



## **GPhC response to the Rebalancing Medicines Legislation and Pharmacy Regulation: consultations on 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 develop our approach to regulating 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 are pleased to be able to respond to the four UK health departments consultation on two draft section 60 orders that bring parity in respect of dispensing errors for hospital pharmacy, and provide clarity about the respective roles of the superintendent and responsible pharmacist. 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 through both the rebalancing programme board and the Partners Forum.

## **Introduction**

It is clear that the public expectation of 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.

To ensure that pharmacy can continue to play a central role in the health, safety and well-being of patients and the public in Great Britain, we must play our part in providing assurance to patients and the public about pharmacy professionals and registered pharmacies. We welcome changes to legislation that aim to support a culture of learning and development, and the parity that will exist between those working in registered pharmacies and hospital pharmacy, and other services.

The changes proposed to the roles of the superintendent and responsible pharmacists will ensure that those working in these roles can be clear about their responsibilities and the expectations placed upon them. These proposals build on the previous consultations of the DHSC and together should ensure that patients and the public continue to receive safe and effective care from pharmacy.

Before responding to the consultation questions, we have set out below information that is of relevance to the consultation.

### **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 it has done to date.

All concerns raised with the GPhC about a registrant in relation to a dispensing error are looked into using policies and procedures which are used to guide the way in which we consider 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 making 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 placed on pharmacy owners.

### **2. Our approach to standards development and policy**

Prioritising safe and effective care for patients and the public and maintaining the confidence of those we regulate are vital parts of the way in which we meet our regulatory obligations.

We consistently take a collaborative approach to standards and policy development. We use a variety of methods to engage with patients and the public, and individuals and organisations across the pharmacy and health sectors, and to inform and test our proposals rigorously before we finalise and implement them. This has been recently demonstrated in our work to develop standards for pharmacy professionals, revalidation and changes to regulating registered pharmacies. We will continue to use this same evidence-based and inclusive approach to develop regulatory standards.

We are aware that some of the proposals within the consultation, for example responsible pharmacist absence and the potential for responsible pharmacists to be in charge of more than one pharmacy are issues on which there are a range of strongly-held views across pharmacy. If the outcomes of the consultation result in those rules being set by the GPhC, we will work with patients and the public and with individuals and organisations across pharmacy to ensure that future rules continue to safeguard patients and the public. We will do that by listening, looking at the evidence, seeking views on proposals and then setting clear standards and policies.

### 3. Rules development

We believe it is for the Government to decide the scope of our statutory responsibilities and we would not generally call to be given extra powers. However we support proposals which taken as a package seek to provide a clear framework for the delivery of safe and effective pharmacy services, from organisational governance through to the day to day operation of a pharmacy.

The GPhC currently has responsibility for the development of Rules as set out in the Pharmacy Order 2010. This includes for example Fitness to Practise Rules and Registration Rules. GPhC Rules are subject to statutory, formal consultation and must be approved by the Privy Council. GPhC Rules are also subject to the “negative resolution” scrutiny procedure in the UK Parliament.

If legislation is amended so that the GPhC is responsible for developing RP rules, we would as is the case for other policy development work, develop the content of any Rules in collaboration with patients and the public and pharmacy, including pharmacy professionals and stakeholders from across Great Britain.

### 4. Financial implications

The consultation proposes that the GPhC will be responsible for the development of three new sets of standards, and alongside these the development of responsible pharmacist Rules. As the DHSC will be aware, we review our income and expenditure regularly and subject to the outcomes of the consultation, we will factor this new work in to our financial planning. As a responsible regulator, we will ensure that wherever possible we align work so that we work efficiently and effectively and make the

best use of our resources. In so far as the proposals transfer responsibility for certain matters from Ministers to the regulatory bodies, they also transfer the costs of that work from the public purse to those who pay regulatory fees. It is important that stakeholders are aware of this point.

## Consultation Questions

### **PART ONE: Extension of the preparation and dispensing error defences to pharmacy professionals working in hospitals or other pharmacy services**

***Question 1: Do you agree with the approach to provide a defence for registered pharmacy professionals working in a hospital pharmacy, similar to that implemented for registered pharmacies (predominately community pharmacy)?***

Yes. We support the decision to introduce parity for pharmacy professionals working in hospitals or other pharmacy services.

***Question 2: Do you agree that in the case of hospital pharmacy services, this should be extended to include dispensing errors by registered pharmacy professionals which are made anywhere as part of a hospital pharmacy service, and so including elsewhere in the hospital, for example on a ward or in a hospital facility that does not have a recognisable pharmacy but supplies dispensed medicines in accordance with the directions of a prescriber?***

Yes. We support the proposal. The culture of learning and improvement must extend to the whole pharmacy service and this approach should support that.

***Question 3: Do you agree in principle with the proposal to extend the defences for registered pharmacy professionals making an inadvertent dispensing error to include other relevant pharmacy services?***

Yes. It is also important to future proof the legislation, so that that pharmacy professionals who work in other pharmacy services can continue to benefit from the defence as service provision continues to develop and evolve.

***Question 4: Are there any other pharmacy services that you feel should be included within the scope of the new defences as specified in article 8 of the draft Order, i.e. that are not mentioned in the consultation document, and meet the criteria?***

No.

***Question 5: Do you agree with the proposals that a pharmacy service that potentially benefits from the extended defences must have a Chief Pharmacist in order to rely on the extended defences?***

Yes in principle. We welcome the recognition that across Great Britain the term chief pharmacist is not used universally, and therefore in order for the extended defences to be relied upon, a chief pharmacist, or pharmacist with the designated responsibilities of a chief pharmacist is needed.

We note that the proposals as drafted would preclude a pharmacy technician from holding this senior role as the defence would not then apply.

***Question 6: Do you agree that the pharmacy regulators should be enabled to set standards in respect of pharmacists who are Chief Pharmacists (or who are designated the responsibilities of a Chief Pharmacist), including a description of the professional responsibilities of a Chief Pharmacist?***

Yes. We support this proposal and have outlined in the introduction our approach to standards and policy development.

***Question 7: Do you agree that the conditions of the defences for pharmacy professionals working in hospitals and other pharmacy services should broadly align with those required to be met by pharmacy professionals working in registered pharmacies?***

Yes. In so far as is possible, we believe that there should be parity between these proposals and the existing defence for those working in registered pharmacies.

***Question 8: Do you agree that the defences should apply where an inadvertent preparation or dispensing error is made in a situation where a pharmacist was both the prescriber and dispenser?***

Yes.

***Question 9: Do you agree that the defences should apply where an inadvertent error is made in a situation where a pharmacist sells or supplies a medicine against any patient group direction?***

Yes.

***Question 10: Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.***

N/A

***Question 11: Do you have any additional evidence which we should consider in developing the assessment of the impact of this policy on equality?***

N/A

## **PART TWO: SUPERINTENDENT PHARMACISTS AND RESPONSIBLE PHARMACISTS**

***Question 1: Do you agree that the Superintendent Pharmacist should be a senior manager of the retail pharmacy business (which may be just one part of the company for which they work) with the authority to make decisions that affect the running of the retail pharmacy business so far as concerns the retail sale of medicinal products and the supply of such products?***

Yes. The role of the superintendent pharmacist is vital in ensuring that patients and the public receive safe and effective pharmacy services. Those who act as superintendents must have the authority to make decisions that affect the running of the retail pharmacy business, and we welcome the clarity that the proposals bring in relation to the role of the superintendent pharmacist.

***Question 2: Do you agree with the removal of the restriction for companies with “chemist” in their title such that the Superintendent Pharmacist no longer has to be a member of the board of the body corporate?***

Yes.

***Question 3: Do you agree with the proposed general duty for the role of the Superintendent Pharmacist?***

Yes, we agree with the proposed general duty and the alignment with the general duty of the responsible pharmacist.

***Question 4: Do you agree that the Superintendent Pharmacist general duty should extend to all medicines – general sale list (GSL) medicines, as well as prescription only medicines (POM) and pharmacy (P) medicines?***

Yes. Whilst GSL medicines can be sold from other retail outlets, we believe that when these are sold from registered pharmacies the superintendent should be accountable and responsible in the same way that they are for POM and P medicines.

***Question 5: Do you agree that the role of the Superintendent Pharmacist should extend to other services, such as clinical and public health services?***

Yes. Registered pharmacies provide a range of clinical and public health services and as this continues to grow and expand it is important that the superintendent is equally accountable for these too.

***Question 6: Do you agree that the restriction whereby a Superintendent Pharmacist can only be a Superintendent Pharmacist for one business at any given time should be removed from primary legislation and the issue be left to the pharmacy regulators?***

Yes. We support the rationale provided. We know that the ownership structures of registered pharmacies can be complex, and this proposal will enable proportionality and flexibility.

***Question 7: Do you agree with the proposal to retain the requirement for Superintendent Pharmacists to notify the General Pharmaceutical Council when they stop being Superintendent Pharmacist for a particular pharmacy and to extend the requirement to Northern Ireland and the Pharmaceutical Society of Northern Ireland?***

Yes, we support the proposal to retain the requirement for superintendent pharmacists to notify the GPhC when they stop being a superintendent pharmacist for a particular pharmacy.

***Question 8: Do you agree with the proposal to provide the pharmacy regulators with power to set professional standards for Superintendent Pharmacists and describe their role?***

Yes. The superintendent pharmacist plays a vital role in ensuring that patients and the public receive safe and effective care from registered pharmacies. We support the proposal that the regulator sets regulatory standards for those working in this important role.

***Question 9: Do you agree that the statutory duty of the Responsible Pharmacist should be engaged only for the time when the Responsible Pharmacist is actually designated the RP role for that pharmacy, and is therefore in charge?***

Yes. We do not believe that it is appropriate for a pharmacist to be held accountable for the safe and effective running of the retail pharmacy business on a given day when they have not been designated as the responsible pharmacist. Under the proposals, the respective responsibilities and accountabilities of superintendent and responsible pharmacists are more appropriately and clearly delineated than they are under current legislation. We welcome this.

***Question 10: Do you agree that the trigger for when there needs to be an RP in charge of the premises is when medicines are being sold or supplied, or handled, assembled prepared or dispensed at or from the premises with a view to sale or supply?***

We broadly support these proposals. As is the case now, we understand this to mean a registered pharmacy could operate without a designated responsible pharmacist but with clinical services, for example blood pressure monitoring or diabetes testing, being provided to patients and the public.



Subject to the proposals within the consultation, pharmacy regulators will have a number of regulatory standards which could apply to the delivery of clinical pharmacy services in circumstances where there is no designated RP, these include the standards for registered pharmacies, standards for superintendent pharmacists and the standards for pharmacy professionals. Therefore the way the quality of clinical services are regulated at or from registered pharmacies will be through these standards.

***Question 11: Do you agree that Responsible Pharmacist's duties should be clarified so that it is clear these are related to the operation of the pharmacy business "at or from" the particular premises (e.g. including home deliveries of medicines)?***

Yes, we welcome this clarity.

***Question 12: Do you agree that the pharmacy regulators rather than Ministers should set out the detail of the Responsible Pharmacist's statutory responsibilities?***

Please see response to Q16.

***Question 13: Do you agree that the pharmacy regulators should have the power to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time?***

Please see response to Q16.

***Question 14: Do you agree that the duty on the Responsible Pharmacist to establish, maintain and keep procedures under review is removed and instead is subsumed into the general duties of Superintendent Pharmacists?***

Yes. We strongly support this proposal. Accountability for standard operating procedures must rest with the person who has the authority for the running of the retail pharmacy business, in this case the superintendent pharmacist.

***Question 15: Do you agree that the duties relating to record keeping should be set out by the pharmacy regulators, rather than in Ministerial legislation, and be enforced where appropriate via fitness to practise procedures?***

Please see response to Q16.

***Question 16: Do you agree that the pharmacy regulators should be provided with a new general rule/regulation making power in respect to the Responsible Pharmacist and remove the specific Ministerial regulation making powers in respect of:***

- (a) the qualification and experience of Responsible Pharmacists;***
- (b) the Responsible Pharmacist and supervision;***
- (c) procedures; and***
- (d) the record-keeping of the Responsible Pharmacist***

The GPhC would not normally comment on decisions about the scope of our statutory responsibilities which is rightly a decision for Government. However we support proposals which taken as a package seek to provide a clear framework for the delivery of safe and effective pharmacy services, from organisational governance through to the day to day operation of a pharmacy. We therefore support the proposals set out in the consultation.

***Question 17: Do you agree that the pharmacy regulators should be given new powers to set professional standards for Responsible Pharmacists and describe their role?***

Yes.

***Question 18: Do you agree that the Pharmacy (Northern Ireland) Order 1976 should be amended to provide for the appointment of a Deputy Registrar and to provide that the Deputy Registrar may be authorised by the Registrar to act on their behalf in any matter?***

N/A

***Question 19: Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.***

N/A

***Question 20: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?***

N/A