2.2.2 Recruitment and training standards

*With regards to attracting and retaining more empowered and competent staff,* 93 per cent of online survey respondents reported that they ensure their staff have the appropriate skills, qualifications and competence for the safe and effective provision of the pharmacy services they provide.

*Regarding staff recruitment, training and development,* community pharmacy professionals generally felt that the new approach to pharmacy regulation has encouraged them to:

■ follow rigorous recruitment processes to attract and retain staff with relevant competencies and knowledge;

■ ensure staff receive adequate support, particularly during busy periods, to deliver efficiently, and

■ offer or mandate thorough training to further staff development, knowledge and skills as well as to improve work performance and satisfaction.

> Each staff member is personally trained by a qualified member of our training staff - usually a Pharmacist acting as a tutor […]. We always follow NPA training programmes and others to ensure that all of our pharmacy staff are highly qualified (Online survey respondent, 2015).

In particular, most online survey respondents indicated that the whole pharmacy team is encouraged to be fully involved in assisting in daily activities and to acquire first-hand knowledge of the new interventions to better understand their role and learn to provide a good experience of care to patients. They further recognised the vital role of staff involvement in inspections, particularly for "contributing towards painting the pharmacy in a good light".

> We always talk […] as a group and very often, my staff will come up with very good ideas as to how we can sort out the workload as efficiently as possible and provide a better service to our patients (Online survey respondent, 2015).

#### 4.2.2.3 *Promotion of the interaction between users of pharmacy services and pharmacy team*

**Community pharmacy professionals indicated that, as a result of the new approach to regulation, they promote better interactions between users of pharmacy services and the pharmacy team** – by actively seeking to protect the privacy, dignity and confidentiality of patients and the public who receive their pharmacy services (96 per cent of respondents).

Evidence from the online census indicates that community pharmacy professionals are generally keen to adopt a more proactive approach towards patients and users of pharmacy. This includes:

■ getting to know patients better by monitoring their health and use of medication;
■ educating patients about illness management/prevention and treatment in order to encourage them to play a more active role in their health care, and
■ offering information, advice and related support to patients.

> All our patients receive counselling and are offered one-to-one advice if needed in the consultation area where they are encouraged to ask questions (Online survey respondent, 2015).

## 4.3 Evidence of sustained improvement

Measurement is limited on how far pharmacies are actively engaged in achieving and sustaining compliance and improvement under the new regulatory approach. This is because the new regime has been introduced relatively early, and many pharmacies either have not yet undergone inspection or follow-up (except those rated "poor"). Therefore, limited data means impacts cannot be captured at this stage. This sub-section does, however, attempt to at least provide guidance for future impact evaluation.

The evidence from the online census suggests that although pharmacists adhere to the standards, **there is little encouragement to go beyond what is required or advised by inspectors to further improve the quality of community pharmacy -** only 24 per cent of pharmacies go beyond the level required by the standards, with 36 per cent not sure whether they do or not.

**Figure 4.4    Some pharmacy practices go beyond the level required by the GPhC's standards**
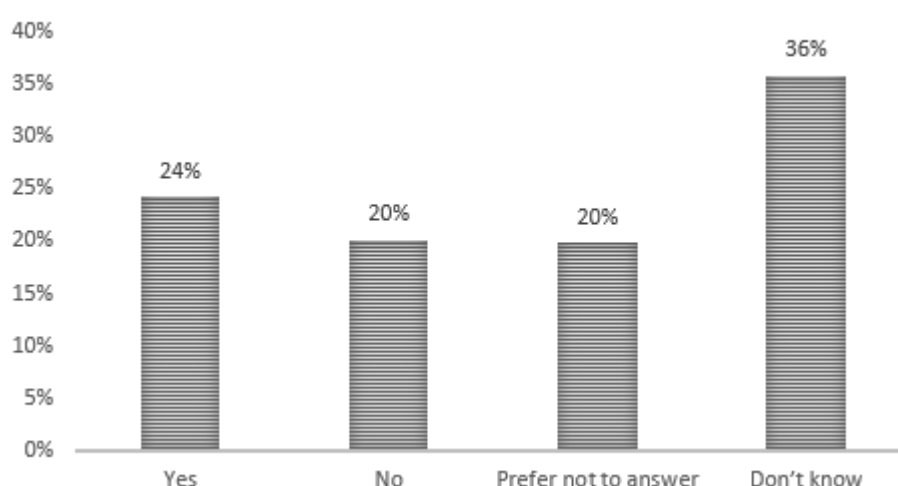


*Base: community pharmacy professionals: 3729.*

Respondents to online census who stated they did go beyond the new standards provided examples of additional services they offer to improve the patient experience, including: (1) free delivery; (2) home visits; (3) out-of-hours services; (4) help with medication management; (5) liaison with GPs when in doubt; (6) smoking-cessation and vaccination services, and (7) special care services for the most vulnerable (e.g. the elderly).

GPhC inspectors generally felt that pharmacists and their teams do not tend to "go the extra mile".

> [pharmacists] do not really think outside the box […] and by the looks of it, pharmacists seem to be quite content to rely on examples inspectors suggest to them as opposed to […] providing compelling examples they can draw from their day-to-day work at the pharmacy to show how they achieve compliance and sustain improvement (GPhC inspector, 2015).

The evidence corroborates findings reported previously that pharmacy professionals would benefit from more guidance and support, from the GPhC and other relevant organisations, on how to meet the standards and achieve improved patient and pharmacy outcomes.

**How far the different interventions, particularly inspections and action-planning, encourage continued focus on improvement is, to some extent, difficult to assess – inspections have historically been carried out every three years, on average, and at this stage there is little post-inspection data available.** For pharmacies that achieve "satisfactory" ratings and beyond, no follow-up visit is required, making it difficult for inspectors to track progress. However, in such instances, although action plans are not required, inspectors explained they would encourage the pharmacy team towards certain areas of improvement. This is generally well-received by community pharmacy professionals.

> I've received emails from owners where they explain that their teams have found the whole inspection process supportive and very encouraging and that they would be taking all recommendations on board to improve even in cases where they were rated "good" (GPhC inspector, 2015).

**Where action plans are required, stakeholder organisations and GPhC inspectors are uncertain whether they lead to sustained improvement.** Some stakeholders pointed out that the majority of pharmacies do not have an action plan in place. In any case, there has not yet been sufficient time to judge how effective action planning is in generating sustained development long-term. Although the general consensus among GPhC inspectors and stakeholder organisations is that where an action plan is implemented (typically for the pharmacies with poor rating), it leads to improvement, but it is not clear whether action planning results in continued improvement.

> Most definitely, particularly among poorly-rated pharmacies. I think the action plan is very effective in helping them make the changes. Upon re-visiting and following-up after they've had time to make changes in accordance with the action plan, the pharmacy is a totally different place. And we do get positive feedback from the pharmacist and the pharmacy team in relation to action-planning and how it's helped them improve (GPhC inspector, 2015).

**Inspectors and stakeholder organisations have generally found community pharmacy professionals to be engaged in action plans.** In particular, they have seen greater involvement from pharmacy owners who may have passed on procedures to the pharmacy manager (but may not have followed up whether these are in place). Action plans will often stress that management procedures are not up to scratch, prompting pharmacy owners or superintendent pharmacists to address shortcomings and improve standard operating procedures. One stakeholder organisation in particular has stressed the important role of pharmacy owners and superintendents in sustaining improvement via action plans:

> […] some pharmacies just see it as a box to be ticked – we have an action plan, make a quick suggested change, reassessment and then just go about it how we used to for the next three years. This would be the path of least resistance. However, if the owner is fully engaged with the process and actually wants to improve the action plan will highlight the areas they need to focus on (Stakeholder organisation, 2015).

Regarding pharmacies that do not receive the action plans, some GPhC inspectors and stakeholder organisations stated the difficulty of estimating whether standards have improved, at least for well performing pharmacies, because pharmacies without an action plan are generally doing a "good job" and therefore are likely to meet the standards in any case.

**The potential for inspection reports and ratings to encourage continued focus on quality provision of pharmacy services and improvement is uncertain.** The GPhC inspectors and stakeholder organisations held mixed views regarding the relevance of inspection reports and ratings in sustaining improved outcomes. While reports and ratings tend to act as a "wake-up call," pushing pharmacies towards greater compliance, some inspectors felt that such changes are not maintained long-term, partly because they are not yet publicly available:

> I don't think reports/ratings provide an incentive to sustain improvement at the moment as we don't currently publish reports and ratings. I don't think there are too many pharmacies out there who have been inspected who want to get higher ratings and show their pharmacy in the best light. They are just content with showing they have met the requirements (GPhC inspector, 2015).

At the same time, a few GPhC inspectors and stakeholder organisations felt that although the term "satisfactory" might have a negative connotation (and that the wide definition of "satisfactory" might discourage community pharmacy professionals from embracing improvement), ratings are important because they motivate pharmacies to give their best and improve and sustain that level (Section 5 below analyses this in more detail).

> [Rating]…can impact pharmacists in two ways: they may see it as a driver for improvement, as they want to be rated good; or they may think they have put in a lot of effort for a satisfactory score, and think it is not worth the effort in the future. This is because the range for "satisfactory" is very wide, with pharmacists who are miles away from a good grade being rated the same as those who are virtually good (Stakeholder organisation, 2015).

# 5    Scope for improvements

This section suggests ways the GPhC could further develop change or improvement to the new regulatory interventions, as outlined by study participants.

## 5.1    Key messages

**Standards**

- The majority of GPhC inspectors and stakeholder organisations and community pharmacy professionals interviewed pointed to the lack of guidance for pharmacists about how to achieve the standards. In particular, the stakeholder organisations argued that it would be helpful to have information providing illustrative examples of how to better achieve standards and therefore ratings.
- In addition, a few community pharmacy professionals and GPhC inspectors mentioned that simplifying the wording of some of the standards and avoiding unnecessary duplication might reduce uncertainties about what is required to achieve them.
- The majority of GPhC inspectors interviewed suggested that standards that overlap (for example around governance) should be merged to provide more clarity and time to focus on the areas of most concern during inspections.

**Inspections**

- Most of the evidence gathered as part of this research indicates that the GPhC's new regulatory approach is working well.
- As the majority of community pharmacy professionals find GPhC inspector's feedback important during the inspection process, receiving such feedback was a key suggestion..
- Further, some community pharmacy professionals would prefer to have regular visits from the inspectors which, in their opinion, would help maintain a continued focus on standards and improvement. However, due to the new regime being introduced as recently as 2013, there has been little scope for the GPhC inspectors to follow-up with inspected pharmacies. These views are generally supported by the opinion of GPhC inspectors and some of the stakeholder organisations interviewed.
- Some community pharmacy professionals raised the need for more consistent compliance from inspectors in providing sufficient notice of inspections. .

**Action plans**

- Community pharmacy professionals were generally positive about action plans, except for timescales allowed for implementing changes, which they felt are "not realistic" (limited staffing resources to effect implementation were cited widely), reiterating their views as discussed in Section 3.
- Extending the window for implementing actions plans beyond the 30-day period would be more helpful to pharmacies because certain remedial actions are fairly complex. This would help avoid any unnecessary pressures on internal resources and pharmacies failing to implement the changes.
- A minority of respondents indicated that the recommendations included in the action plans needed to be clearer and more constructive.

**Reporting and rating**

- Most community pharmacy professionals and GPhC inspectors and stakeholder organisations complained that the term "satisfactory" is misleading and does not truly reflect the extent of efforts made by pharmacists to adhere to the GPhC's principles.

- There is general support from all study participants for greater definition in grades, particularly in relation to the "satisfactory" rating.

- There is a perceived lack of guidance for inspectors on how to rate pharmacies, i.e. not enough practical examples to link pharmacy evidence to the inspection framework, resulting in the majority of pharmacies being rated "satisfactory".

- There is not enough information regarding what evidence and measures pharmacies need to prepare to achieve a certain rating.
- Suggestions for improvement included an introduction of more gradated scoring systems that better capture variation in performance, or simpler pass/fail ratings that limit scope for misinterpretation.

**Publication of reports and ratings**

- The general view is that the publication of inspection reports and ratings could help improve sector performance and increase accountability of pharmacies when meeting the standards.

- Pharmacies provided no evidence on the impact of the rating before publication (as the system works now) as opposed to the potential impact of the rating after publication.

- The vast majority of GPhC inspectors and stakeholder organisations supported the proposals to publish the reports, stressing that they should be succinct and ideally published in the form of a summary.

- There appears to be more reticence on the part of community pharmacy professionals than GPhC inspectors and stakeholder organisations to have inspection reports published. For example, online survey respondents noted that publication could put too much stress and pressure on those working in community pharmacies.

- In spite of a certain level of scepticism among GPhC inspectors and stakeholder organisations and community pharmacy professionals about the publication of ratings (largely also due to the rating labels and concerns about the perception of "satisfactory" grade by patients and users of pharmacy), most recognise that the initiative could help improve sector performance.

- The non-community pharmacy professionals who participated in the online survey were also in favour of the GPhC's proposal to publish inspection reports and ratings.

**In summary, the key suggestions for improvements revolve around simplification of some of the standards, post-inspection follow-up visits and feedback from GPhC inspectors, re-considering the "satisfactory" rating, and extending the window for the completion of action plans. At the same time, the study participants generally believe that the publication of reports and ratings is likely to improve sector performance.**

## 5.2 Standards

**A few community pharmacy professionals and GPhC inspectors believe that the wording of the standards could be simplified to reduce uncertainties about what is required** and, to a certain degree, to minimise duplication wherever possible.

> "I think some slight re-wording of some standards could also be useful – 1.6 talks about ensuring that "all necessary records for the safe provision of pharmacy services are kept and maintained" – I think the word "all" implies that the inspector should go through each and every record to verify that they are being maintained. I think that one could be broadened out a little bit more and offer more flexibility to inspectors (GPhC inspector, 2015).

About 6 per cent of community pharmacy professionals offered suggestions as to how the standards could be improved further. Some pharmacists felt that the wording of the current standards could be simplified, because currently there is excessive and unnecessary jargon. These respondents would prefer to have the standards written more succinctly and to be presented in a format that is simple for pharmacy staff to navigate.

The need to simplify the standards was also raised by some inspectors who felt that some, notably standards 1.1 and 1.2; standards 2.1 and 2.2; standards 4.2 and 4.3; and several elements within principles 3 and 5 are "repetitive" or "overlap too much […] making them unwieldy to administer during inspections."

**Almost all of the interviewed GPhC inspectors suggested that some of the standards should merge.** This is because some standards overlap (around governance and pharmacy staff, for instance), making them unwieldy to administer during inspections. Additionally, merging some of the standards would allow community pharmacy professionals to identify risks more easily as they would have more time during the inspections to focus on the areas of the most concern.

Finally, on various occasions, inspectors explained that the evidence required during inspections by the decision-making framework does not always reflect the practical situation in the pharmacy:

> I think because these guidance documents for inspectors are written in such a "high-level" way that for most inspectors, including myself, it is difficult to relate them to any practical examples that we see in the pharmacy. Similarly, although pharmacists may have read these documents (e.g. the decision-making framework), they find it too vague, too conceptual and do not provide them with clear direction as to what outcome-focused examples they should provide to achieve good ratings (GPhC inspector, 2015).

**The majority of stakeholders and community pharmacy professionals interviewed pointed to the lack of guidance for community pharmacy professionals about how to better achieve the standards.** In particular, the stakeholder organisations argued that it would be helpful to have illustrative examples of how to comply with the standards – examples of best practice. Many online survey respondents would appreciate examples to understand how to better implement the new standards. This is in addition to the advice and information already available from organisations such as Royal Pharmaceutical Society, National Pharmaceutical Association and the GPhC.

> More guidance would help increase understanding of what needs to be done to meet the standards (GPhC inspector, 2015).

A few online survey respondents also mentioned the need for a more guidance:

> [there is a need for] use of clear language with examples or even better a clear tick box statements of all the standards to be met without leaving things as they are at present where it is up to the inspector to decide how the standards are met without any guidance (Online survey respondent, 2015).

## 5.3 Inspections

**The majority of community pharmacy professionals responding to the census and interviews suggested adopting a more collaborative approach to inspections that focuses on providing more constructive feedback, including more concrete examples of how better ratings can be achieved** – community pharmacy professionals believe that they would benefit more from inspections if inspectors were to:

> provide explanatory feedback […] and telling the pharmacist what needs improving and applying measureable methods that are convenient for the pharmacy to implement (Online survey respondent, 2015).

This feedback could include, for example, feedback on why a judgement was made, with clear indication of where the pharmacy had failed to meet the standards, and what it could have done to be compliant. One online survey respondent stressed that it is important to

provide feedback regarding what could elevate a community pharmacy from "satisfactory" to "good", rather than focusing only on those underperforming.

This is in line with the findings outlined in Section 3 above that the majority of community pharmacy professionals (87 per cent) feels that GPhC inspector's feedback is important during the inspection process. However, since the new approach was introduced in 2013, there has been little scope for GPhC inspectors to follow-up with the inspected pharmacies.

**Having sufficient notice prior to inspections** was another key suggestion put forward by some online survey respondents to improve the inspection process. While inspectors generally reported that notification letters are sent six weeks before an inspection takes place, some community pharmacy professionals felt that inspectors tend to be inconsistent in their approach and failed to provide sufficient notice. One community pharmacy professional provided an example where the inspection pre-notification was only sent by email, and to a non-existent email account. As such, the pharmacy only received a few weeks' notice.

> Having prior notice could help as this would enable pharmacies to plan staff and have more staff available on the day of the inspection, especially if the visit is likely to take place on a very busy day (GPhC inspector, 2015).

**Pharmacists have also suggested that inspections should focus on the delivery of key pharmacy services – such as Medicines Use Review (MURs)[33] in England – and adopt a more partnership-based approach to regulation in the community pharmacy sector.**

In the same vein, community pharmacy professionals suggested that inspectors ought to observe the delivery of key services such as MURs to have a better understanding of the interaction between users of pharmacy services and the pharmacy team, the provision of advice or supply of medication and how these are documented.

> I think inspections do not necessarily reflect good patient care. To know if good advice is being given the inspector should observe an MUR or NMS consultation (Online survey respondent, 2015).

**Further, some community pharmacy professionals would prefer to have routine monitoring visits by inspectors** which, in their opinion, would help maintain continued focus on standards and improvement. To achieve this, many online survey respondents suggested that more visits and inspections should be scheduled:

> […] the possibility of additional visits is likely to keep pharmacies focused (Online survey respondent, 2015).

> The frequency of inspections should be proportionate to the risk from the pharmacy. The inspections should also not take place on a fixed three year window, otherwise pharmacists "will rest on their laurels for two-and-a-half years before the threat of inspection comes round again. It should be more random on duration between inspections (Stakeholder organisation, 2015).

## 5.4    Action-planning

**Pharmacists were generally positive about action plans, except for timescales set for implementing changes, which they felt were "not realistic".** One critical issue raised was: "the window allowed for taking remedial action", which many respondents characterised

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[33] The Medicines Use Review (MUR) consists of accredited pharmacists undertaking structured adherence-centred reviews with patients on multiple medicines, particularly those receiving medicines for long term conditions. More information is available here: http://psnc.org.uk/services-commissioning/advanced-services/murs/.

as "tight." This reiterates the discussion from Section 3 above - a few stakeholder organisations have stressed that action plans ought to be fair by providing enough time to pharmacies to take remedial action.

Indeed, around two-fifths of respondents who provided suggestions on improvements to the process of developing an action plan felt that the timescales provided for formulating and implementing the plans was inadequate and required more flexibility. Respondents cited staffing and resource constraints, as well as the difficulty of implementing specific recommendations in time, for example, those which required construction work and financial and other decisions to be taken at senior management or head office level.

Specifically, the following examples were provided:

> […] for construction, several weeks is not realistic. For returning an action plan, the few weeks allowed is a tight time frame if there are several decisions which may include agreeing on finance before implementation (Online survey respondent, 2015).

Extending the window for implementing actions plans beyond the 30-day period would be more helpful to pharmacies as certain remedial actions are complex. This would help avoid any unnecessary pressures on internal resources and pharmacies failing to implement the changes:

> The time frame for action plans is very tight, particularly when carrying out remedial building work or, in our case, soundproofing the consulting room. This is because some of these things are more complex and cannot be solved easily in 30 days (Online survey respondent, 2015).

**A minority of respondents indicated that the recommendations implemented by the action plans needed to be clearer and more constructive.** Suggestions included the need for clearer advice and information on how to achieve targets and emphasis on more practical solutions that can be addressed at operational level. A very small number also felt that the findings of the inspection reports could also be summarised and structured in a more accessible way.

## 5.5    Reporting and rating

**Community pharmacy professionals, stakeholder organisations and GPhC inspectors believe that the current grading system is not appropriate.**

Around a fifth of community pharmacy professionals felt that the current inspection rating system was too ambiguous and suggested the need to improve this to better reflect their true performance. Specifically, the rating process is perceived as "inconsistent" from inspector to inspector and "flawed" as "the available grades are not varied enough", leading to most pharmacies falling in the "satisfactory" category.

Community pharmacy professionals further feared that "satisfactory" could be perceived as "below average" or "just good enough", giving a negative image of the profession to the wider public. Some online census respondents asked for the GPhC to set goals for each grade and explain how to move from "satisfactory" to "good", noting that the majority of pharmacies are graded as "satisfactory". Alternative ratings were suggested as solution, such as more gradated scoring systems that better capture variation in performance, or simpler pass/fail ratings which limited scope for misinterpretation.

The need for additional grading levels has, to some extent, been raised by GPhC inspectors and stakeholder organisations as well. Many reported that the term "satisfactory' might not be working well.

> The vast majority of pharmacies are doing a good job but most pharmacies get a rating of "satisfactory" which is often very demotivating to them. I think the ratings do help raise the standards but we are in danger of demotivating if we don't have another look at the gradings (GPhC Inspector, 2015).

Some of the suggestions for improvements provided by the stakeholder organisations included improving the terminology of "satisfactory" by, for example, looking at how other health regulators define it, and also their experience of it.

One stakeholder suggested that there is more guidance needed with regards to what satisfactory means:

> The "satisfactory" makes people very demotivated, because if you have not got an action plan to fill in when you get a "satisfactory" then you should be under a "good" grade. So for a vast majority of pharmacist to come under satisfactory does not portray a good image of the profession. At the same time, it is not clear what "poor" means (Stakeholder organisation, 2015).

## 5.6    Publication of reports and ratings

**The study respondents thought that the publication of inspection reports and ratings could help improve sector performance and increase accountability of pharmacies when meeting the standards.** While the majority of GPhC inspectors and stakeholder organisations argued in favour of the publication, the views of community pharmacy professionals were somewhat different. When asked whether they thought publishing inspection reports and ratings would have added value for pharmacies and patients, 39 per cent of online survey respondents agreed, while an additional 31 per cent disagreed.

**Figure 5.1    Views on whether the publication of reports and ratings will have any added value for pharmacies and patients**
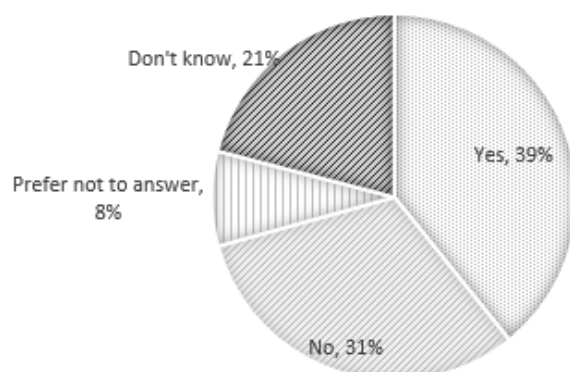


*Source: Online census. Base: community pharmacy professionals: 3,689*

However, there was some variation between the pharmacy professionals working in multiples (43 per cent agreed) and independent community pharmacy professionals (only 33 per cent agreed). There was also some variance between inspected (42 per cent agreed) and not inspected pharmacies (36 per cent agreed), which reflects that inspected pharmacies are more familiar with inspection reports and are therefore more likely to see the benefits of their publication. Additionally, more pharmacy technicians were in favour of the GPhC's proposal to publish inspection reports and ratings, as opposed to pharmacists (50 per cent versus 36 per cent respectively).

**Figure 5.2** **Whether publishing inspection reports and ratings could impact on pharmacies and patients. The act of publishing reports/ratings could…**
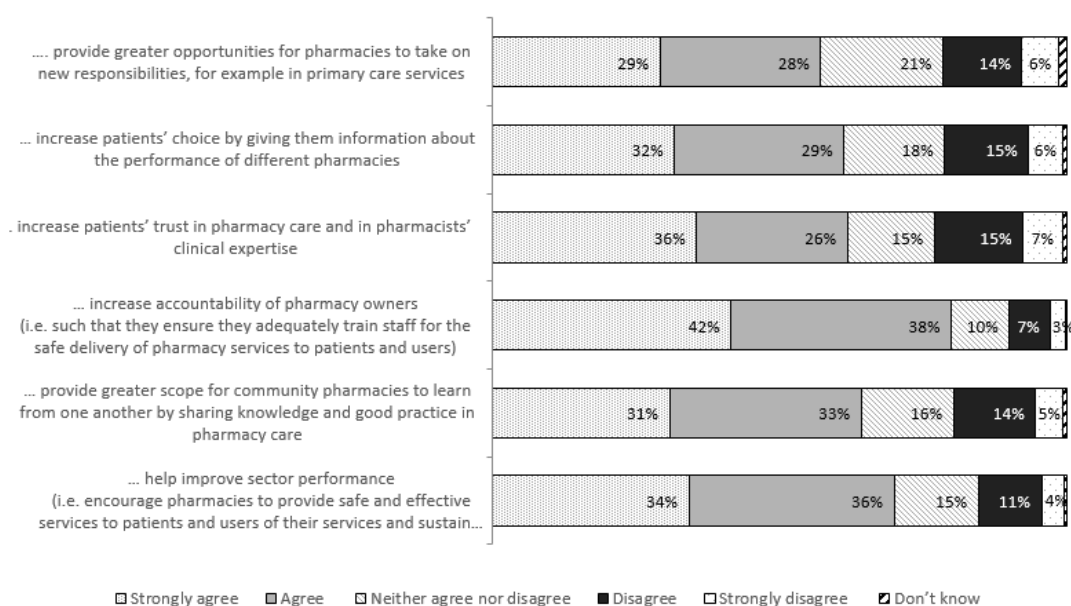


Base: community pharmacy professionals who said "yes" or "no" to: Do you think publishing inspection reports and rating would have any added value for pharmacies and patients?: 2566; 2588; 2590; 2590; 2587; 2593.

When asked about the potential benefits of publishing reports and ratings, most community pharmacy professionals recognised that the initiative could help improve sector performance (70 per cent) and increase accountability of pharmacy owners, such that they ensure they adequately train staff for the safe delivery of pharmacy services to patients and users of these services (80 per cent). Community pharmacy professionals operating in multiples were more likely to agree and even strongly agree with these statements than those working in independent pharmacies. For example, 46 per cent of those operating in multiples thought publishing reports and ratings could increase accountability of pharmacy owners in comparison to only 33 per cent of respondents working in independent pharmacies. Finally, pharmacy technicians were also more likely to agree with these statements than pharmacists (Figure 5.3). For instance, 58 per cent of pharmacy technicians thought publishing reports and ratings could increase patients' trust in pharmacy care and in pharmacists' clinical expertise, compared to only 30 per cent of pharmacists.

**Figure 5.3** **Percentage of respondents who strongly agreed with statements concerning reporting and rating**
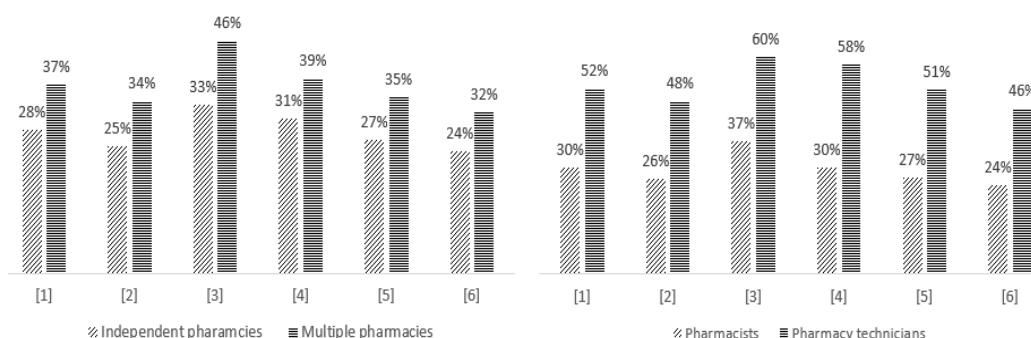


The act of publishing reports/ratings could…

*[1] … help improve sector performance*
*[2] … provide greater scope for community pharmacies to learn from one another by sharing knowledge and good practice in pharmacy care*
*[3] … increase accountability of pharmacy owners*
*[4] … increase patients' trust in pharmacy care and in pharmacists' clinical expertise*
*[5] … increase patients' choice by giving them information about the performance of different pharmacies*
*[6] …. provide greater opportunities for pharmacies to take on new responsibilities, for example in primary care services*
*Base: community pharmacy professionals. Independent pharmacies: 659; 656; 659; 659; 658; 653. Multiple pharmacies: 1763; 1760; 1760; 1760; 1759; 1745. Pharmacists: 1807; 1801; 1803; 1803; 1802; 1786. Pharmacy technicians: 559; 559; 560; 560; 559; 556.*

**The vast majority** of GPhC inspectors and stakeholder organisations **supported the proposals to publish the reports stressing that they should be succinct and ideally published in the form of a summary**, or that a full (but redacted due to confidentiality reasons) report should be made available on request. Also, one stakeholder organisation pointed to the need to be careful what information is published – for example, pharmacies that dispense a lot of methadone, revealing too much information might expose them to the risk of robbery. One GPhC inspector stressed that the publication of reports is likely, first and foremost, to be beneficial to the patients and users of pharmacy:

> The public have a right to know to decide which pharmacy to pick up their prescriptions from (GPhC inspector, 2015).

Respondents also highlighted the possible downsides of publishing reports. They consider that publication could put too much pressure on pharmacists or it could lead to misunderstanding of how "good" or "bad" a pharmacy is. One example given by a stakeholder organisation referred to a situation when the opinion of a patient or user of a pharmacy may be affected by a "poor" rating, even if the pharmacy improves and is subsequently awarded a "satisfactory" grade.

Indeed, **the opinions were mixed regarding the publication of ratings, particularly around the language of key grading terms**:

> In principle, I agree with the publishing […] however it will need to be done in a fair way with the use the right language and the right grading mechanism to be able to do that in a good way (Stakeholder organisation, 2015).
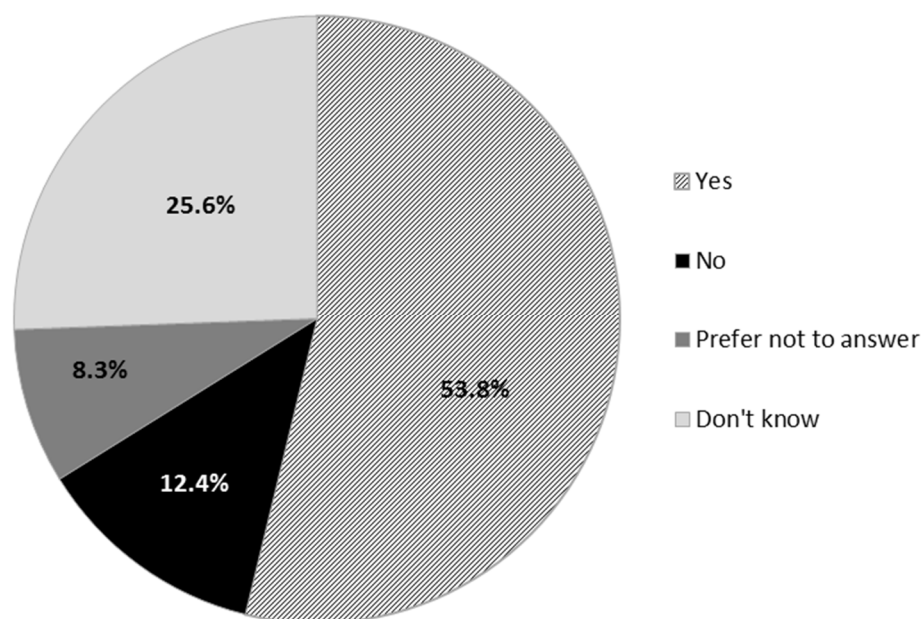
> Naming and shaming is the biggest drawback of the report. But on the other hand if something is being done very well it's good for the society to share it (Online survey respondent, 2015).

A few community pharmacy professionals also worry how patients and users of pharmacy will perceive the term "satisfactory", as discussed in Sub-section 5.5 above.

**Also, just more than half of the non-community pharmacy professionals who participated in the online survey (54 per cent) were in favour of the GPhC's proposal to publish inspection reports and ratings.[34]** Among the respondents who showed support for the proposal, some felt that the publication of reports and ratings would "allow patients to see which of the pharmacies employ clinically-competent pharmacists" or "allow patients to make more informed choices." A few other respondents also felt that increased competition that will stem from making reports and ratings public will "encourage pharmacies to give more varied and competent services." This is in line with the general views of community pharmacy sector (see Figure 5.1).

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[34] See Annex 8 for a detail sample profile of non-community pharmacy professionals.

**Figure 5.4    Views of non-community pharmacy professionals on whether the publication of reports and ratings will have any added value for pharmacies and patients**



Legend:
- Yes
- No
- Prefer not to answer
- Don't know

Values: 53.8% (Yes), 12.4% (No), 8.3% (Prefer not to answer), 25.6% (Don't know)

*Base: non-community pharmacy professionals, excluding non-responses: 1,392.*

However, a few respondents warned that the information shared with the public must be carefully considered to avoid any misinterpretation. Some respondents also felt that the name of the pharmacy should be kept confidential and that the publication of reports and ratings should only be used to allow community pharmacists to learn from one another and drive better performance in community pharmacy, rather than "naming and shaming" others.

# 6 Conclusions and recommendations

This section summarises the analysis and conclusions of this study to evaluate the GPhC's new approach to regulating pharmacies registered in England, Scotland and Wales as experienced by the community pharmacy professionals, GPhC inspectors and stakeholder organisations. Specifically, this section discusses the steps taken in this study and the emerging findings with respect to process and impact evaluations (as outlined by the intervention logic model in Section 1.2 above). It also assesses suggestions for improvements put forward by the study participants, and finally sets out recommendations for the GPhC to consider to further improve the effectiveness of the newly-introduced interventions in the community pharmacy sector, and also to inform any future follow-up on the evaluation of the GPhC's regulatory approach.

## 6.1 Key messages

**Summary of findings**

- Most of the evidence gathered as part of this research indicates that the GPhC's new regulatory approach is working well.
- The new standards are generally well-understood by community pharmacy professionals, although a few concerns were raised as regards the lack of clarity in some of the wording of some standards, and the level of duplication among certain standards.
- Inspections are a key intervention tool (supported by action plans) – pharmacy professionals and GPhC inspectors and stakeholder organisations involved in the study praised inspections for their ability to drive up standards and promote good practice. However, there is an appetite for more frequent visits and post-inspection follow-up – the study results show that follow-up evidence is helpful and effective in helping to improve and become compliant.

- Evidence gathered in this study indicates general appreciation for action-planning. Action plans highlight priority areas for action and help pharmacies to rectify failings and deliver higher-quality and safer pharmacy services. However, there is some degree of consensus, particularly among pharmacy professionals, around the need to extend the window for implementing actions plans beyond the 30-day period. This would help avoid any unnecessary pressure on internal resources and pharmacies failing to implement the changes within the set timeframe.
- The new approach helps to embed a culture within community pharmacy that supports a greater focus on patients by complying with standards and participating in inspections.
- Multiples were more likely (although the difference is marginal) than independents to consider their services to be patient-focused as a result of standards (86 per cent of as compared to 81 per cent respectively). This is potentially due to multiples being more proactive and investing more heavily in staff training, as well as providing regular guidance and knowledge-sharing opportunities.
- There is no clear-cut evidence as to whether the new approach is helping sustain improvements in community pharmacy. The new approach is still in its early days and further rounds of inspections are required to provide an indication of the actions undertaken by pharmacies to sustain improvements.
- Although inspection reports and resulting ratings constitute valuable tools, notably in helping pharmacies focus on areas of most relevance to patients and users of pharmacy services, there were concerns raised by pharmacy professionals and GPhC inspectors regarding lack of clarity and differentiation between ratings. There is desire for further guidance on the rating system.

## 6.1 Overview of the evaluation exercise steps taken

The study aims to provide the GPhC with a better understanding of how well the new regulatory approach is working in practice and the success of its objectives. An intervention logic model (as depicted in Section 1.2 above) was used as a framework to assess the direct impacts of the new regulatory interventions (such as improved awareness, increased compliance, etc.) and how these impact on changes in pharmacy and patient outcomes (such as safer premises, improved pharmacist-patient interactions, etc.). These have been tested and evidenced through data gathered as part of a literature review and primary research with community pharmacy professionals, GPhC inspectors and stakeholder organisations. This evidence has been triangulated to generate conclusions. The findings of this study will inform the GPhC's ongoing regulatory reforms and further improve the effectiveness of newly-introduced interventions in the community pharmacy sector.

## 6.2 Summary of findings

### 6.2.1 Whether the new approach to regulation is consistent with the GPhC's ambitions, wider objectives and goals

The new GPhC framework seems to be working well as perceived by those working in community pharmacies, GPhC inspectors and stakeholder organisations. Standards are generally well-understood by community pharmacy professionals because they set out clearly what is expected of them to meet the standards.

Further, there is evidence that the current framework encourages community pharmacy professionals to act on their own initiative when meeting the regulatory standards. However, some community pharmacy professionals still practise a traditional tick-box approach to regulation suggesting that the shift towards the new approach may take longer. However, the following aspects of the framework seem not to be working well, as stressed by a few study participants:

■ There is a perception that guidance for inspectors on how to rate pharmacies is insufficient, i.e. there are not enough practical examples to link pharmacy evidence to the inspection framework.
■ There is not enough information regarding what evidence and measures pharmacies need to prepare to achieve a certain rating.

### 6.2.2 Whether the new interventions work well

The four interventions introduced under the new approach seem to be working as intended, and help deliver better outcomes for patients and users of pharmacy services. This is achieved through the framework intervention tools, albeit each impacts the pharmacy outcomes differently, and to a varying degree.

**The principles and standards** underpinning the new approach are clear in general although there were some differences across online census respondents in terms of their experience of the standards:

■ Pharmacy technicians generally showed a slightly higher level of understanding than pharmacists. This reflects the increasingly important role pharmacy technician's play during inspections, as the new approach to regulation encourages the involvement of the whole pharmacy team.
■ Community pharmacy professionals operating in multiples indicated a higher level of understanding of all five principles underlying the new GPhC standards as opposed to those based in independent community pharmacies. These differences are mainly due to "more training and guidance" provided to staff in multiple than in independent settings.

Multiples have also been more actively involved than others in promoting the standards internally to staff (via internal training sessions, for example).

■ Community pharmacy professionals based in England and Scotland seem to have a slightly higher level of awareness of the standards than those based in Wales.

**Inspections** are working well and there is evidence that inspections are increasingly helping to promote awareness of the standards in the community pharmacy sector. Indeed, those working in pharmacies inspected under the new inspection approach were more likely to say they clearly understood principles and fully implemented relevant standards (particularly regarding governance arrangements and staff empowerment) than those working in pharmacies not yet inspected.

Inspections are seen as an opportunity to further "educate" pharmacy teams. Most interviewees and online survey respondents felt that engaging with the whole pharmacy team during the inspections is crucial to driving better compliance and achieving patient-focused outcomes. This inspection element is more important to pharmacy technicians than pharmacists. Indeed, greater involvement of the pharmacy team is regarded as a means to obtaining "the whole team's buy-in".

**Actions plans** are generally well-received by community pharmacy professionals because they allow them to rectify the most serious failings and to improve areas most relevant to patient safety. Action plans target specific areas deemed lacking by the inspector, allowing respondents to define priorities for improvements and assign responsibilities for rectifying failings as effectively as possible. However, a few GPhC inspectors and stakeholder organisations pointed out that action plans should be fair by providing enough time for pharmacies to take remedial action.

**Inspection reports** are a valuable tool when thinking about and implementing improvements in quality and performance, as well as helping focus on areas most relevant to patients and users of pharmacy services. Indeed, inspected pharmacies were more likely to be of this opinion than those not yet inspected. While GPhC inspectors and stakeholder organisations generally recognised that ratings incentivise pharmacies to focus on the standards and improve, the general opinion was that certain ratings, in particular the "satisfactory" rating, are misleading and often demotivating for pharmacies. This is exacerbated in the opinion of GPhC inspectors and stakeholder organisations that the term "satisfactory" is perceived negatively by both patients and users of pharmacy as well as other pharmacies. The current rating system might therefore discourage pharmacies.

### 6.2.3 Whether outcomes targeted under the new approach are being achieved

There is evidence that the culture is gradually shifting from one that previously focused primarily on rules and compliance, towards a focus on patient outcomes and improvement. This is thanks to interventions such as reviewed standards and more outcome-focused inspections.

Indeed, there is evidence that the standards encourage the pharmacy team to realise the importance of their roles and responsibilities and to "think outside the box". Most community pharmacy professionals increased patient focus by working in line with the standards embedded in their daily work practices and training policies. In particular, the whole pharmacy team is encouraged to be fully involved in assisting in day-to-day activities and acquire first-hand knowledge. A higher proportion of pharmacy technicians said that the new GPhC standards encourage them to increase their focus on patients, as compared to pharmacists. Multiples were more likely (although the difference is marginal) than independents to consider their services to be patient-focused as a result of standards (86 per cent compared to 81 per cent respectively), potentially by more regularly reviewing and monitoring the safety and quality of their pharmacy services, and maintaining all necessary records for the safe provision of pharmacy services on their premises.

Inspections are key to maintaining good levels of practice. They help community pharmacy professionals focus more on their patients and users of pharmacy, and encourage them to enhance the services they offer. For example, community pharmacies often provide additional services to patients and pharmacy users such as emergency services and home visits. Also, the new approach to regulation encourages community pharmacy professionals to promote better interactions between users of pharmacy services and pharmacy team, i.e. they are generally keen to adopt a more proactive approach towards patients and users of pharmacy services.

While the new approach to regulation is changing the culture, a few GPhC inspectors have stated that this change is slow (i.e. the standards have not driven the change in culture fully as yet), and that not all pharmacies have succeeded yet in focusing on a more patient-centred culture.

While there is evidence of a shift in culture, there is little information yet to suggest that the new approach leads to sustained improvements. How far the different interventions, in particular inspections and action-planning, encourage continued focus on improvement is, to some extent, difficult to assess – historically, inspections have been carried out around every three years and there is little post-inspection data yet available.

However, where an action plan is implemented, while it leads to an improvement, it is not clear whether it results in *continued* improvement. Further, there is mixed evidence regarding the relevance of inspection reports and ratings in sustaining improved outcomes. While reports and ratings tend to act as a "wake-up call," pushing pharmacies towards greater compliance, some GPhC inspectors felt that such changes are not maintained long-term, partly because these are not yet publicly available. The publication of reports is likely to create an incentive for community pharmacy professionals to continually uphold standards. However, a few GPhC inspectors and stakeholder organisations pointed out that the new ratings system might discourage pharmacies because the rating term "satisfactory" is perceived negatively and the wide definition of "satisfactory" might discourage pharmacies from sustaining compliance and embracing improvement.

### 6.2.4 Whether there is any scope for improvement to the newly-introduced regulatory interventions, as suggested by study participants

Study participants have suggested the following developments to the GPhC's regulatory approach (listed by the intervention tool):

#### 6.2.4.1 Standards

A few community pharmacy professionals and GPhC inspectors believe that the wording of the standards could be simplified to reduce uncertainties around what is required and, to a certain degree, to minimise duplication wherever possible. Standards that overlap (for example around governance) should merge to provide more clarity and time to focus on the areas of most concern during inspections.

The majority of stakeholders and community pharmacy professionals interviewed pointed to the lack of guidance for community pharmacy professionals about how to better achieve the standards. In particular, the stakeholder organisations argued that it would be helpful to have illustrative examples of how to comply with the standards – examples of best practice. Many online survey respondents would also appreciate examples to help them understand how to better implement the new standards, and what evidence and measures pharmacies need to prepare to achieve a certain rating.

#### 6.2.4.2 Inspections

The majority of community pharmacy professionals responding to the census suggested a more collaborative approach to inspections that focuses on providing more constructive feedback, including more concrete examples of how pharmacies can achieve better ratings.

Sufficient notice prior to inspections was another key suggestion put forward by some online survey respondents to improve the inspection process. While inspectors generally reported that notification letters are sent six weeks before an inspection takes place, some community pharmacy professionals felt that inspectors tend to be inconsistent in their approach and failed to provide sufficient notice.

### 6.2.4.3 Action plans

Pharmacists were generally positive about action plans, except for timescales allowed for implementing change, which they felt were "not realistic". One critical issue related to: "the window allowed for taking remedial action", which many respondents characterised as "tight." Extending the window for implementing action plans beyond the 30-day period would therefore be more helpful to pharmacists.

### 6.2.4.4 Reporting and rating

Community pharmacy professionals, stakeholder organisations and GPhC inspectors believe that the current grading system is not appropriate. Around a fifth of community pharmacy professionals felt that the current inspection rating system was too ambiguous and suggested the need to improve this to better reflect their true performance. Greater definition in grades, particularly in relation to the "satisfactory" rating, was suggested.

### 6.2.4.5 Publication of reports and ratings

In spite of a certain level of scepticism among GPhC inspectors and stakeholder organisations and community pharmacy professionals about the publication of ratings (largely also due to the rating labels and the potential perception of "satisfactory" grade by patients and users of pharmacy), most recognise that the initiative could improve sector performance (stressing that published reports should be succinct, not contain confidential information, and ideally published in the form of a summary).

## 6.3 Recommendations

### 6.3.1 Standards

Given a high level of understanding and awareness of the standards, there is no immediate requirement for intervention in this direction.

Nevertheless, a few study participants stressed that simplifying the wording of some of the standards and avoiding unnecessary duplication might reduce uncertainties over the evidence and measures required to achieve them. Further, the majority of GPhC inspectors interviewed suggested that standards that overlap (for example around governance) should merge to provide more clarity and time to focus on the areas of most concern during inspections.

> **Recommendation 1:** It is recognised that different stakeholder types will provide different views on the wording and design of the standards. It is therefore suggested that during future evaluations of their approach to regulating community pharmacies the GPhC consider investigating whether simplification of the wording of standards is still required, and whether GPhC inspectors still consider that some of the standards overlap and reduce clarity.

Community pharmacy professionals operating in multiples indicated a higher level of understanding of all five principles underlying the new GPhC standards as opposed to those based in independent community pharmacies. These differences may be potentially due to "more training and guidance" provided to staff in multiples than in independent pharmacies. The knowledge sharing experience also plays an important role in spreading awareness of the standards among multiples' branches. As a result, those working in multiples report they are also more likely than those working in independents to increase their patient focus as a result of standards.

> **Recommendation 2:** It is recognised that training and promotional tools play an important role in increasing the understanding of the standards (while emphasising the patient-focused approach). The difference in the understanding of the standards between multiple and independent pharmacies should be further explored, to see how the differences could be narrowed.

### 6.3.2    Inspections

Inspections are a key intervention tool (supported by action plans) – they drive the standards and promote good practice. Feedback from inspectors and more frequent inspections were key suggestions put forward by pharmacists to improve the inspection process.

Indeed, inspections in some other sectors can be more frequent. For example, inspections by CQC tend to occur at a maximum of two year intervals (Annex 9 provides data on the frequency of inspections practised by other regulators).  The frequency of inspections depends, among other factors such as public complaints for example, on the grading or risk rating assigned – those settings with a very high risk are likely to be inspected more often than others. Similarly, in the pharmacy sector priority could be given to pharmacies with poor ratings – these could be inspected more often than those with higher ratings. This approach is likely to reduce the burden on well-performing pharmacies at the same time providing a clear incentive to improve performance. A more flexible approach to inspection frequency would also minimise additional resource requirements placed on inspectors.

> **Recommendation 3:** Consider the introduction of a more flexible approach to inspections where the frequency of inspections depends on the rating of the pharmacy, with those rated "poor" receiving inspections more often than pharmacies rated "satisfactory" and above. Complaints could also be considered as a driver of inspections.

Further, the analysis shows that some community pharmacy professionals would like regular visits from the inspectors which, in their opinion, would help maintain a continued focus on standards and improvement.

> **Recommendation 4:** The GPhC could consider, subject to capacity constraints, introducing follow-up contact (i.e. phone calls or emails), regardless of the rating of the pharmacy. This could take the form of a questionnaire, for example, with which the GPhC inspectors would check the implementation progress (for pharmacies with action plans), or check if a pharmacy has experienced any issues since the inspection. In parallel, this would also be an opportunity for the GPhC to gather feedback on the new approach.

### 6.3.3    Action plans

> **Recommendation 5:** There is evidence that extending the window for implementing actions plans beyond the 30-day period would help avoid any unnecessary pressures on internal resources and pharmacies failing to implement the changes. Although no immediate action is necessary, the GPhC could consider paying particular attention to this in the follow-up evaluation exercise.

### 6.3.4    Reporting and rating

There is a desire for greater clarity and differentiation between ratings. There is also a request from some GPhC inspectors and pharmacies for more guidance on how to rate pharmacies under the standards, and the evidence and measures needed to progress to the next rating. More specifically, some community pharmacy professionals and GPhC inspectors and stakeholder organisations stated that the term "satisfactory" is misleading because it is perceived negatively by the community pharmacy sector, and may be

perceived negatively by patients and users of pharmacies. Many believe it does not encourage pharmacies to make continued efforts to improve, and therefore does not benefit patients as much as it could.

> ***Recommendation 6:*** The new inspection model and decision-making framework should be better aligned to increase clarity and consistency for GPhC inspectors, and to improve understanding and interpretation of standards to be achieved by pharmacies. This should complement what is already available on stakeholder organisations' websites (for instance NPA and RPS).

> ***Recommendation 7:*** The GPhC could consider the approaches to rating adopted by other regulators (preliminary analysis of existing evidence is presented in Annex 9). These could be used as lessons learnt in the future evaluations of the GPhC's approach to rating. The GPhC could also consider engaging more widely with community pharmacy professionals to identify potential solutions to the issues of clarity and differentiation, and to build consensus on a way forward.

> ***Recommendation 8:*** Given concerns expressed by respondents about the possible perception of a satisfactory rating label by patients and users of pharmacy services, any review of the rating system (arising from Recommendation 7) should be subject to public testing and engagement to assess its potential impact.

### 6.3.5 Publication of reports and ratings

Regarding the publication of reports and ratings, there is evidence that the initiative could help improve sector performance, increase accountability of pharmacy owners, and increase patients' trust in pharmacy care. The publication of reports and ratings is likely to increase incentives for continued improvement because pharmacies are concerned about their reputation.

> ***Recommendation 9:*** The GPhC has signalled its intention to publish inspection reports, and this study supports this approach. We propose a publication of (succinct) summary reports that do not disclose confidential information about inspected pharmacy. These should be easily available to download from the GPhC website.

> ***Recommendation 10:*** With regards to ratings, publication of these is also recommended but in conjunction with Recommendation 6 above to ensure the right understanding, interpretation and communication of ratings to the community pharmacy sector and to patients and users of pharmacy. The ratings could be available online as well as visibly placed on pharmacy premises. The GPhC could consider establishing a searchable ratings database similar to those provided by other regulators which enable customers to compare ratings by postcode)[35].

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[35] FSA and CQC. Also Ofsted could be used as an example of best practice but it only publishes report by postcodes.