GPhC response to the Rebalancing Medicines Legislation and Pharmacy Regulation: draft Orders under section 60 of the Health Act 1999 consultation

Background

The General Pharmaceutical Council (GPhC) is the regulatory body for pharmacists, pharmacy technicians and registered pharmacies in England, Scotland and Wales. The GPhC has an ambitious strategy for the regulation of pharmacy. We are committed to carrying out our objectives efficiently and effectively whilst also identifying ourselves as having a role to play in promoting improvement in standards and ultimately in health.

Our privileged position as the regulator of both registered pharmacies and individual pharmacy professionals gives us the opportunity to play a significant role in promoting improvements and managing risks across pharmacy and in providing assurance to patients and the public that pharmacies and pharmacy professionals are working to the right standards.

We believe it is every patient's right to expect good quality services from the professionals and organisations that provide healthcare in Great Britain. This means receiving pharmacy services that are not only safe but that improve health and well-being and are centred on and tailored for local patients and health needs.

Our work to completely overhaul the way we inspect registered pharmacies is an example of how we are working together with pharmacy professionals and pharmacy owners to deliver these improvements and this assurance for patients. We have moved from an outdated inspection model to one that is proportionate, patient-centred and informed by risk, where pharmacies are inspected against a single set of standards that describe what needs to be achieved for patients.

We are pleased to be able to respond to the Department of Health's consultation on two draft section 60 orders that make changes to the criminal sanction associated with dispensing errors and to the Pharmacy Order 2010. As a member of the rebalancing programme board the GPhC has contributed to this work since it began. We welcome the consultation and the collaborative approach to developing these policy proposals.

Introduction

It is clear that the public expectation on the NHS and healthcare services is changing. As a result pharmacy professionals' roles and their contributions to public health are growing, and there is every sign that this will continue for many years to come.

The changes set out in the two draft s60 orders play an important part in preparing pharmacy for its enhanced role, but must be seen as only part of the transformation that is needed. We believe that further changes will be required to ensure pharmacy is making an

enhanced and critical role in delivering improvements in the health of the public – a key aim of all governments across Great Britain. These changes will need to come from government, from regulators, from those who provide NHS pharmacy services and the professionals working within pharmacy and their leadership bodies. In short, all stakeholders will need to show leadership if the changes required are to become a reality.

The conversation within pharmacy about dispensing errors has historically focussed on fear, blame and strict liability. A fear of prosecution and a fear that the regulator will seek to 'blame' a pharmacy professional. We believe it is time for the conversation to change and for the focus to shift to what the positive contributions pharmacy can make to patient outcomes; what they need to do differently to make a greater contribution. For that focus to change it is fundamental that professionals are being open when things go wrong so that trust can be maintained, not only in pharmacy but in the healthcare system as a whole. Patients and service users need honesty when things go wrong, an apology and an assurance that there is real reflection on what went wrong, what lessons will be learnt and how improvements will be made. It is now time – with this small but important change in the law – for the pharmacy professions and those who are responsible for the management and governance of pharmacy services to deliver this change, individually and collectively with leadership and support from organisations such the Royal Pharmaceutical Society and the Association of Pharmacy Technicians UK.

It is also important that we, as the regulator, are clear about how we manage concerns that are raised with us, in particular concerns that relate to dispensing errors, so that the fear of prosecution is not replaced by fear of the regulator.

Our work to modernise the way in which registered pharmacies are regulated is built on the principle that it is pharmacy owners, working alongside the professionals and teams in pharmacies who have responsibility for the design and delivery of quality pharmacy services. We recognise the wide range of pharmacy services that are delivered at or from registered pharmacies, the diversity of registered pharmacies and that our standards and regulatory approach should reflect this diversity. We are pleased that the proposed legislation, which recognises that services can be provided *at or from* registered pharmacies, makes this explicit.

We believe that a national regulator that sets prescriptive rules for how pharmacies manage, design and deliver pharmacy services would be detrimental to patient outcomes. Instead, our focus on outcomes provides the flexibility to deliver services that meet local needs. Our prototype inspection model provides patients and users of pharmacy services with assurance that our standards are being met without a prescriptive approach. Our conversation with pharmacy teams moves the onus on the pharmacy owner and team to show us how they meet the standards, rather than a simple compliance approach where the regulator ticks boxes and loses sight of the outcomes to be achieved.

1. Concerns about dispensing errors that are raised with the GPhC

The GPhC will continue to manage concerns about the occurrence of dispensing errors in the same way that has done to date.

All concerns raised with the GPhC about a registrant in relation to a dispensing error are investigated using policies and procedures which are used to guide the way in which we investigate concerns raised about the fitness to practise of registrants. Single dispensing errors would not in our view constitute a fitness to practise concern, if there was not a wider pattern of errors or significant aggravating factors.

All single dispensing errors which are reported to us are however considered by the GPhC. This is what patients and users of pharmacy services would expect and it is right that we continue to do this.

We make clear in our standards the importance of honesty, candour and learning. These requirements on the registered professional are complemented by our standards for registered pharmacies which all pharmacies registered with the GPhC must meet and which our inspection team monitor and enforce. Our inspection decision framework identifies the importance of recording, reporting and learning from errors and near misses. This will continue to be a key focus of our inspections and an ongoing requirement.

2. Modernising Pharmacy Regulation

In February 2015, the GPhC published a discussion paper 'Modernising pharmacy regulation: from prototype to full implementation'. The paper highlights the progress that has been made to modernise pharmacy regulation and also highlights those areas where we intend to adapt and change the prototype inspection model. It also sets out a projected timetable for carrying out further engagement on a number of issues.

The GPhC is committed to developing a model for pharmacy regulation that is informed by feedback from those we regulate and patients and the users of pharmacy services. Our work to regulate registered pharmacies is reliant on the progress of the s60 order that makes the necessary changes to our governing legislation the Pharmacy Order.

We welcome the proposals of this consultation that will enable us to move forwards from prototype to implementation, and would urge the government to proceed with these changes at the earliest possible opportunity.

3. Business regulation

We are aware that there may be individuals or organisations who view the changes to our enforcement powers in relation to registered pharmacies as similar to that of other systems regulators such as the Care Quality Commission in England.

Notwithstanding the changes to the Medicines Act, It is important to be clear that the GPhC does not have a register of pharmacy owners currently, nor will it have the power to create one if the s60 order, as drafted proceeds. It would for Government to decide whether this is a role for the GPhC.

Consultation Questions

Question 1: Do you agree with our overall approach, i.e. to retain the criminal offence in section 64 and to provide a new defence for pharmacy professionals against prosecution for inadvertent dispensing errors, subject to certain conditions?

Yes. Although the criminal law is first and foremost a matter for government and for Parliament, our work as the regulator has highlighted the need for more to be done to encourage the kinds of behaviours identified in the Berwick report, as critical in any safety and learning culture. We support a change in the law and the proposals have been developed in a collaborative, open and properly tested manner. We therefore support the overall approach proposed, and believe that what is proposed provides a workable solution to the current s64 strict liability offence.

Question 2: Do you agree that, once a defendant has done enough to show that the relevant pharmacy professional might have been acting in the course of his or her profession, the prosecution should have to show, beyond a reasonable doubt, that the pharmacy professional was not "acting in the course of his or her profession" in order to secure a conviction?

Yes. We note that the common terminology used in criminal courts is no longer 'beyond all reasonable doubt' and is instead 'so that you are sure'.

Question 3: Do you agree the two proposed illustrative grounds that the prosecution could rely on to establish that the pharmacy professional was not acting in the course of their profession, if they were proven beyond reasonable doubt?

Yes.

Question 4: Do you agree that where a pharmacy professional does not follow procedures established for the pharmacy and an error takes place, this should not, on its own, constitute grounds for a decision in criminal proceedings that the pharmacy professional is not acting in the course of their profession?

Yes. Whilst procedures established for the pharmacy serve an important purpose within the system, we believe that it is the decisions pharmacists and pharmacy technicians make in their day-to-day work which make the most significant and positive contribution to quality improvements in pharmacy and in managing risks to patients. It is important that the proposed defence reflects the need for individual professionals to exercise their judgement and be prepared to demonstrate how what action they have taken is in the interests of their patients and the users of pharmacy services.

Question 5: Do you agree that for the defence to apply, the sale or supply of the medicine must have been in pursuance of either a prescription or (in the case of sales) directions from an appropriate prescriber?

Yes.

Question 6: In your view, should it be part of a defence where someone is charged with a dispensing error that if an appropriate person at the pharmacy knew about the problem before the defendant was charged, all reasonable attempts were made to contact the patient unless it was reasonably decided not to do so?

Yes. Acting with openness and honesty when things go wrong is an essential duty for all pharmacists and pharmacy technicians. Our published standards of conduct, ethics and performance say registrants must respond honestly, openly and politely to complaints and criticism. Along with other regulators of healthcare professionals, the General Pharmaceutical Council (GPhC) has signed a joint statement on openness and honesty - the professional duty of candour.

The statement reflects the GPhC's requirement that pharmacists and pharmacy technicians need to be open and transparent at all times, and the essential duty for all professionals to be candid.

We note that the consultation provides examples of when it may be reasonable to not notify the patient, examples include where the patient informs the pharmacist of the error, or where the patient is a child, and therefore notification would be to the parent or carer. We understand that there may be limited times when it could be seen as not reasonable to notify the patient. However, the duty of candour is effectively more than a notification that something has gone wrong; it is also about offering an apology and reflecting on learning and improvement. This means that every pharmacy professional or owner should be candid when things go wrong.

Question 7: Do you agree that the unregistered staff involved in the sale or supply of a medicine (including, for example pharmacy assistants who hand over medicines that have been dispensed or van drivers who deliver medicines to patients) or the owner of the pharmacy where a dispensing error occurs should potentially be able to benefit from the new defences?

Yes.

Question 8: Do you agree that the defence should not apply in cases where unregistered staff involved in sale or supply of medicine deliberately interfere with the medicine being sold or supplied at or from the pharmacy?

Yes. It is right that patient and users of pharmacy services are properly protected from individuals who consciously and deliberately intend to cause harm or put at risk the health, safety and wellbeing of patients and the users of pharmacy services.

Question 9: Do you agree with the overall approach to the new defence in section 67B in relation to the offence in section 63, i.e. to retain the criminal offence and provide a new defence subject to essentially the same conditions as will apply in relation to section 64? If you think different, additional or fewer conditions should apply, could you explain what, if any, conditions you think should apply.

Yes.

Question 10: Do you agree that in relation to GPhC, the obligation to set standards in rules should be removed?

Yes. When we were established in 2010 Parliament provided us with a range of new powers and responsibilities including setting standards for registered pharmacies. In developing these standards and associated inspection model, we committed to doing so in a way which is consistent with good regulatory practice. We wanted to ensure that we took full account of the approach developed by the Better Regulation Executive and taken forward by Sir Philip Hampton. As such we have consciously moved away from a model which looks at enforcement to one where we work with those we regulated to encourage and enable them to focus on outcomes; the things that matter to patients. This in turn makes them much easier to understand, both by those we are regulated, as well as patients and the public in whose interest we work.

This new approach does not lend itself to having published standards set out in legal rules for a number of reasons:

Firstly, placing standards in rules means that by their very nature they are inflexible embedding a compliance model whereby technical breaches of rules, may have no direct impact on patient safety but whereby a regulatory response is required. This, in turn, runs the risk of a bureaucratic and disproportionate approach.

It is important to state putting standards in Rules would require the GPhC to set prescriptive standards as Rules by their very nature do not lend themselves to outcome focussed standards where the focus can be on the patients, in preference to an output measurement.

Secondly, our approach to regulating registered pharmacies enables us to recognise the context in which the pharmacy services are delivered. By context we mean the location and type of pharmacy; the volume and range of services and the patient groups the pharmacy

serves. By recognising the local context registered pharmacies can tailor their work to the needs of the local population. Registered pharmacies are found in a variety of settings, from large supermarkets and hospitals to smaller registered pharmacies on the high street. Pharmacies are owned by individual pharmacists through to large international companies. The depth and breadth of pharmacies and pharmacy services means that a single set of prescriptive standards in rules would be difficult to design, restrictive in nature and stifle innovation, particular by small and medium sized organisations.

Thirdly, requiring our standards to be placed in Rules would limit our ability to respond to changes in practice, innovation by pharmacy businesses or wider public policy. If any of these wider external changes required us to look again at our standards, we would need legislative change to provide updates, even potentially if these changes were small. This would, in our view, but disproportionate, inflexible, burdensome and run contrary to good regulatory practice. The s60 order also changes accountability for meeting our standards for registered pharmacies from the pharmacy owner and superintendent pharmacist to solely the pharmacist owner. We support this change; however we would urge the government to proceed at the earliest possible opportunity with the proposed changes to superintendent pharmacist responsibilities. Until the changes to superintendent pharmacist responsibilities are made, there is a gap in accountability for these individuals, who have an important governance and management role in relation to the way in which pharmacy services are provided.

Question 11: (for respondents in Northern Ireland): Are you content to place a statutory duty on PSNI to set standards for registered pharmacies?
N/A

Question 12: Do you agree with the approach we are taking to breaches of premises standards by pharmacy owners?

Yes. The GPhC current powers in relation to registered pharmacies are limited, both in relation to who they apply to and also the limited regulatory tools available to us. This is unfair and inequitable.

As a proportionate regulator that only uses the necessary intervention that is needed, we welcome the range of regulatory tools that the s60 order will provide us to regulate registered pharmacies. This will ensure that any regulatory intervention is proportionate. We also welcome the changes which mean our enforcement powers will apply equally to all registered pharmacy owners, therefore providing the regulator with a fair model for regulation.

We support the changes that will result in decisions about failure to meet standards and subsequent suspension or removal of a registered pharmacy from the register being made by fitness to practise committees instead of the Registrar. This change will mean that decisions of this nature are made in an open and transparent way, and that there is an opportunity for shared learning and improvement.

The consultation explains that the removal of standards from Rules, *places 'regulation of pharmacies on the same footing as registrants'*. We want to be clear that the changes proposed do not mean that we can regulate companies directly. The proposals will enable Fitness to Practise committees to make a decision that ultimately would require the removal or suspension of a pharmacy or pharmacies from the register. The GPhC does not hold a register of pharmacy owners and therefore we will not be able to remove the pharmacy owner from a register in the way that we make decisions about a registrant's fitness to practise. We are not an 'economic regulator'.

We are acutely aware that the proposed s60 order changes may lead some organisations to believe that we will, in the future, have powers that are not provided for in the s60 order. A far broader debate and additional changes would be needed if we were to be required to hold a register of owners.

Question 13: Do you agree with the changes to provide for publication of GPhC reports and outcomes from pharmacy inspections?

Yes. The GPhC has from the outset stated our intention to publish inspection reports. One of the core principles of good regulation is that we should be open and transparent; to keep inspection findings secret would, in our view, be inconsistent with that principle. We also know that without the publication of inspection reports and outcomes, pharmacy would be out of step with other regulators both in and outside of health, and there is no justification for this. We believe that patients and the users of pharmacy services would expect to be able to find information about the pharmacies they visit and the inspections we conduct.

We welcome the proposed changes to the Pharmacy Order that will enable the publication of inspection reports and outcomes. Our recently published discussion paper *'Modernising pharmacy regulation: from prototype to full implementation'* recognises that we need further input from all our stakeholders, including patients and users of pharmacy services, as well as those in pharmacy to help us develop an approach publication which is open, transparent, fair and accessible. We have committed to only publishing reports after we have held our consultation in advance of full implementation.

Question 14: Do you agree with the changes to the GPhC powers to obtain information from pharmacy owners?

Yes. Without having more comprehensive information from pharmacy owners, we are limited to a one-size-fits all approach. By collecting some basic information at the point of registration, we hope to be able to take account of relative risk, to act more proportionately and to ensure we build up wider information on risks which we can share with registered pharmacies as well as patients and the public.

Question 15: An IA has been prepared covering the costs and benefits of the dispensing error proposals. Do you agree our assessment? If not, please provide details and estimates of any impacts and costs that you consider are not relevant or, alternatively, have not been taken into account.

No response.

Question 16: Do you consider there are any additional significant impacts or benefits on any sector involved that we have not yet identified? Please provide details and estimates.

No response.

Question 17: As part of preparing this IA we have asked business representatives whether, if the new defence were introduced, it would have a downward impact on employee cost pressures (for instance, any reduction in the risk of being prosecuted could slightly reduce legal or insurance costs). No significant cost impacts have so far been identified. Are there specific impacts on small and micro-businesses that we need to take into account?

No response.

Question 18: At this stage, we do not consider it is feasible to estimate a "typical" cost of prosecutions for dispensing errors on individual professionals or pharmacy businesses because of the small numbers involved over the last decade. Do you agree with this? If not, do you have any relevant information which we can consider?

No response.

Question 19: We have provided an estimate of the magnitude of the cost and benefits that may arise from the potential implementation of the introduction of the change in approach to dispensing errors. These estimates rely on a number of general assumptions – summarised in Annex B of the IA. These include the length of time it takes a pharmacist to deal with different types of dispensing errors. In addition, we have made assumptions regarding the potential benefits from learning and from a lower risk of prosecution. Do you think the assumptions we have made are proportionate and realistic? If not, what assumptions should we use? Please provide an estimate of the cost of such assumption.

Yes.

Question 20: We have prepared an IA covering costs and benefits of the premises standards proposals. Do you agree our assessment? If not, please provide additional information (with estimates) regarding other costs or benefits that you think have not been considered in the IA.

Our standards for registered pharmacies were developed through an extensive period of engagement and formal consultation in 2011 and 2012. The standards were developed in a way

which is consistent with good regulatory practice – focussed on outcomes and in a way which enables pharmacies to take into account their specific local environment, regardless of what services they provide and if they are part of a large corporate organisation, or a small independent pharmacy.

As part of the implementation of those standards, we have carried out extensive consultation and worked hard through large events, regular communications, working with NHS and employing organisations to supplement the direct engagement we have through inspections to ensure the profession and owners are familiar with the content of the standards and the new outcomes-focussed style.

If the standards for registered pharmacies were to be set in Rules, the GPhC would need to undertake a wholesale review of the current standards for registered pharmacies. This would require policy development and extensive engagement and consultation on new draft standards. Although there would be flexibility in the actual costs of this exercise our initial estimates suggest that the costs of a both a significant change in the standards (including moving away from outcomes focussed standards setting) is approximately £200,000. There will be additional work to review our inspection model in light of the requirement for standards to be set in Rules. We are not in a position to monetise this estimate given the significant variables involved.

Question 21: Our initial analysis of the proposed changes to pharmacy premises standards suggests that our preferred option, Option 2, has no significant transition or ongoing costs relative to the current framework. This is based on assumptions in Annex A of the IA. Are our assumptions valid? If not, please identify what other costs and assumptions have not been identified and provide examples and estimates that will help us quantify and monetise the costs.

Yes.

Question 22: We do not consider there will be any specific adverse impacts from this proposal on small or micro businesses. Do you agree? If not, please identify what these impacts are and their likely costs and explain why they are specific to small and micro businesses. Also, please provide evidence on how small and micro businesses would be affected by an alternative prescriptive rules-based approach compared to an outcome-based system. Please say (i) what assumptions we should use (ii) identify the impacts and (iii) estimate their likely costs and explain why they are relevant to small and micro businesses.

The law sets out the requirement for the GPhC to set standards and carry out inspections against those standards. Any alternative approach would continue to require inspections against standards – albeit new standards. Under any model there would be some impact on pharmacies – both large and small. However, we do not believe that there would be a significant difference between the current model of inspection – where we tailor to the local context, focus on outcomes and develop action plans depending on how our inspectors perceive performance against the standards – and an alternative inspection model where the standards were in Rules and a more compliance based approach was developed.

Our key concern would be that while the difference in burden between the two approaches is likely to be negligible, it is our judgement that the effectiveness of an inspection model which is making assessments against Rules would be less effective, inflexible and likely to have a negative impact on confidence of the sector.

We have carried out over 3,600 inspections under our new approach. The approach is designed to provide assurance of patient safety and to encourage improvement in pharmacies. Where we identify that standards have not been met we require the pharmacy to complete an action plan setting out the improvements that they will complete in order to meet our standards.

Very deliberately, we do not specify exactly how a pharmacy should carry out these improvements. This recognises that there are many ways a pharmacy can act to meet the standards taking into account their size, the number of patients they serve and the location. In our view this is particularly important if we are not to impose unnecessary burdens on 'small or micro' size businesses.

Question 23: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?
No response.