Response ID ANON-QD6Y-F2F1-K

Submitted to **Rebalancing Medicines Legislation and Pharmacy Regulation: Two Draft Section 60 Orders**
Submitted on **2018-09-11 16:54:04**

Executive Summary

Introduction

1 What is your name?

Name:
Aileen Bryson

2 What is your email address?

Email:
aileen.bryson@rpharms.com

3 Which of these best describes you/your profession?

Other public sector

If Other, please elaborate.:
Professional body

4 Are you responding as an individual or as part of an organisation?

Organisation

If you selected Organisation, what is the name of your organisation?:
Royal Pharmaceutical Society

Other

If Other, please elaborate.:
GB . We have representation in England , Scotland and Wales.

5 If you're answering as an individual please tell us your ethnic origin:

Not Answered

If other, please describe your ethnic origin:

Not Answered

If other, please give details of your ethnic background.:

Not Answered

If other, please enter details of your ethnic background:

Not Answered

If other, please give details of your ethnic origin.:

Not Answered

If other, please provide details of your ethnic background:

Not Answered

6 How we will use your response:

Yes

Yes

Your response, Your organisation's name

7 Leave blank to proceed to Part One - Extension of the preparation and dispensing error defences to pharmacy professionals working in hospitals and other relevant pharmacy services;Tick to skip Part One and proceed directly to Part Two - Superintendent Pharmacists and Responsible Pharmacists.

Skip to Part Two:
No

Part One: Extension of the preparation and dispensing error defences to pharmacy professionals working hospitals and other relevant pharmacy services

8 Part 1 – 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

Do you have any comments?:
In principle we agree with this approach to give parity for all pharmacy professionals wherever they are practicing.

9 Part 1 – 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

Do you have any comments?:
This will be necessary to accommodate the variety of systems and process used in hospitals to dispense medicines across one legal entity. This defence should extend to anywhere under the governance of the chief pharmacist (or equivalent) role.

10 Part 1 – 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

Do you have any comments?:
This is necessary because pharmacy services for dispensing and supply of medicines can take place in a variety of settings under the same governance arrangements as the main pharmacy.

11 Part 1 – 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?

Yes

Do you have any comments?:
All pharmacy services which are governed by a chief pharmacist or equivalent pharmacist role should be eligible for the defence and the legislation. Pharmacy professionals will need to be clear that in order to have the defence when practicing in the normal course of their business they need to have the appropriate governance arrangements in place with either a superintendent or designated “chief pharmacist” role.

E.g. there are some areas of the country where pharmacist and /or technician are working in GP dispensing practices. It will need to be clear that unless they have a chief pharmacist role for governance and / or are regulated by the CQC or equivalents, and fit all the other criteria this group could be left in a situation of practising on normal course of professional business by with no defence.

12 Part 1 – 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

Do you have any comments?:
This role is important for good clinical governance and clear lines of responsibility to ensure safe process and procedures wherever the pharmacy services are delivered. It aligns well with the superintendent role in community pharmacies.

The GPhC must be informed when a superintendent changes in an organisation. Should the same therefore be asked of chief pharmacists and should the public be able to see who has overall responsibility for any organisation?
Registrant will need to be given guidance to check that there is a chief pharmacist or equivalent role wherever they are working.

13 Part 1 – 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

Do you have any comments?:
If the proposals for a chief pharmacist role are accepted then standards will be helpful to clarify roles and responsibilities for overall safe dispensing procedures. It is the role of the professional body to set professional standards. Any standards set by the regulator should be regulatory to ensure safety of the public as is their remit and should refer where appropriate to professional standards such as the RPS Hospital standards. I.e. the regulator describes the standards required to comply with the regulations. The standards from the professional body demonstrate how to achieve this. They are developmental for the profession moving forward, illustrating best practice and facilitating benchmarking against current practice, with a view to continuous quality improvement. The process for developing RPS professional standards is extremely robust and now NICE accredited.

14 Part 1 – 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

Do you have any comments?:
These should align as closely as possible. The principle should be that all pharmacy professionals can avail themselves of the defence while working in the normal course of their business if they have the correct governance arrangements in place and f=then fulfil the other criteria for that incident. The public also need to know that all pharmacy professionals are working to the same standards of care wherever they are practicing.

15 Part 1 – 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

Do you have any comments?:
These are separate discreet tasks. Prescribing should not negatively influence the care taken over dispensing. The knowledge of what was intended to be prescribed should actually increase awareness of what must be dispensed. Guidance is available on how to manage this situation as safely as possible and this should be highlighted.

16 Part 1 – 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

Do you have any comments?:
The supply process is the same for this.

17 Part 1 – 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.

No view

Do you have any comments?:

18 Part 1 – Question 11: Do you have any additional evidence which we should consider in developing the assessment of the impact of this policy on equality?

No view

Do you have any comments?:

19 Leave blank to proceed to Part Two - Superintendent Pharmacists and Responsible Pharmacists; Tick to skip Part Two and proceed directly to submitting your response to the consultation.

Skip to Submitting Your Response:
No

Part Two: Superintendent Pharmacists and Responsible Pharmacists

20 Part 2 – 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

Do you have any comments?:
This role has overall responsibility for safe processes, procedures and working practices for all the pharmacy services where the sale and supply of medicines are involved, and for the organisational systems and processes required to provide those services safely.

21 Part 2 – 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

Do you have any comments?:
The key consideration is not where the superintendent sits in a corporate structure but that the superintendent has overall responsibility for the professional practice in the pharmacy and is empowered to make the decisions necessary for the professional running of the pharmacy.
Wherever the superintendent sits in the organisation this responsibility must be absolute. If authority is only feasible via a seat on a board in any particular organisation then this where the superintendent must suit. If however an alternative structure exists which allows overall responsibility and decision making then this would be acceptable.

The acknowledgement that medicines are not normal items of commerce is key to the safe and professional running of a pharmacy business wherever it is situated, even when this is only one part of a larger business. Superintendents must not be subjected to pressures or corporate decisions which compromise the safe and efficient running of the pharmacy

The changes in legislation should enshrine the principle of absolute authority for the safe running of the pharmacy to empower superintendents professionally wherever they sit within an organisation.
Does the definition of senior manager ensure this authority?

22 Part 2 – Question 3:Do you agree with the proposed general duty for the role of the Superintendent Pharmacist?

Yes

Do you have any comments?:
We agree that the general duty of the Superintendent Pharmacist refers to the ways in which the business is carried on and is an overall responsibility for the organisational systems and processes. We agree that taking the responsibility for establishing, maintaining and reviewing SOPs should be the responsibility of the SP rather than the RP and this gives clarity to each role.

23 Part 2 – 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

Do you have any comments?:
The superintendent should have overall responsibility for the processes involved in the sale and supply of all medicines from a pharmacy.

24 Part 2 – 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

Do you have any comments?:
This should extend to all services from the pharmacy. Medicines or advice regarding medicines are integral to all pharmacy services and the superintendent pharmacist should have overall responsibility for the way these are carried out.

25 Part 2 – 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

Do you have any comments?:
In principle we support the general move from legislation to regulation. This particular anomaly should be amended to accommodate independent pharmacies who wish to make a joint appointment for a superintendent responsible for more than one legal entity. It would give parity with corporate bodies where one person can be responsible for numerous pharmacies only because they belong to the one legal entity.

26 Part 2 – 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

Do you have any comments?:
The GPhC should always be informed of changes in a timely manner to ensure a clear audit trail if incidents occur and to have the correct point of contact for each organisation. Should this requirement apply to chief pharmacists for registered premises and a similar system in place to inform the other healthcare regulators and the public?

27 Part 2 – 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?

No

Do you have any comments?:
GPhC should set high level outcome based regulatory standards to ensure public safety in the running of registered pharmacies. I.e. these are the standards expected to comply with the regulations. Description of the role is more suited to guidance to aid interpretation of the standards.

Professional standards are the remit of the professional body. They are developmental for the profession moving forward, illustrating best practice and facilitating benchmarking against current practice, with a view to continuous quality improvement. The process for developing RPS professional standards is extremely robust and now NICE accredited.

Professional standards will show pharmacists how to comply with regulatory standards and illustrate best practice to benchmark their practice against. They are designed to be supportive, enabling and professionally challenging.
There is a requirement for both regulatory and professional standards to be used in practice this is well illustrated in the quote below:

“THE GENERAL PHARMACEUTICAL COUNCIL BELIEVES THAT PHARMACISTS AND THEIR TEAMS SHOULD BE AWARE OF AND USE ALL RELEVANT PROFESSIONAL STANDARDS AND GUIDANCE, BOTH REGULATORY AND PROFESSIONAL, TO DELIVER PERSON-CENTRED CARE AND GOOD QUALITY OUTCOMES.” Duncan Rudkin, Chief Executive, GPhC.

28 Part 2 – 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

Do you have any comments?:
There should always be a designated RP when the pharmacy is open who is responsible for the day to day activity in the pharmacy. This duty ends when the pharmacy closes as another pharmacist might be the Responsible Pharmacist when the pharmacy next opens. This is in contrast to the Superintendent whose responsibility is not time limited.

29 Part 2 – 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?

Yes

Do you have any comments?:
There should be an RP whenever the pharmacy is open or work is being carried out to prepare for the sale and supply of medicines. The RP is responsible for the day to day running and conduct of staff for all pharmacy activities being undertaken at that particular time.

30 Part 2 – 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

Do you have any comments?:
This would be a useful clarification. The Responsible Pharmacist duties should encompass the delivery of all pharmacy services from the particular premises on a day to day basis and the Superintendent be responsible for the overall organisational processes to be adhered to.

31 Part 2 – Question 12:Do you agree that the pharmacy regulators rather than Ministers should set out the detail of the Responsible Pharmacist’s statutory responsibilities?

Yes

Do you have any comments?:
This is the principle of re-balancing and will allow more flexibility in future as pharmacy practice changes and evolves to suit clinical requirements.

32 Part 2 – 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?

Yes

Do you have any comments?:
This is the principle of re-balancing. Being the RP in charge of one pharmacy at any one time should be the norm. We expect any regulator to make this clear but to allow exceptions for emergencies where patient care would be compromised, such as extreme weather or a pandemic situation.

33 Part 2 – 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

Do you have any comments?:
The Superintendent should have overall responsibility for safe procedures and the Responsible Pharmacist should ensure safe and efficient day to day running of the pharmacy. We expect any guidance from the regulator to reflect the ethos of the consultation document and to be clear in their standards that this includes using professional judgement in the best interests of patients which may necessitate a deviation from usual procedures

34 Part 2 – 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?

Yes

Do you have any comments?:
We agree this is more appropriate. Record keeping is standard pharmacy practice and therefore should be the remit of the regulator who will ensure safe procedures are in place through their inspections. This will also allow more flexibility if practice changes and record keeping procedures need to be adapted to accommodate this.

35 Part 2 – 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:(e) the qualification and experience of Responsible Pharmacists;(f) the Responsible Pharmacist and supervision;(g) procedures; and (h) the record-keeping of the Responsible Pharmacist

Yes

Do you have any comments?:
In principle we support this shift to the regulator with the caveats of Privy Council intervention and representation to the Minister when necessary.
The role of the regulator is to ensure public safety which in principle could encompass all of the aspects listed in Q16.
The GPhC already stipulates the necessary criteria for undergraduate and pre- registration training and so consideration of the experience required as an RP is a natural progression from that.
Providing power to the regulator will support new ways of working and enable a more flexible approach to pharmacy practice. However, any changes to supervision and the experience required to take on an RP role will have major implications for the workforce and will need wide consultation.

We would expect the regulator to have an outcomes-based approach which focuses on the safe running of the pharmacy, empowering professional judgement in individual situations rather than rigid specifics.
Moving power into regulation places more responsibility on the regulator to ensure that the standards they produce and the systems they have for inspection will be robust enough to uncover any areas of risk to patients. This must be in tandem with empowering individual RPs to decide how to manage their pharmacies, ensuring the public have safe and timely access to their medicines.
Regulation should be enabling, giving the RP flexibility and autonomy in professional practice on a day to day basis.

In future the regulator might not be pharmacy specific and therefore might not have the same level of in depth knowledge of the profession that exists at present.
There does need to be a route to ensure an appropriate level of scrutiny and a recourse to Parliament as a last resort for any contentious issues.
Any changes to the structure of healthcare regulation will require further consultation.

36 Part 2 – 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?

No

Do you have any comments?:
Professional standards are the remit of the professional body. The regulator should only be setting regulatory standards. I.e. an outcomes-based approach to what is required in the running of a pharmacy to ensure the safety of the public. Professional standards set out how to achieve this, including gold standards and best practice to benchmark against.

37 Part 2 – 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?

No view

Do you have any comments?:

38 Part 2 – 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.

No view

Do you have any comments?:

39 Part 2 – Question 20: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?

No view

Do you have any comments?: