



# Response to the DHSC consultation on Rebalancing Medicines Legislation and Professional Regulation: draft Orders under section 60 of the Health Act 1999

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## Introduction

The Pharmaceutical Services Negotiating Committee (PSNC) welcomes the opportunity to respond to the consultation and the draft orders:

- Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018; and,
- Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

**We are broadly supportive of the proposals as described in the consultation document, which we consider should assist the development and delivery of pharmacy services, to the benefit of patients and the public.**

We consider that there are issues still to clarify and these include some of the issues identified at the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board Partners' Forum on 24th July 2018.

Our issues are as follows:

- Capturing the full emerging roles and responsibilities of superintendent pharmacists and responsible pharmacists and the relationship between the two roles: both dispensing and in wider service provision;
- Ensuring that the superintendent pharmacist is sufficiently senior within the retail pharmacy business to carry out the role;
- Clarifying any potential additional implications of the proposed changes to the Medicines Act, which relate to the role of the responsible pharmacist;
- Requiring pharmacy regulators to consult with interested parties before setting any professional standards relating only to responsible pharmacists and/or superintendent pharmacists;
- Ensuring patient safety is afforded the same level of consideration as minimising burdens on business, in respect of the pharmacy regulators' powers;
- The protection in place around how a future "super-regulator", that might subsume the role of the General Pharmaceutical Council, could use the new powers proposed for pharmacy regulators.

Our response to each of the questions in relation to the Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018 is set out on the following pages.

## Part 2 — The draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

**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?**

Broadly yes.

The proposal recognises the involvement of other senior managers in the management of retail pharmacy businesses, while at the same time seeking to maintain the unique statutory and professional position of the superintendent pharmacist.

The superintendent pharmacist's unique position, which underpins the governance of retail pharmacy businesses, is sought with the new proposed duty for superintendent pharmacists (the proposed new duty in section 72AA of the Medicines Act 1968, question 3 below) and the ability of the pharmacy regulators to set professional standards for superintendent pharmacists (proposed amendment of article 48 of the Pharmacy Order 2010, question 8 below).

However, while the overall structure is sound, the proposed statutory provisions no longer set out either the wide role of the superintendent pharmacist that is currently envisaged by use of the term 'management' of the business, or the detail of '...keeping [and] preparing ... medicines ...'. The new duty provides some guidance, but the emphasis remains on the retail sale of medicines or their supply in circumstances corresponding to retail sale (dispensing against prescriptions). There is, therefore, considerable reliance on future professional standards to determine and describe in detail the duties and responsibilities of superintendent pharmacists.

Accordingly, greater clarity is sought on:

- the duties and responsibilities of the 'senior manager superintendent pharmacist', particularly alongside other senior managers who may be involved in the retail pharmacy business; and,
- the likely professional standards for superintendent pharmacists that will be issued initially by the pharmacy regulators.

Also, due to the significance of the professional standards to the proposed governance framework, we suggest that the pharmacy regulators should be under a duty to consult interested parties before setting standards that relate only to responsible pharmacists and/or superintendent pharmacists.

**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?**

Membership of a company's board, even though this is only required for companies using the title 'chemist', signifies a level of seniority for the position that is not matched by the description of 'senior manager' and it will be important that the revised provisions of the Medicines Act 1968 and the associated professional standards ensure that superintendent pharmacists have sufficient authority to provide the necessary professional pharmacy oversight of

the retail pharmacy business, for the benefit of patients and the public. As indicated above, greater clarity is sought on the duties and responsibilities of the 'senior manager superintendent pharmacist'.

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

Broadly yes, but subject to the above comments.

The proposed general duty gives the superintendent pharmacist 'the duty .. in relation to the retail pharmacy business to secure that the business is carried on in ways that ensure its safe and effective running so far as concerns the retail sale of medicinal products ... and supply of such products [dispensed against prescriptions].'

The current governance structure provides that the superintendent pharmacist has an overarching responsibility for the keeping, preparing and dispensing of medicines and is assisted in that role by responsible pharmacists for each of the pharmacy premises. If a responsible pharmacist's statutory duty is not engaged when he or she is not actually designated that role, the Act might provide explicitly that the superintendent pharmacist's duty relates to the keeping and preparing of medicines as well as their sale and supply, to ensure that there are no gaps in the professional accountability for medicines kept, prepared, sold or supplied by the business.

**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. This is long overdue.

**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. Clinical and public health services should be part of a superintendent pharmacist's role. Such services are included within Essential, Advanced and (locally) Enhanced Pharmaceutical Services delivered by NHS community pharmacies and are part of pharmacy practice.

**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. This proposal may assist bigger and smaller retail pharmacy businesses alike, as indicated in the consultation.

The removal of this restriction may result in the emergence of 'professional' superintendent pharmacists, who carry out the role for several retail pharmacy businesses. While such persons may have knowledge and experience of the role and responsibilities of a superintendent pharmacist, there is also a need for them to be sufficiently familiar with the relevant retail pharmacy business and to have the necessary time and resources, to be able to ensure the safe and effective running of the business. Such issues are likely to be addressed in professional standards issued by the pharmacy regulators and our previous comments on initial professional standards and appropriate consultation apply here.

**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.

**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, this is a pragmatic and sensible approach as the pharmacy regulators can respond to developments in pharmacy practice relatively quickly.

There is also a need to ensure consistency between the professional standards issued by the pharmacy regulators.

Due to the significance of the professional standards to the proposed governance framework, we suggest that the pharmacy regulators should be under a duty to consult interested parties before setting standards that relate only to responsible pharmacists and/or superintendent pharmacists.

**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?**

Broadly, yes.

Additional clarity is sought on the roles of, and relationship between, responsible pharmacists and the superintendent pharmacist.

In addition, the current governance structure provides that the superintendent pharmacist has an overarching responsibility for the keeping, preparing and dispensing of medicines and is assisted in that role by responsible pharmacists for each of the pharmacy premises. If a responsible pharmacist's statutory duty is not engaged when he or she is not actually designated that role, the Act might provide explicitly that the superintendent pharmacist's duty relates to the keeping and preparing of medicines as well as their sale and supply, to ensure that there are no gaps in the professional accountability for medicines kept, prepared, sold or supplied by the business.

**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, although additional clarity is sought on the role of the responsible pharmacist and (see our answer to question 11) any potential additional implications of the proposed changes to the Medicines Act, which relate to the role of the responsible pharmacist.

**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)?**

Clarification is sought on any potential additional implications of the proposed changes to the Medicines Act, which relate to the role of the responsible pharmacist.

The consultation document indicates that the proposed changes are necessary *'to clarify that the RP's duty relates to the operation of the pharmacy business 'at or from' the particular premises (e.g. including home deliveries of medicines) for which the RP is in charge.'*

However, for home deliveries, the supply takes place 'at' the pharmacy premises and relevant pharmacists are professionally responsible for the sale or supply of the medicine to the patient (including to the patient's home); and a responsible pharmacist's relevant duties or professional standards can be set by the pharmacy regulators.

Accordingly, first, the need for the statutory changes is unclear and, second, the distinction between supply 'at' a pharmacy premises and supply 'from' a pharmacy premises is unclear.

This is particularly relevant since it is proposed that pharmacy regulators will have power to set out the detail of responsible pharmacists' statutory responsibilities.

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

Broadly, yes although it is unclear why this is necessary when pharmacy regulators can set responsible pharmacists' professional standards.

It is suggested that the pharmacy regulators should be under a statutory duty to consult interested parties before issuing any statutory responsibilities relating to responsible pharmacists.

As discussed at the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board Partners' Forum on 24th July 2018, there is a need to recognise protection of patient safety as well as business efficiency, on the face of the Medicines Act. This should apply to responsible pharmacists and superintendent pharmacists.

**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, this is a pragmatic and sensible approach as the pharmacy regulators can respond to developments in pharmacy practice relatively quickly.

There is also a need to ensure consistency between the professional standards issued by the pharmacy regulators.

**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.

**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 practice procedures?**

Yes.

**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. As discussed at the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board Partners' Forum on 24th July 2018, there is a need to consider how any new super regulator might use powers introduced for pharmacy regulators.

We suggest that a statutory duty to consult interested parties, before setting professional standards that relate only to responsible pharmacists and/or superintendent pharmacists, would add some protection to the use of such powers by any future super regulator (as well as assisting pharmacy regulators with the use of such powers).

**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, this is a pragmatic and sensible approach as the pharmacy regulators can respond to developments in pharmacy practice relatively quickly.

There is also a need to ensure consistency between the professional standards issued by the pharmacy regulators.

Due to the significance of the professional standards to the proposed governance framework, we suggest that the pharmacy regulators should be under a duty to consult interested parties before setting standards that relate only to responsible pharmacists and/or superintendent pharmacists.

**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?**

Yes.

**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.**

We suggest that there will be additional regulatory burden in that:

- All pharmacists and pharmacy technicians will need to familiarise themselves with the proposed changes as well as all pharmacy staff in patient facing roles, because the governance structure within retail pharmacy businesses is relevant to all those involved in the sale and supply of medicines to the public and patients.
- While welcomed, the increased workload for the pharmacy regulators is a cost to pharmacists, pharmacy technicians and retail pharmacy businesses registered with those regulators.

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

No.

**About PSNC**

PSNC promotes and supports the interests of all NHS community pharmacies in England. We are recognised by the Secretary of State for Health as the body that represents NHS pharmacy contractors. We work closely with Local Pharmaceutical Committees to support their role as the local NHS representative organisations.

Our goal is to develop the NHS community pharmacy service, and to enable community pharmacies to offer an increased range of high quality and fully funded services; services that meet the needs of local communities, provide good value for the NHS and deliver excellent health outcomes for patients.