Community Pharmacy Scotland

Rebalancing Medicines Legislation and Pharmacy Regulation

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Who are Community Pharmacy Scotland (CPS) & what do they do?

Who we are

We are the organisation which represents community pharmacy contractor owners in almost every aspect of their working lives, and are the voice of these vital healthcare professionals as they deliver pharmaceutical care to the people of Scotland.

We are empowered to represent the owners of Scotland's 1256 community pharmacies and negotiate on their behalf with the Scottish Government. This covers all matters of terms of service and contractors' NHS service activity including remuneration and reimbursement for the provision of NHS pharmaceutical services.

What we do

We work with the Scottish Government on the development of new pharmaceutical care services and ensure that the framework exists to allow the owners of Scotland's community pharmacies to deliver these services.

The Scottish community pharmacy contract puts the care of the individual right at its centre and with its focus on pharmaceutical care and improving clinical outcomes, community pharmacy contractors and their employee pharmacists are playing an increasingly important role in maximising therapeutic outcomes and improving medicine safety. Community pharmacy is at the heart of every community and plays an important part in the drive to ensure that the health professions provide the services and care the people of Scotland require and deserve.

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Introduction

The Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board (RPB) was established to consider the legislation and regulation associated with Pharmacy in the UK, with the express aim of ensuring that these are designed to provide safety for service users whilst reducing the barriers to the responsible development of practice, innovation and a systematic approach to quality in Pharmacy.
In short, the broad view is that Pharmacy is over-legislated for in this country, leaving little flexibility for development and evolution of the profession – some of the current legislation has been in place for many decades when the landscape of healthcare was completely different, and some more recent legislation such as the RP regulations has already proven to restrict the ability of service providers to adapt their business models for changing needs. Public safety must always be assured, so if there is a move away from this being so heavily legislation-led then the only reasonable choice is to give powers to the regulator allowing them to set rules and standards as appropriate. There are several advantages to doing this:

• The GPhC has greater scope to amend their rules and standards as practice evolves than there is to make routine changes to the law. It is also able to do this at far greater speed than the law can be changed.

• The GPhC tend to consult with the profession when they mean to make significant changes, and we have seen them listen to responses and adjust their proposed actions appropriately. This opportunity to influence is limited and infrequent when it comes to lawmaking.

• The GPhC would be able to make exceptions to their own rules to allow for the controlled, responsible development of practice. This power lies with ministers for some of the current legislation, but the process is not simple nor often successful.

• The consequences of any failure to abide by rules or meet standards would all be related to Fitness to Practice and registration outcomes – not criminal prosecution as could currently be the case.

• The RPB's next and final area to be explored is that of Supervision in relation to Pharmacy. Supporting this direction of travel towards regulator-led definitions of standards may give CPS a rare opportunity to influence the supervision debate in favour of the flexibilities called for as part of our Vision. This consultation broaches the subject by calling for GSL sales to be allowed to carry on in the absence of an RP. Even if the regulator did not agree with other tasks following suit at this moment in time, it would allow for the debate to be ongoing, and tests of change to be carried out and evaluated.

This consultation looks specifically at two areas:

Part 1: The conditions under which the recently introduced defence against inadvertent dispensing errors should be extended to non-registered Pharmacies (includes prisons, care homes and hospitals but not dispensing doctors).

Part 2: Clarifying and strengthening the governance around the specified roles of Responsible Pharmacist (RP) and Superintendent Pharmacist (SP) in registered Pharmacies.

Part 1 lays out the intention to extend the defence against inadvertent dispensing errors to unregistered pharmacies – but only where a Chief Pharmacist with appropriate powers, responsibility and accountability is appointed. It is hoped that this will give assurance of there being a basic standard of organisational governance in place for meaningful learning and change as a result of errors to occur.
Part 2 proposes that the roles of SP and RP are outlined in the primary legislation, but that it will be for the regulator to define how each role is fulfilled (for example, by setting standards). This will see a reduction in the level of detail in the RP legislation.

The full consultation document can be accessed here. Our response is included below.

Part 1 – The draft Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018

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.

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 believe that if the correct organisational governance and learning culture is in place, then the physical location of the professional and the work being carried out are of little relevance.

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, as long as the correct organisational governance is in place for meaningful learning to come from error reporting.

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. There must be a person with the power to make changes within a greater organisational structure to avoid repeating even inadvertent errors, and they should carry the associated responsibility and accountability for this.

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. This will provide clarity for a newly established role, particularly for those who are not a part of the profession but who are in senior management positions in the greater organisational structure within which the pharmacies in question operate. We expect that by setting standards, local variation in the role, responsibilities and remit will be minimised.

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.

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. As in community pharmacy, this is occasionally unavoidable. As long as the appropriate system governance is in place, a Pharmacist should not have to consider the prospect of being subjected to criminal proceedings when they are making the professional decision of ensuring timely supplies of medication.

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.

No.

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.

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?

Yes. It is our view that the Superintendent Pharmacist could only be held to account for organisational shortcomings if they had also held sufficient authority and were able to make meaningful changes with respect to the operation of the business.

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. This will allow for more flexibility in how the role may be fulfilled.

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

Yes. This provides further clarity for not just the SP role, but that of the RP as well.

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.

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. This approach is preferable to attempting to legislate for the safe and effective functioning of these services. The regulator will be able to more rapidly adapt their guidance and standards as the healthcare landscape evolves, and have the ability to create overarching principles rather than detailed rules – allowing flexibility for responsible development.

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. It has been repeatedly demonstrated that a single person can successfully fulfil the role of superintendent for a large company, so this anomaly in legislation serves no purpose, and in fact may be an unnecessary barrier to consistency in organisational structurers.
We also see that this change could bring the potential to have an improved support structure for career development, where prospective SPs may be mentored or overseen by a person more experienced in the

role. This would allow the more senior Pharmacist from another legal entity to act as SP as the person new to the role gains experience and knowledge equipping them to fulfil the role of clinical lead for a whole organisation.

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, provided the regulator continues to engage with the profession when they are considering setting standards. The language used in setting these standards should be aligned to those of the Chief Pharmacist.

In defining the standards, we are of the opinion that the regulator takes the opportunity to undertake work to publicise the different pharmacy roles, to further increase public assurance in organisational governance and improve clarity.

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, though care must be taken to ensure that this is not misconstrued as meaning that the RP does not hold part of the responsibility for continuous improvement at the premises and the resolution of issues arising when designated as RP.

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. However, this goes hand in hand with the discussion around supervision in Pharmacy. It is our view that there should be a single RP in charge of the premises when these activities are undertaken, but there should be the flexibility to allow some or all of them to continue in their absence if they make the professional decision that their team is confident and competent to do so. As care and services are transferred to the community from secondary and primary care and the population ages, the RP's skills are more likely to be needed outwith the premises. This should not mean that safe and effective access to medicines cannot be provided to patients and the public at the same time. We are of the opinion that there should not be a limited list of activities which trigger the need for an RP, as this approach is not future-proofed. Although general guidance would be appreciated, it should be for the SP (acting under the standards of the regulator) to work with their respective RPs in making decisions about what staff at each individual premises can and cannot do with an RP.

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.

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. As we move on to the discussion around Supervision and what this means in the current and future world of Pharmacy in the UK, it is crucial that the RP role and responsibilities can be regularly re-assessed in the light of any changes made to legislation.

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. The process for granting an exception is likely to be much more straightforward in the hands of the regulator, and it is right that there is the opportunity to test new models of operation in a controlled manner. In addition, this will bring added flexibility for exceptional circumstances such as extreme weather conditions. As part of the washup from early 2018's red weather warnings, a piece of work is underway to bring the network of pharmacies in Scotland closer, setting up broad principles for supporting one another in the event that a Pharmacist cannot get to the pharmacy that they are supposed to be working in that day. The current RP arrangements have severely restricted what is possible to allow continuity of care for communities in what could be times of great need.

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. The legislation need not go into this level of detail, and as SOPs tend to be the same or very similar across pharmacies in the one organisation, it is clear that the creation and maintenance of SOPs fits within the wider remit of the SP role. However, we expect that any guidance relating to SOP maintenance will recommend that Pharmacists regularly acting as RP in the business are involved when reviews are underway.

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. This is in line with the pragmatic approach taken to minor record-keeping omissions with respect to premises inspections.

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 – the movement of all of these powers will make the exploration of new ways of working possible, which is not currently the case.

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. The principles that are being used for the approach to describing the SP role should also be used for the RP, provided that any proposed standards are consulted upon before being set.

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.

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.

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

No.