



## **RPS response to the ‘Evaluation of the impact of the RP regulations’**

The Royal Pharmaceutical Society has received and acknowledged the report of the impact of the Responsible Pharmacist Regulations, which was commissioned in conjunction with the Professional Forum of the Pharmaceutical Society of Northern Ireland from TNS-BMRB. The need for such research came from the consistent views of many pharmacists who felt that changes were adding unnecessary complexity to their practice without any benefit to their patients. We therefore felt it important to have wide ranging research to investigate these anecdotal reports.

The RPS regards the research findings as being an authoritative, independent and extremely useful assessment of the current situation in both hospital and community pharmacy and further considers that addressing these issues to be fundamental to its work around professional empowerment.

There is now a tremendous amount of work to be done to address the issues identified in the report. We have been greatly impressed by the willingness of representative bodies, unions, regulators and all other stakeholders to work together on these issues in the interests of patients and pharmacists.

We recognise that the Government introduced the RP regulations as part one of a two part legislative process, the second part being changes to the supervision rules. However, before any changes to supervision are embarked upon, there must be a firmer grounding of the RP regulations. Specifically the report’s recommendations could address this primary issue, as well as the others which it has highlighted.

The RPS believes that this report, its findings and recommendations have given the profession, its leaders and stakeholders a clear mandate to affect change which will both improve the professional lives of pharmacists and pharmacy staff and, critically, increase patient safety and patient care. The Society is acutely aware that to achieve improvements collaboration with everyone in the sector is required. We will, through our actions, demonstrate this approach and wish success to be judged through the improvements our members and their patients see and experience.

The RPS have responded in full to each of the recommendations

The three National Pharmacy Boards of RPS have made the following initial responses to the recommendations .

### **I. Distinguish the responsibilities between the RP and the superintendent/ owner**

Lack of clarity around who has responsibility must be addressed and pharmacists must not be expected to have responsibility, embedded in law, over what they cannot control.

The RPS can play a role in the demarcation of responsibilities although amendments to the RP regulations may be required in this area. The forthcoming GPhC consultation on the standards for retail pharmacy premises would seem to be a useful vehicle within which to provide required clarity.

The RPS would like to engender a way of working in which the different professional roles of superintendent and RP operate harmoniously in the interests of patient care. Broadly we support the recommendation that: "Overall, superintendents or owners should have responsibilities for matters relating to the business and premises." The RP should be responsible for matters relating to the care of the patients. However, the situation is very complex and not merely about what is organisational and what is local. Ultimately, whenever patients' safety is put at risk, the pharmacist in the pharmacy must be able to take immediate action locally, in the interests of patients, regardless of where responsibility lies.

Where the superintendent does not work in the pharmacy, he or she must put in place easy, direct reporting systems. These systems will encourage the reporting of any remedial action required within the pharmacy. Reporting must be seen as a benefit to good practice, encouraged by the superintendent and be embedded within the organisation's culture. It would be within all pharmacists' professional duties to use these reporting mechanisms.

Uniquely amongst regulators of health professionals the GPhC also regulates pharmacy premises. For example in dentistry, individual dentists are regulated by the General Dental Council and premises by the Care Quality Commission (CQC). CQC is a "systems regulator" that regulates activities across organisations rather than the individuals that work within it.

Systems regulation is concerned with factors such as making sure that the environment is clean as well as ensuring staffing levels for services are safe.

The GPhC, as a systems regulator as well as the regulator of pharmacy professionals, has great influence over the environment in which pharmacy professionals work. The GPhC has stated it wishes to be an outcome focused regulator. Combining systems regulation with an outcome focus would, we hope, mean the GPhC would expect to see system wide solutions. Therefore GPhC should be concerned with, for example, the operation of organisation wide safety incident reporting procedures and organisational demonstration of how learning from incidents occurs. The RPS is willing and able to play a role in the sharing of good practice in this area.

The interplay between "systems" or "organisational" regulation and the regulation of individual pharmacists must be clear to all those in the sector.

The GPhC through the development of their new standards for premises has an opportunity to engage and explain to the profession the process by which they will regulate organisations and businesses that provide pharmacy services, as well as how they regulate individual pharmacists.

The pharmacy sector as a whole would benefit from joined up regulation between commissioners and different regulators. For example thought should be given to how pharmacies are registered to ensure they

meet required standards, both NHS contractual standards and professional regulatory standards. This should include how they are inspected to check that they continue to meet these standards and how, and against whom, action is taken if they don't.

## **2. Empower the RP to make decisions around how absence is used as well as to make changes to safety procedures**

There must be a re-ignition of professionalism, organisation wide within companies as well as team and individual professionalism, leaving no doubt that professional judgement is at the heart of good clinical practice. Professional empowerment needs to be seen as the route to delivery of improved practice and greater safety, actively promoted by all. Those in senior leadership or management roles within the profession must lead by example. If cultures, structures or processes take away the ability to exercise patient centred professional judgement then these should be challenged. The whole of pharmacy must agree that professional empowerment is key if we are to become better clinical practitioners, be convincing providers to commissioners, and improve safety.

The RPS has always stated that the RP should only be absent from the pharmacy for professional reasons. We strongly support this recommendation giving the RP control over their absence for professional reasons.

The RPS will continue to provide its members with clear guidance on the control an RP has over their day to day practice. This will dovetail with the standards that we expect the GPhC to produce within their standards for retail pharmacy premises. There is clearly also a need for community pharmacy negotiators and NHS employers' representatives to implement changes to the contractual framework. The RPS will play a role in informing these future changes in ways that benefit patients and pharmacists.

## **3. Provide clarity on the role of the technician and liability in relation to dispensing errors**

Clarity around the roles of pharmacy staff is important to good practice and we would like to work with other professional bodies, governments, the criminal justice system, employers and the regulators to make mutually supportive declarations that clearly state where professional and legal accountability lies. This will allow some clarity and reassurance over the coming years when it can be embedded in future models of practice, regulation and legislative change. With this reassurance a barrier to the advancement of pharmacy practice will be removed, allowing pharmacists to act in the best interests of their patients.

In order to move from the dispensing bench to more patient consultation based services pharmacists must have certainty that systems and the use of criminal and professional regulatory sanctions against professionals will support this transition.

Removing automatic criminalisation of dispensing errors and instilling confidence in the competence of support staff are both essential factors.

The RPS will continue to work towards resolution of the automatic criminalisation of single dispensing errors by pharmacists. We would also want to work with the GPhC on the scope of practice of registered pharmacy technicians and their responsibilities within the medicines supply function.

These declarations will provide a mutual understanding of both the law; its interpretation, enforcement and consequence of breaches spelled out by the government, regulators, the crown prosecution service, employers, insurers, unions and the NHS. The messages around consequence must be co-created and co-

owned. Fairness, proportionality and the force of ethical accountability must be articulated by the profession's leaders, regulators and government in a way that translates meaningfully within the day to day practice of pharmacists.

Far from a 'blame culture' pharmacy should be moving towards a "just culture" in which people are held to account for their decisions as well as encouraging reporting and learning from mistakes. A "just culture" would include measurable improvement in defined outcomes for patient safety.

The RPS wishes to work with all bodies to move to create a quality management system that maximises the contribution of everyone involved in pharmacy. The responsibility of all players in the pharmacy, from the owners, the area managers, the superintendents, the pharmacists and all of the staff should be understood and mutually supportive systems created. Continuous improvement would maximise patient safety and pharmaceutical care.

#### **4. Clarify the policy intent around absence; define what can be done; enable the clinical role of the pharmacist.**

The forthcoming DH consultation on supervision is a prime opportunity for policy makers to provide the profession with a clear vision of how both the RP regulations and future changes to supervision will impact on practice and why they are needed to improve patient care and safety. The RPS has played a role in developing discussion on this issue across the profession, and will continue to do so. There is much to be gained through decision making on this issue based on a mutual understanding on the need for change and expected benefits by both the profession and government policy makers.

The RP regulations refer to the absence of the RP, the future supervision requirements will deal with the level of pharmacist supervision required whether provided by the RP or another pharmacist. The RPS believes that supervision requirements (or regulations) should be amended and has developed 5 high level statements on supervision.

Statement 5: Changes to the role of pharmacists towards increasing clinical and public health service provision are to be promoted. Supervision requirements (or regulations) should be amended so that direct hands on supervision of the assembly of prescriptions can be delegated to a registered pharmacy technician. We strongly believe that with suitable support in place this delegation can be effective and safe when the pharmacist is readily accessible within the healthcare facility<sup>1</sup>. This ready accessibility of the pharmacist will enable progressive, high quality, pharmaceutical care for patients. Furthermore, we believe that the public rightly expect a pharmacist to be present within the healthcare facility whenever the pharmacy is open.

#### **5. Reduce the complexity of SOPs to a minimal standardised framework**

There is a need to have a paradigm shift in how SOPs are used, with clear understanding of when they are beneficial to patient safety and when they are driven by the organisational needs of employers. There is clear evidence in the research to indicate that the use of SOPs is too prescriptive and too wide, producing disempowered or defensive practice that is not benefiting patients. All stakeholders should know what they

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<sup>1</sup> The RPS would define a healthcare facility as a building in which the public would expect to receive professional healthcare and this would include a hospital, a pharmacy or other larger premises containing a registered pharmacy, healthcare centre or medical practice.

are really for, when they should and should not be used, and how their presence and use will be considered by the regulators.

The purpose of standard operating procedures needs to be re-affirmed and agreed by everyone in the profession and by regulators. SOPs are not interchangeable with good practice; they support it. The RPS is very keen to work with employers, unions and other interested parties to develop some high level principles that will explore, for example, the ability of pharmacists to vary or override SOPs when it is in the best interests of patients. Collective teams within pharmacies and organisations should be creating quality management systems which use standards as a way of ensuring good clinical practice. Situations which are not standard or process driven should not be included within standard operating procedures. SOPs should not be used to define non process driven activity unless a clear rationale can be found that supports safety.

The RPS wishes to work with employers, unions and regulators to take forward its work on “Locums: Working as a Responsible Pharmacist”, drawing upon existing good practice. This should create a common data set available across all community pharmacies and will provide a uniform approach to which activities should be subject to SOPs and what level of skill mix within a pharmacy team is best suited to carry them out.

## **6. Address the poor strategic fit with hospitals**

Patients should be able to access a pharmacist and receive similar levels of pharmaceutical care from a pharmacist whether the setting is in secondary or primary care irrespective of the RP regulations.

The RP regulations are required to be used in hospital settings when they are operating as a registered pharmacy. This is driven by a need to utilise exemptions to the Medicines Act that are available to retail pharmacy businesses. This makes the implementation of the RP regulations in hospitals confusing, clumsy and liable to further change as envisaged in the current MHRA consultation on the Medicines Act. We agree with the recommendation and will work with policy makers, regulators and leaders in hospital pharmacy to ensure legislative revisions in the Medicines Act have a beneficial impact upon hospital practice.

## **7. Address the impact on locums**

The implementation of the RP regulations has had greater implications for the practice of locum pharmacists than any other part of the workforce. We would therefore agree with the concept of a “locum test” as a measure of beneficial changes to the way RP is operated. We would be keen to understand what currently constitutes good practice and to work with employers to spread this across the industry.

The superintendent should be empowered to have procedures and mechanisms in place that would ensure the presence of appropriate staffing levels, including skill mix, so that if an emergency locum attends a pharmacy the pharmacy is able to operate ensuring levels of patient safety are not jeopardised. The ‘locum test’ would be a test of the RP regulations: changes or clarifications thereto and any procedures put in place to enable better working, must not impact adversely on the locum workforce. At present an emergency locum has little chance of reading, assimilating and approving a large number of SOPs. Locums must not be put in the invidious position of choosing between not being able to fulfil their legal responsibilities with respect to the RP regulations and denying many patients timely pharmaceutical care.

While the recommendation is aimed at employers who provide SOPs it could equally apply to those who regulate, produce guidance or commission services which have an expectation or requirement to use an SOP.

## **8. Ensure the Regulations are future facing, accommodating changing models of professional practice**

Any changes to professional leadership, regulatory practice or the legal framework need to be set in the context of the profession's aspirations, as well as policy drivers around local empowerment, patient focus and personalised care. Additionally the focus on reward for health gain, quality and patient experience will inevitably mean a shift from volume payment based on activity to a system based on improving health outcomes. Scenarios developed by professional bodies and regulators should consider what safe and effective care will look like in the coming years, accounting for political, economic, social and technical drivers. Specifically, they should consider whether any professional or regulatory response has the flexibility to meet the future demands of the profession. There is now an opportunity to work across the profession to aspire and help co-create this shared vision of the future.

This recommendation is central to moving forward and reminds us all that changes in regulation and legal frameworks will be with us for a considerable length of time. The profession would benefit from a clear understanding of the direction of travel which the RP regulations and the supervision consultation are intended to take us. The RPS will play its role as the leadership body for the profession in this; however it would be far more powerful if the vision is one that is shared by policy makers, trade bodies, employers, regulators, unions and most importantly the profession itself. The RPS will work to bring this sharing of our future into a reality.

Pharmacy needs a clear co-created and co-owned pathway for the profession's future; this must include a very clear narrative about how this will affect both individuals and organisations. There must be an opportunity for this to be debated maturely and shaped by everyone affected. In these challenging economic times, pharmacy has a unique opportunity to benefit patients and reduce NHS costs.

In conclusion, this RPS believes that this report, its findings and recommendations have given the profession, its leaders and stakeholders a clear mandate to affect change which will both improve the professional lives of pharmacists and pharmacy staff and, critically, increase patient safety and patient care. The Society is acutely aware that to achieve improvements collaboration with everyone in the sector is required. We will, through our actions, demonstrate this approach and wish success to be judged through the improvements our members and their patients see and experience.