Modernising pharmacy regulation: A consultation on the draft standards for registered pharmacies.

Royal Pharmaceutical Society Response

The Royal Pharmaceutical Society (RPS) is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

Leadership, representation and advocacy: promoting the status of the pharmacy profession and ensuring that pharmacy's voice is heard by governments, the media and the public.

Professional development, education and support: helping pharmacists to advance their careers through professional advancement, career advice and guidance on good practice.

Professional networking and publications: creating a series of communication channels to enable pharmacists to discuss areas of common interest.

Executive Summary

The RPS supports the direction of travel indicated in this consultation document as the General Pharmaceutical Council (GPhC) moves towards risk-based regulation. We acknowledge the support of the GPhC in the move towards a just culture where individual professionals are empowered and enabled to carry out their professional practice in a safe and effective environment. This must be underpinned by robust systems regulation. We agree with the approach to develop an outcomes overview rather than a detailed and prescriptive approach to regulation and we would like to offer our assistance in the implementation. We believe that regulation should not stifle innovation and are pleased to see the GPhC also holds this view. The principle of risk-based regulation is one we support; however, the need remains for proactive inspection in appropriate circumstances.

We accept, as the GPhC also acknowledges, that there is more work to do and we would welcome the opportunity to work with the GPhC in the development of systems to ensure that risk-based regulation is meaningful and successful for the pharmacy profession. In this response we have outlined our thoughts on how systems regulation could be best implemented for the pharmacy profession. We appreciate and understand that it is difficult to provide clarity in all areas at this stage of the process and that there may be areas where further detailed guidance is required. We would be happy to work with GPhC to identify these areas and clarify the detail required. The RPS will provide guidance for its members in relevant areas not covered by GPhC standards and related guidance.

We have major concerns for the safety of the public in relation to the proposed changes to the handling of Pharmacy medicines (P medicines). Changes to the safe handling of medicines should not be incorporated into an already complex consultation on standards for registered pharmacies. Moreover, as recently as 2007, the pharmacy regulator rejected any proposed changes to the handling of P medicines following a focused consultation on this as a single issue.

The regulatory environment covering hospital pharmacy is extremely complex. This in itself presents either a risk to the public of an activity not being regulated because it falls between the activities of multiple regulators, or has the potential to create regulatory duplication and unnecessary bureaucracy. In light of this, the RPS believes that the principle regulators: GPhC, Care Quality Commission (CQC), Health Inspectorate Wales, Healthcare Improvement Scotland and the MHRA, should be aligned in their approach. This matter is further complicated by the imminent repeal of section 10(7) of the Medicines Act which is a strong driver for the registration of hospital pharmacies with the GPhC to gain an exemption to the Medicines and Healthcare products Regulatory Agency (MHRA) licensing. We would expect the GPhC to be instrumental in creating clarity in the regulatory environment for hospital pharmacy. The RPS has developed standards for hospital pharmacy which will be published soon. They reflect current best practice and have wide support amongst registrants working in hospitals. We would expect these to be a useful benchmark for regulators to use in their dealings with hospital pharmacy. The GPhC may need to have a high level agreement with the NHS as to how the NHS demonstrates its corporate governance around medicines.

We also believe that those pharmacies purely supplying veterinary medicines should continue to be registered with the GPhC.

General comments

We have some general comments to make on this consultation which are noted below.

1. Risk-based regulation:

In principle, we welcome the approach the GPhC is taking to move from rules-based to risk-based regulation. We endorse the principles that these new standards provide pharmacists with flexibility around to how they comply with the standards as they are 'empowered to use their professional judgement'. However, we have concerns that there could be a dislocation between the strategic thinking of the GPhC council and Fitness to Practice cases, for example the recent controversy around pharmacists not being able to touch patients. Fitness to Practice cases need to reflect the scope for professional judgement and not inhibit professional development where this is in patients' interests.

We believe that there are a number of areas where it is essential for the GPhC, as the regulator, to set standards. The areas where essential standards are required are:

- Standards to ensure that pharmacists and pharmacy staff take appropriate rest breaks in line with the European Working Time Directive. This will support pharmacists in ensuring a just culture is enabled within pharmacies.

- Standards to ensure that appropriate staffing levels are identified and in place to maintain the safe and effective running of a pharmacy. This has been demonstrated as an area of concern by CQC where they have cited low staffing levels as a reason for poor quality service delivery.[1]

We would also like to point out the following areas which need to be clarified before the standards are implemented.

1.1 The length of time for transition:

We believe that a transition phase is needed to enable data to be identified which would be useful indicators of risk. There needs to be a sufficient period of time to accumulate and analyse sufficient data to support an evidenced approach to risk-based regulation. This is a not an inconsiderable task.

There is little in the consultation specifically about a transition phase, although it is mentioned in question 23. We would like to suggest that there is a transition phase of sufficient length to ensure that the profession feels confident in the methodology, and hence feels that they are subject to a just regulatory process. This data is required to enable both the regulator and the professional body to identify what is high and low risk for the profession and for patient safety.

We would expect the GPhC to clearly outline the timetable so the profession can prepare for implementation. The GPhC must validate tools it will use for risk assessment during this transition phase. It also needs to show how it will review and improve the data collected in order to ensure that it does correlate to risk. The analysis of this data should increasingly focus the work of the inspectorate towards risky practice.

1.2 Assessment of risk:

Currently, there is no clarity about the data that is being used to make the decisions in relation to what is high or low risk.

The GPhC must gather evidence to demonstrate and define high or low risk and justify why a particular level of risk is assigned to a system or activity. This will also enable the GPhC to justify why a particular pharmacy is considered as a low or high risk. We are not aware of another way of justifying to patients and the profession of how a risk-based approach to regulation will be safe.

Data and evidence is needed to support the decisions in relation to assessment of risk. If the GPhC is receiving data from a number of sources (as suggested in the consultation) then it will need to normalise this data to decrease the variability and standardise the results. Currently, Primary Care Organisations, which include Health Boards, (PCOs) collect data around contracts but the criteria they use to collect such data varies across different PCOs. Therefore, the data provided is not consistent across the country or across Great Britain. It is quite likely that the assessment of the same risk will need to vary from country to country. The GPhC needs to interact with PCOs to avoid duplication of regulation and to keep lines of communication open with the NHS contracts departments. We would welcome the opportunity to work with the GPhC on this.

For the purposes of transparency, it would be helpful for the GPhC to share their experiences as a regulator, where they have identified particular problem areas. The areas of highest risk could then be

[1] http://www.cqc.org.uk/media/cqc-inspectors-demand-improvements-safety-and-staffing-levels-somerset-care-home

identified and inspections could target and focus on these areas. The RPS would like to offer their assistance in identifying these areas.

Pharmacy service providers need to be responsible for gathering risk data themselves so they can demonstrate to the regulator what they have identified as high or low risk areas. This would involve having systems in place for internal audits, incident reporting and learning from these as well as customer feedback and staff surveys and feedback. Many of these elements are already part of the clinical governance requirements of the contractual framework for community pharmacy in England and Wales.

1.3 Recognising the limits of risk based regulation:

Although many systems regulators have moved to a risk-based approach, most have retained an element of registration based on absolute standards which allows the service users and the public to be assured of what guarantees of quality and safety are in place.

Risk-based regulation needs to build on compliance to standards, and for a modern regulatory system the demonstration of this, so there still needs to be an element of guidance on how compliance is achieved. How compliance is assessed in the future may change and it should be the responsibility of pharmacy organisations to demonstrate that they are complying and the regulator's responsibility to sample compliance. However, there will still be some areas which will need more stringent requirements (i.e. 'must dos') and we have suggested some of these areas in our response.

2. Systems Regulation:

We support the move from regulation focused solely on individual accountability to that of collective responsibility. For systems regulation to be successful, the regulator has to rely on the culture and processes within an organisation, whether that is an independent pharmacy, a large multiple or a hospital, to ensure safety. The onus needs to be on the organisation to demonstrate compliance with standards. For example, if an organisation finds that it has a systemic problem with compliance to standards or it has no way of knowing if people carrying out services on its behalf are complying with its systems then the organisation needs to find a solution to this issue. This is a huge cultural shift within organisations that employ professionals who may rely merely on "tick box" compliance rather than testing if the reality of care given by the organisation reflects the standards it expects.

For large multiples, this would require rigorous and standardised processes to be in place at head office level to ensure that all pharmacies within that organisation complied with the GPhC standards. This does not mean more bureaucracy and more standard operating procedures (SOPs). Regulatory inspection which looks only at SOP presence rather than compliance as an indicator of safety would be missing the point of systems regulations. Regulators need to focus on how SOP's improve safety and how they are used in the workplace. If there is no practical application of written SOPs, then the organisation will need to demonstrate compliance in another manner. We believe that over prescriptive SOPs repress professional judgement within the workplace, leading to defensive practice, poor patient care and higher costs. SOPs are merely a baseline for the normal functioning of mechanical operations and must not become a substitute for professional judgement.

In summary, an organisation will need to be responsible for proving application of the standards, and must be able to demonstrate how they have complied.

2.1 Introducing system based regulation: suggested reform of the role of superintendent pharmacist

The superintendent pharmacist **should be** a senior manager within a company providing pharmacy services who is accountable to the GPhC for maintaining safety standards required by its regulatory role, as well as additional standards specified by the NHS, CQC or other commissioner or regulator.

He or she must have corporate authority for ensuring that all operations and safety system activities can be financed and carried out to the standard required.

In the regulation of safety the superintendent pharmacist is a key figure given that their influence on the standards of a pharmacy organisation is significant. Therefore, the working relationship between the GPhC and the superintendent pharmacist will play an important part in the regulatory oversight of a pharmacy organisation.

As part of the routine regulatory oversight programme, the GPhC inspectorate should normally arrange to meet with the superintendent pharmacist on a frequent enough basis to discuss any issues associated with the safety management of the pharmacy organisation.

The GPhC should produce guidance that aims to help the superintendent determine the level of knowledge and understanding expected of their role. The guidance should also aim to describe the type of attitudes to regulation and safety management that the GPhC wishes to encourage at superintendent pharmacist level.

The GPhC need to consider how they satisfy themselves that the superintendent pharmacist is performing the role that is required of them within systems regulation.

2.2 Guidance for those appointed as a superintendent pharmacist

It is in the interests of both the applicant (i.e. the corporate organisation) and the GPhC that the superintendent pharmacist is well prepared so that he / she has the required knowledge, understanding and orientation on safety management in place. Guidance is needed in this area from the GPhC.

Seniority

One would expect that the superintendent pharmacist would normally be at a level in the organisation no lower than Chief Executive, President, Managing Director, General Manager or similar title. However, it is not necessary for him/her to be the 'controlling mind' of the organisation. It is perfectly possible for the superintendent pharmacist to be answerable to and directed by another person or persons, and still retain the appropriate level of authority to ensure that activities are financed adequately and carried out to an acceptable standard.

However, the organisation needs to provide evidence that can be used to demonstrate seniority. The superintendent pharmacist should expect to discuss how the organisation will make decisions that significantly affect the operation, and his or her role in those decisions.

2.3 General principles of Quality and Safety Systems in pharmacy

The RPS believes that the GPhC has a role in providing leadership around quality and safety.

The creation of **both** quality and safety management systems is essential for system-based regulation and needs to be introduced before the introduction of systems-based regulation, i.e. the quality and safe systems need to be implemented before they can be regulated against.

Introducing quality systems into pharmacy

Although many pharmacies are working within what could be described as a quality system, such a system has not yet been defined for the pharmacy profession. The RPS is starting discussions with the Association of Pharmacy Technicians UK (APTUK) and the Pharmaceutical Society of Northern Ireland (PSNI) about developing the concept of quality systems and what this may mean for pharmacy. Whilst elements of quality systems will be incorporated into standards set by the regulator, it will be up to the professional body, working in collaboration with other pharmacy organisations, to define best practice systems that support improvement in the quality within the profession.

The superintendent pharmacist should be able to demonstrate a sound knowledge of the components of quality systems and practices and how these are applied within his/her own organisation including, in particular, knowledge of his/her own role.

The GPhC will need to be satisfied that the superintendent pharmacist:

- is committed to developing systems to improve quality, part of which establishes and maintains required standards;
- has established, published and practically endorses policy that improves quality for patients; and
- understands the value of evaluating and auditing the impact of initiatives that aim to improve quality of care for patients and public

The GPhC inspector will seek confirmation that the superintendent pharmacists attitude to quality of service and care is positive and not merely a matter of compliance. It is essential that the inspector understands the relative roles of the superintendent pharmacist, the responsible pharmacists and other pharmacists, pharmacy technicians and pharmacy staff that work in the system.

Introducing Safety Management Systems and patient safety programmes into pharmacy

The superintendent pharmacist should be able to demonstrate a commitment to the management of safety and a sound knowledge of Safety Management System principles and practices where such a system operates within the organisation for which he/she is responsible including, in particular, knowledge of his/her own role. Where a formal Safety Management System does not operate, the superintendent pharmacist should understand his/her role in achieving compliance with the GPhC standards.

The superintendent pharmacist should be aware of the requirements and the relevance of Safety Management System principles to patient safety. He or she should consult the person(s) responsible for the programme in their organisation, such as the responsible pharmacist, to gain an understanding of its operation and the role of pharmacists in it.

Much more thinking and discussion needs to happen about safety and quality systems including mutually agreed understanding of terms such as Quality Systems, Safety Management Systems and other terms we have used before these can be applied as an effective form of regulation.

We have deliberately introduced these terms as a starting point for discussion. However, we believe that without clear leadership from both the RPS and the GPhC on definition and guidance it will be very difficult to operate convincing system-based regulation that protects the public.

The airline industry regulator, the Civil Aviation Authority, have done much of this already for their sector. Information can be found at www.caa.co.uk/sms. We believe this is a useful starting point for the principles of Safety Management and Quality Systems.

Good practice at an organisational level means that there should be internal audits to ensure that any risks are minimised so that both the organisation and the regulator can feel confident that the systems in place are safe. This would also ensure that the superintendent pharmacist can account to the regulator.

Feedback from staff will be an important part of systems regulation. However, this feedback and learning needs to be disseminated across the profession rather than sitting within just one pharmacy organisation, whether, a hospital pharmacy, a large multiple or an independent pharmacy. This would mean that the whole profession could take on board any learning and the overall quality of systems used by pharmacy professionals would increase. Such learning would be an incremental public benefit of a systems regulation approach.

3. Just culture

The RPS believes there is a need to create a just culture in pharmacy and we are pleased that the GPhC is supportive of this aim. Research we commissioned indicates that many pharmacists are suspending their professional judgment in order to protect themselves from accusations of blame. Cultural factors in the pharmacy context play a large part in this, with a lessened sense of trust and cooperation between professionals and the institutions, employers and others who are meant to work alongside them to support and promote patient safety.[2]

A just culture is a culture which is based upon fairness and is achieved when attitudes, behaviour and practices are in accordance with what is fair and right.

It differs from a punitive culture which is a culture based upon punishment but which also stifles learning and reporting of concerns.

It also differs from a no-blame culture which is based on the concept of never assigning blame and so suffers from lack of accountability.

We believe the pharmacy regulator could do much to move to a just culture. In other high risk industries such as the airline and building industries, the regulator is the main proponent for encouraging culture change of this type.

A just culture makes people and patients safer compared with the alternative punitive culture or no-blame culture. It is achieved by promoting fairer accountability and a necessary learning.

Upon application to the provision of healthcare and pharmacy services, this entails being able to learn from mistakes or incidents, to be able to share lessons learnt (throughout the profession where appropriate) and to use this shared learning to reduce the likelihood of similar mistakes and incidents from happening again which is a vital component contributing to making patients and people safer.

[2] Responsible pharmacist impact research at http://www.rpharms.com/promoting-pharmacy/professional-empowerment.asp

When a mistake or incident occurs, we all want assurances that actions are being taken so that it will *never happen again* and that there will be fair accountability. Whilst a just culture cannot guarantee that mistakes or incidents will not re-occur, it can and does help to prevent them from happening.

We believe the regulator needs to show by example that it applies just culture principles to all its activity and work, encouraging engagement of all other stakeholders with the just culture philosophy and measuring uptake of this culture across pharmacy organisations.

3.1 Just culture and patient safety incidents

Patient safety can be improved by reporting concerns and learning from these reports. Reporting concerns will only take place if individuals feel they will not be victimised and that it is 'safe' to report these concerns. To provide assurance and confidence, everybody needs to know where they stand.

The airline industry has been embedding just culture principles into its practice for decades to improve safety. Adapting from what the industry has learnt, together with the consideration of similar workstreams within the NHS, we believe in the following just culture principles for patient safety incidents:

1. Patient safety is paramount.
2. Deliberate harm and unacceptable risk impacting on patient safety must not be tolerated
3. Patient safety is maintained by raising concerns, and learning from incidents to improve systems, standards, policies, legislation and people.
4. To ensure that concerns will be raised and learning from incidents takes place, individual accountability must always be fair and proportionate, viewed in the context of root cause, system deficiencies, mitigating circumstances and the entirety of contributing factors. .

The NHS has developed an incident decision tree based upon the work of Professor James Reason[3], an expert on patient safety and this decision-making approach embodies just culture principles. The incident decision tree uses a series of tests to decide on the appropriate course of action following an incident.

We believe the GPhC could do much to encourage this methodology across pharmacy organisations and critically promote the sharing of patient safety information between pharmacy organisations; something which is not currently happening.

3.2 Just culture and raising concerns:

We are pleased to note that the GPhC are applying to become a prescribed regulator for the purposes of whistleblowing. The Public Interest Disclosure Act protects the person raising a concern from being penalised by their employer if certain criteria, (the concern is honest and genuine concern and is disclosed for the right reasons) are met. The person raising the concern can raise it at 3 levels; through employers, regulators or the public domain. The list of prescribed regulators, which includes CQC, ensures that the person raising the concern knows that this is a valid place to go. The list is for those regulators who are involved in systems regulation, making the GPhC's application appropriate.

[3] Meadows S, Baker K, Butler J. The Incident Decision Tree: Guidelines for Action Following Patient Safety Incidents. In: Henriksen k, Battles JB, Marks ES, et al., editors. Advances in Patient Safety: From Research to Implementation (Volume 4: Programs, Tools and Products). Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 Feb

Pharmacists are aware of their professional duties yet they may be working in an environment where they have witnessed other individuals raising concerns only for these to be ignored. Raising concerns will never be risk free but it needs to be made safer and the GPhC has a significant role to play here. We would like to make some points in relation to pharmacists raising concerns and these are outlined below:

- There needs to be proportionality in holding professionals to account; the more senior the role the more they should be empowered to raise a concern. This would particularly apply to the superintendent pharmacist role.
- There needs to be a balance between the responsibility of the individual to report any concerns and the responsibility of an organisation in receiving and dealing with such reports. A structured and robust approach is needed when organisations fail to receive and deal with a genuine concern that has been raised. This would promote a culture of open reporting and would discourage the failure to deal with concerns properly and would enhance public confidence in the process.
- A safe environment needs to be established where raising a concern should be a clear responsibility of any pharmacy organisation and the professionals working within it. There is a substantial amount of guidance on what constitutes best practice in whistleblowing arrangements[4] [5].Compliance with this best practice could be a measure of achieving regulatory standards.

Finally, we would welcome a robust focus by the GPhC on what pharmacy owners are doing, as part of their systems regulation, in relation to the establishment of good whistleblowing arrangements. The GPhC must take on this role if it wishes to become a recognised systems regulator.

4. Inspection Model:

The current inspection model allows for an inspection of an individual pharmacy to occur around once every three years. The new model seems to suggest that the time between inspections is increased for those pharmacies deemed to be at low risk but decreased for those deemed to be at high risk. The frequency of inspection needs to be determined based on risk but this must be constantly reviewed in light of the outcomes to ensure and maintain patient and public safety. If this time period is increased beyond three years, the regulator will have to assure itself that the systems it has in place are robust and that such pharmacies truly remain low risk. However, if the GPhC decides to retain the three year time period as a maximum between inspections, then they will need to consider increasing their resources to enable the inspectorate to visit those pharmacies deemed high risk on a more regular basis. We would ask the GPhC to clarify what they are planning regarding resources for the inspection model. If there is to be no increase in resources, will the GPhC be reducing activity in other areas or otherwise utilising its reserves to implement the new inspection model?

A solution to help with the inspection model and to underpin system regulation would be for the GPhC to spend more time inspecting organisations at a corporate level. As suggested above, by empowering the superintendent pharmacist, this could be a very effective form of regulation which allows

[4] http://www.rpharms.com/support-tools/8-core-principles-for-community-pharmacy-whistleblowing.asp
[5] http://www.pharmacyregulation.org/sites/default/files/GPHC%20Guidance%20on%20raising%20concerns.pdf

organisations to demonstrate compliance, reduce the burden of inspection on organisations and allow more effective use of resources by the GPhC.

Currently around 50% of pharmacies are owned by 10 companies. The GPhC could ask organisations to provide assurance that quality and safety systems were in place at a corporate level, and that these systems were being applied throughout the pharmacies owned by that organisation. By spending time at an organisational level the GPhC could then undertake inspection of a sample of individual premises to be confident that systems were being implemented. This would reduce the number of individual visits needed to be made by inspectors and would also firmly place the responsibility of systems regulation at the organisational level which, we believe, is where it should be. This would enable the GPhC to comply with the Hampton principle around 'reducing inspections where risks are low, but increasing them where necessary[6]'.

As outlined in the consultation document, the inspectorate need to be repurposed and move more towards a model of providing advice before adversarial and legal enforcement. This is consistent with the Hampton principle on making much more use of advice, applying the principle of risk assessment[7]. However, the GPhC should be enabled to impose sanctions and limitations on pharmacy organisations in specific cases. The removal of approval should be a last resort, although the ability to impose limitations or suspension on a particular pharmacy, as part of an organisation, should be available to the regulator, for example reducing the scope of service provision until a problem is fixed.

There is no clarification of the process that the GPhC will undertake if the organisation does not comply with the standards. There needs to be a structured and transparent process in place which is clearly laid out so that all parties know where they stand when compliance with standards is not achieved. Initially the process should enable the inspectorate to raise a 'finding' and offer advice to the organisation on how to achieve compliance. A time line for achievement should be agreed. If compliance is not achieved within this timeline then the level of 'finding' should be increased and actions such as suspension and imposition of limitations considered. Limitations and suspension could be limited to one particular branch/pharmacy within an organisation and may not need to apply across the whole organisation. The GPhC must ensure that its sanctions and penalties act as a deterrent to non- compliance. Sanctions and penalties which are never used are unlikely to provide any deterrent. Such a process would require the buy in and acceptance of the pharmacy profession and all pharmacy operators.

5. High risk areas:

5.1 Self-selection of P medicines

We believe that the reason for maintaining the prohibition on the self-selection of P medicines is to ensure patient and public safety. We believe that the public will be put at risk if the GPhC move ahead with the proposed changes outlined in this consultation concerning P medicines. If self-selection of P medicines is enabled then there will be inconsistency across Great Britain as it will be up to the individual superintendent or pharmacy owner as to how they implement this. This will cause confusion for the public as some P medicines may be on open display in one pharmacy but not in another.

[6] http://webarchive.nationalarchives.gov.uk/+/http://www.bis.gov.uk/policies/better-regulation/improving-regulatory-delivery/assessing-our-regulatory-system

[7] http://webarchive.nationalarchives.gov.uk/+/http://www.bis.gov.uk/policies/better-regulation/improving-regulatory-delivery/assessing-our-regulatory-system

If the placement of P medicines were left to the discretion of each organisation we would consider this a significant risk to patient safety. In fact, a review of the overall categorisation of all medicines could be implemented to ensure patient safety is paramount. For example, certain GSL medicines also have a significant impact on patient safety. We would like the GPhC to clarify where the evidence to justify a change from the current system of self-selection has come from.

The 'P' category is crucial to the extended roles of pharmacists and to enable formerly 'POM' medicines to be made accessible to members of the public. For every sale of a so-called 'POM to P' product, a visit to the GP may be saved. This represents significant time saving for the individual and a saving of around £30 to the NHS. We would like to see more 'POM to P' switches but within an environment that is safe for patients and the public.

The RPS has the ambition to make Britain a safer place to receive medicines, all medicines of whatever category. As such we have outlined the case for retaining the current safeguards, see Appendix A, and we do not believe that the 'P' category medicines should be made available for self-selection.

The MHRA have pointed out that under UK legislation a pharmacy medicine must be sold or supplied under the supervision of a pharmacist. Supervision is not defined in UK legislation and how it is interpreted remains a matter for the pharmacy profession. However, the MHRA has expressed concerns in that when it assess an application to change the legal status of a medicine from POM to P, or when reviewing safety issues concerning an existing P medicine, the role of the pharmacist is an important consideration for them in determining whether a medicine can be sold safely and effectively without the involvement of a prescriber.

5.2 Locums

We recognise that healthcare systems rely on a flexible and mobile workforce. The current pharmacy workforce consists of a high proportion of locums. As of 2008 27.8% of actively employed (or self employed) pharmacists are locums.[8]

There is risk in introducing pharmacists to premises when they are unfamiliar with the systems and processes.

According to the law governing the Responsible Pharmacist Regulations, locums are expected to read through the SOPs for that particular pharmacy in order to understand the systems in place. We know from research evidence that most emergency locums will not have the opportunity to either read or understand these SOPs.[9] We have no evidence as to whether this practice is a high risk activity. However, as part of a risk-based approach, the regulator must assure itself either that this is not a necessary way of ensuring compliance to its standards or that an organisation makes provisions for this requirement to be fulfilled. Therefore, there is an ongoing risk that locum pharmacists will not be complying with the systems developed and implemented by the organisation. The GPhC could help by developing a core set of SOPs to be implemented across all pharmacy organisations. We would be happy to assist in their development as we feel they would mitigate some of the risks outlined above.

[8] http://www.rpharms.com/about-pharmacy-pdfs/census08.pdf

[9] Responsible pharmacist impact research at http://www.rpharms.com/promoting-pharmacy/professional-empowerment.asp

Pharmacy organisations that rely upon a high proportion of locum pharmacists must appreciate the risks of doing so and develop processes to help mitigate these risks. It is the responsibility of the organisations to ensure staff(including locums) are aware of the systems, and to provide the relevant training for them. The training should provide a satisfactory level of knowledge of organisational procedures. It is the employer's responsibility to ensure their employee pharmacists and locums can operate the pharmacy to the required standards.

Locums can be extremely useful in providing an overview of what systems work well in practice and which ones are potentially more risky. They have a significant role in sharing processes and procedures that reduce risks to the patient and these could be shared with the regulator or via their professional body.

Comments on Principles

In general, we feel that the principles are appropriate and cover the most relevant areas. They are high level principles and will therefore require further guidance for registrants in many cases. We believe that these should be developed in some cases by the GPhC themselves to add to the four recently published documents, and in other cases we would develop guidance as the professional body. In either case collaboration between the two organisations would be beneficial.

Principle one:

We agree with the overall concept of this principle which focuses on ensuring that pharmacy services are professional.

- Standard 1.1 states that the safety and quality of pharmacy services are regularly reviewed and monitored. We would suggest that the GPhC considers the development of a framework or more detailed guidance against which the safety and quality of pharmacy services can be monitored. Also see our suggestions under 'Systems Regulations' on page 4
- Standard 1.3 covers a huge area of work and again there needs to be underpinning guidance with regards to what constitutes a safe and effective way of carrying out services.
- Standard 1.4 talks about clear lines of accountability for all of the services provided and we would like to understand more about how organisations are able to demonstrate this. Again further clarity and guidance will be required.
- Standard 1.5 states that 'the roles of individuals involved in providing and managing pharmacy services are clearly defined'. We would suggest that the GPhC needs to provide clarity around the roles, responsibilities and accountabilities of pharmacy technicians as GPhC registrants. Guidance will also be required for other pharmacy staff. We would be pleased to work with the GPhC on this particular area of work.
- Standard 1.7should be strengthened. It does not identify what action the GPhC will undertake if compliance is not achieved (see our earlier comments on page 9 of our response under 'Inspection Model ').
- Standard 1.9 considers the maintenance of records within the pharmacy. There needs to be clarification regarding how long these records should be kept for.
- Standards 1.10 and 1.11 are already covered by legal and contractual requirements

- Standard 1.11 relates to the protection of children and vulnerable adults. This will require underpinning guidance to provide a list of actions and points that an organisation should consider in order to achieve compliance with this standard.
- Some pharmacy organisations may consider the increased use of Standard SOPs to demonstrate compliance with these standards. We would consider this inappropriate as an over-reliance on SOPs will restrict professional empowerment. We hope the GPhC would support this view as we move towards a just culture. It would also be outwith the Hampton principle on substantially reducing the need for form-filling and other regulatory information requirements[10]. Pharmacists should be enabled to use their professional judgement and SOPs should be seen as a quality tool and guidance rather than a strict set of procedures which replace patient-centred professionalism.

Compliance indicators for Principle one:

Currently, if pharmacists make a single dispensing error they could face criminal prosecution. The RPS, together with other bodies, is working to change this. However, whilst this legislation is still in place, pharmacists may feel constrained in relation to the reporting of dispensing errors either within their organisation or more widely. Pharmacists and their staff are well placed to identify areas of risk and to raise concerns and they need to be supported to do this.

We would suggest that the GPhC should compile a central database of reports around near misses, incidents and dispensing errors in relation to the pharmacy profession. This will enable them to have oversight of the areas of risk and also enable them to share the learning across the whole profession and suggest systems that could reduce risks. An organisation needs to be looking across the picture and identify trends and patterns. This could be dealt with by a trusted third-party and supplied to the regulator as an annonymised report to overcome any conflicts of interest or concerns around trust.

One of the compliance indicators suggests using a risk register. It would be helpful if GPhC could consider developing a generic template to facilitate compliance with the standards for organisations.

We would query how organisations should demonstrate that they listen to feedback from staff, patients and the public and would ask for further clarity as to how compliance can be achieved in this area.

Principle two:

We fully endorse this principle which states that '*staff members and anyone involved in providing services, must be competent and empowered'.* This would obviously need to include locum pharmacists. As identified previously, locums (especially emergency locums) need to be supported to understand the organisational and operational procedures within pharmacy organisations. Overall, the roles and accountabilities of all pharmacy staff need to be clarified. In particular, we propose that all accuracy checkers must be registered pharmacy technicians.

- Standard 2.3 should be made more generic as staff should be able to raise concerns about all aspects of the GPhC standards and not just those that will have an impact on patient safety.
- Standard 2.4 could benefit from being rewritten as 'The professional judgement of staff should not be compromised by incentives or targets'.

[10] http://webarchive.nationalarchives.gov.uk/+/http://www.bis.gov.uk/policies/better-regulation/improving-regulatory-delivery/assessing-our-regulatory-system

- Standard 2.5 mentions having the right number and mix of staff. Currently there is nothing to measure this against or assist organisations in making this decision. There needs to be underpinning evidence to outline what staff (both numbers and skill mix) are required to ensure a service is provided safely. We would propose a 'balanced scorecard' approach which takes into account the totality of the working environment including staff and the use of technology.
- We fully support standard 2.6 as the RPS has aspirations to move the profession towards a 'just culture' where pharmacists are empowered and enabled to use their professional judgement. However, we would query how the GPhC intends to measure compliance against this indicator.

Compliance indicators for Principle two:

The first bullet point relates to verification of the qualification of staff. We would suggest adding an additional point that ensures any locum staff are trained in relation to the operational procedures for that particular organisation. Obviously, there may need to be exceptions in place in relation to emergency locums.

One of the bullet points states that 'staff with management and control responsibilities have the genuine authority they need to live up to their legal and professional duties'. This means that the superintendent needs to have the authority to ensure operational processes comply with the regulatory standards and he/she must have the power to enact change where this is required. Please see our comments under 'Systems Regulation' on page 4 of this response.

In order to demonstrate compliance with standard 2.5, a rationale for the responsibility ascribed to each role should include the training level required and an audit of the achievement of that level.

The final bullet point is just a reiteration of the standard and does not assist organisations in demonstrating compliance. Organisations working in a commercial environment or NHS units would welcome guidance on this matter.

Principle three:

Under this principle the GPhC states that 'Any associated premises, for example non-registered premises used to store medicines, must also comply with these standards where applicable'. We would like to seek clarity from the GPhC as to why non-registered premises also need to comply with the standards and how the GPhC intends to monitor and assess these non-registered premises over which they have no clear jurisdiction.

- Standard 3.3 relates to the design and layout of the pharmacy. We are aware that some pharmacies have an open area where medicines are checked in full view of the public and we would seek clarity as to the suitability of this under this particular standard.
- Standard 3.4 relates to the cleanliness and hygiene of the premises. We would like GPhC to clarify if there is any external guidance that they would expect organisations to adhere to such as guidance from the CQC on Infection Control. It needs to be made explicit that it will be up to pharmacy owners to comply with guidance from other agencies.
- In order to demonstrate compliance with standard 3.7, there would need to be guidance on what environment is safe for the provision of healthcare. This would require a benchmarking or baseline exercise to be undertaken.

Principle four:

- Standard 4.1 mentions that medicines and medical devices need to be obtained from a 'reputable source'. Pharmacies should be provided with a list of reputable sources or some other means of ensuring compliance with this standard. Standards 4.2 and 4.5 are very similar and could be rewritten as: 'You should only use medicines and medical devices that are fit for purpose'.
- Standard 4.4 relates to the safe storage of medicines and prevention of unauthorised access. We would consider the self selection of P medicines to be a safety risk to the public as we have outlined in Appendix A of this response.
- We would ask the GPhC to add an additional standard under this principle (4.7). The following suggested wording is lifted from 4.12 of the 2010 standards for pharmacy owners and superintendent pharmacists of retail pharmacy businesses: Ensure procedures for sales of over the counter medicines enable intervention and professional advice to be given whenever this can assist the safe and effective use of medicines. Pharmacy medicines must not be accessible to the public by self-selection

Compliance indicators for principle four:

Bullet point one is just a reiteration of the standard and offers no guidance as to how compliance can be achieved.

We have outlined the case for retaining the current safeguards to the public in the handling of P medicines (see Appendix A). We do not believe that P category medicines should be made available for self-selection.

The bullet point in relation to the disposal of medicines should be reworded to read: 'Unwanted medicines and medical devices are disposed of in a way that safeguards patients and the public'.

Principle five:

This principle outlines that pre-registration pharmacies are required to have certain publications, equipment and facilities in place in order to undertake pre-registration training. We would argue that all pharmacy premises should be of this standard, not only those employing pre-registration trainees to aid in the development of all pharmacy staff.

Compliance with the standards:

On page 36 of this consultation document the GPhC states that it will explore opportunities to use information from existing sources such as primary care organisations or via NHS complaint mechanisms. We would like to suggest some caution here, as much of the data collected by PCOs is variable and the criteria used to make assessment also varies across organisations. Moreover, such data is being collected for an entirely different purpose and, as such, is inappropriate.

As we have suggested previously, the GPhC should set a ceiling for the maximum time period between inspection visits where the frequency is determined by risk. As we have also suggested, resource implications need to be considered and new methods of inspection, such as inspecting the systems put in place by organisations at the head office level could provide a release of resources to focus on those areas/organisations considered more at risk.

On page 37 of the consultation document the GPhC suggests developing the new model of inspection once the standards have been approved. We would like to suggest that the new model of inspection is developed in parallel with the development of the standards as it is an iterative process.

At the end of the first paragraph on page 37 we would ask for the words 'at short notice' to be removed. If an unannounced inspection is required it should be truly unannounced.

On page 37 the GPhC discusses the development of 'Criteria for decision-making'. This is a significant amount of work and we would be happy to assist the GPhC in the development of these criteria. The RPS, through its members, has a wealth of experience and knowledge of pharmacy practice which can assist in the development of such criteria. As the profession moves to systems regulation based on the assessments of risk, the criteria for making decisions will become more important as they will provide standardisation across the inspectorate and help to reduce subjectivity and variability.

On page 38 of the consultation document the GPhC has stated that: 'the inspection report would be published on the online extract of the register relating to the registered pharmacy'. We would ask the GPhC to reconsider the publication of inspection reports. This may become a disincentive for an organisation to share the risks they have identified and overall lead to a reduction in learning across the profession. This could in time limit the scope of the regulator so this must be approached with caution.

On page 39 the GPhC states that the Fitness to Practice procedures are not the enforcement mechanism for making sure that the standards for registered pharmacies are met. However, they do not provide any clarity on how they will, in practice, enforce or ensure that their standards are met. We would like assurances that the learning from Fitness to Practice cases will also feed into the evidence base for risk assessment so that there is wider learning across the profession.

On page 40 the GPhC states that: '*We* believe our proposed model can help to mitigate these risks'. We would like more clarification as to how the GPhC justifies this assertion as we see no evidence in the document to suggest it will occur.

Answers to the specific questions:

Q1. Do the proposals provide sufficient clarity about the premises that need to be registered with us as a pharmacy?

We find it unacceptable that the GPhC will not register premises where the service consists solely of the sale or supply of medicines for animal use and we would like to understand the rationale for this decision. The RPS fully supports the Veterinary Pharmacy Forum response which is attached as Appendix B.

There is also an issue in relation to those 'hub and spoke' pharmacies where the hub pharmacy acts purely as a wholesale or manufacturer operation. This could see the central hubs failing to meet the regulator's eligibility test for registration.

The regulatory environment covering hospital pharmacy is extremely complex. This in itself presents either a risk to the public of an activity not being regulated because it falls between the activities of

multiple regulators, or has the potential to create regulatory duplication and unnecessary bureaucracy. In light of this the RPS believes that the principle regulators: GPhC; CQC, Health Inspectorate Wales, Health Inspectorate Scotland and the MHRA, should be aligned in their approach. This matter is further complicated by the imminent repeal of section 10(7) of the Medicines Act which is a strong driver for the registration of hospital pharmacies with the GPhC to gain an exemption to MHRA licensing. We would expect the GPhC to be instrumental in creating clarity in the regulatory environment for hospital pharmacy. The RPS has developed standards for hospital pharmacy which will be published soon. They reflect current best practice and have wide support amongst registrants working in hospitals. We would expect these to be a useful benchmark for regulators to use in their dealings with hospital pharmacy.

The GPhC may need to have a high level agreement with the NHS as to how the NHS demonstrates its corporate governance around medicines.

Q2 .Do you have any comments or observations about the proposed two stage test for registration or renewal of registered pharmacies?

We agree with the approach to split the registration process into the two elements of eligibility and compliance, as this will help applicants to understand why they have been rejected, if this is the case.

Q3. The document sets out three situations where we think it may be appropriate to impose conditions on registered pharmacies. In what, if any, other situations should conditions be applied?

In relation to temporary premises we query why such a premises is only registered for a short time before, during and after the event. If a pharmacy has safe systems in place to provide pharmacy services then it should be able to be registered as a mobile service instead of having to re-register each time it wishes to provide such services at each individual event. Such registration should not be time limited but should be open to inspection similar to other pharmacies. This would decrease the administrative burden on the GPhC and fits with the governments 'red tape challenge'.

Q4. Do you have any other comments or observations to make with regard to these specific proposals?

We understand that other regulators, such as the MHRA regulate both wholesalers and manufacturers. However, there must be clarity as to why the wholesale of medicines is considered separately to the supply of medicines to patients (retail) and also as to why the supply of medicines to patients within a hospital setting is deemed to be different to that in a retail/community setting. If anything, the supply of medicines in a hospital could be considered to be of a higher risk as the patients in a hospital are often more vulnerable and the medicines used are often more specialist. This separation of regulation does not fit with the Hampton principle which suggests that the number of regulators should be reduced. As changes to overall regulation are unlikely to occur in the near future we would recommend that there is closer and better communication between all the regulatory bodies that have an impact on the pharmacy, pharmaceutical services and the supply and use of medicines. This is particularly important under the new approach of systems regulation. For example, there may be problems with other parts of the systems, such as the packaging of medicines that cause errors.

Q5. Is it clear where the responsibility for meeting the standards lie?

No. It is currently not clear as to where the responsibility for meeting these standards lie.

Q6. What is unclear?

On page 20 of the consultation document, the GPhC states that 'If the registered pharmacy is owned by a body corporate (for example a company) the superintendent pharmacist also carries responsibility, along with the company'. There needs to be greater clarity around the responsibility and accountability of both the body corporate and the individual superintendent pharmacist. There is also uncertainty about the role of the responsible pharmacist and other members of the pharmacy team with regards to who has responsibility for what.

Q7. The introduction to the standards should set the context and clarify and explain how the standards are relevant to different audiences. What else if anything should be added to the introduction?

We have no comments on the introduction.

Q8 The standards are grouped under five main principles. Under each principle there are three sections – the principle itself, the standards that relate to that principle and examples of how compliance would be shown. Does the structure work well?

The general structure works well but please refer to our answer to Q9 below.

Q9. How could it be improved?

A number of the compliance indicators are just a reiteration of the standards and do not offer assistance as to how compliance with the standards can be achieved. In many cases these indicators need to be expanded upon and further developed in order to help organisations achieve compliance and to ensure a successful process of systems regulation.

Q10. Are the standards under each principle clear?
Q11. What is unclear?
Q12. Is anything missing from the standards under each principle?
Q13. What standards should be added?
Q14. Are the compliance indicators clear?
Q15. What is unclear?
Q16. The indicators are examples only and do not represent a complete list of everything that might indicate compliance with the standards. What if any additional or alternative indicators would it be helpful for us to include here?
Q17. To what extent do you agree or disagree that the standards and compliance indicators provide pharmacies with a clear and usable framework?
Q18. What, if any, further support tools or information would pharmacy owners or superintendent pharmacists need to be able to meet these standards?

For Q10 – Q18 we have no further details to add but please refer to our detailed comments under Principles on pages 11 to 14 of our response.

Q19. What if any concerns do you have about the practical implications of implementing these standards in registered pharmacies?

We have major concerns around the implementation of these standards within registered pharmacies. As mentioned on page 3 of our response, there needs to be a transition phase to allow organisations to ensure they have the systems and processes in place to achieve compliance with these standards. There also needs to be a time period where data is collected and analysed so areas of high and low risk can be identified.

Q20. Our current view is that there will be a need for additional guidance on compliance for certain specific areas either because of the complexity of process or where the model of service may be new or technology based. Potential guidance includes:

- **Compliance guidance for pharmacy owners operating an internet pharmacy**
- **Compliance guidance for registered pharmacies working under an exemption from MHRA licensing requirements.**

To what extent do you agree or disagree with our assessment that compliance guidance will be needed in these areas?

We would agree that guidance is required in the two areas outlined above. The MHRA will shortly be providing guidance following the repeal of Section 10(7) of the Medicines Act. Internet pharmacy is a complex area, particularly around the issue of prevention of counterfeit medicines.

We would be happy to work with the GPhC in the production of guidance in these areas.

Q21. Are there any other areas where you believe compliance guidance will be required?

If the GPhC decide to reverse current policy and allow the self-selection of P medicines then further compliance guidance will be required in this area. We have outlined other areas where we believe additional guidance is required or would be helpful in our detailed comments above. These would potentially include guidance on the prohibition of re-use of patient returns or expired medicines as well as guidance on training of staff and counterfeit medicines. If the GPhC decides not to set essential standards in the areas of rest breaks and staffing levels, then there would also need to be guidance developed for these areas. In particular, the guidance would be extremely important to help the establishment of a just culture as current GPhC standards state 'Make sure staff are able to take appropriate rest breaks and encourage them to do so'. If pharmaceutical companies have registered pharmacies in order to provide homecare services, then this area would also require additional guidance.

Q22. We cannot fully develop our approach to compliance until the standards have been finalised; therefore this section of the document broadly sets out current thinking. Do you have any comments or observations about the broad approach described?

Please see our suggestions under 'Systems Regulation' on page 4 of this response.

Q23. We recognise that everyone, in particular pharmacy owners and superintendent pharmacists, will need support to familiarise themselves with the new standards and get ready for the new approach to regulating registered pharmacies in the transition phase. What can we do to make sure the transition is as straight forward as possible?

Please see our comments on page 3 of our response in relation to the transition phase (Point 1.1).

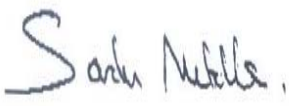
Q24. Do you have any further comments to make about the proposals in this consultation?

We are aware that the GPhC has no jurisdiction over dispensing doctors. However we would question how the systems employed by dispensing doctors are to be regulated to ensure that they are of the same quality as those in aregistered pharmacy. It would be an unacceptable risk if there was a variance in the safety of the services the public receive dependent upon the source of dispensing.

We would also suggest that the GPhC recommends that all registered pharmacies have full access to the internet (which could include restrictions on specified sites) in order to enable pharmacists to have access to the most up-to-date resources to meet patient needs.

The term retail pharmacist pharmacy are used in the Medicines Act but we would suggest that in the standards they should be referred to as community pharmacist/pharmacy as a more modern clinical approach.

The GPhC is also currently consulting on its approach to fees. Following the outcomes of this consultation on registered pharmacies we may form a different view on fees related to pharmacy premises.



Lindsey Gilpin Sandra Melville, Mrs Mair Davies

Chair, English Pharmacy Board

Chair, Scottish Pharmacy Board

Chair, Welsh Pharmacy Board

For further information or any queries you may have on our consultation response please contact Heidi Wright: heidi.wright*@rpharms.com* 0207 572 2602

Ultimately:

Medicines are not ordinary items of commerce.

The GPhC has a duty to patients and the public to ensure that medicines are stored and positioned appropriately to maintain public safety. The RPS believes that allowing the open display of P medicines is an unacceptable risk to patient and public safety.

Legal advice and opinion

In 2004 it was suggested that medicines ***would*** *be treated as ordinary items of commerce* under competition law. Patient and public safety were irrelevant and therefore as such the current ethical prohibition on the self-selection of pharmacy medicines may be deemed as against free trade.

In August 2006, the then regulator, The Royal Pharmaceutical Society of Great Britain (RPSGB), obtained legal advice. On the basis of this legal advice, the RPSGB Council agreed to consult with the profession and the public on the current ethical prohibition on the self-selection of pharmacy medicines. It was hoped that the responses to this consultation would enable the RPSGB to form a view on the necessity and proportionality of the prohibition against self-selection and of the various alternative approaches falling short of complete self-selection of all pharmacy medicines. The RPSGB was then able to introduce a requirement which was best adapted to the public interest considerations at stake. By doing so the RPSGB was also much better placed than it had been to defend its requirements against any challenge that may have been brought under EC and/or UK competition law.

Following the consultation the RPSGB Council decided that the only appropriate position to take was to maintain the public and patients safety mechanism of complete prohibition of self-selection of all pharmacy medicines.

In May 2009 the European Court of Justice past judgement in Case C-531/06 and in Joined Cases C-171/07 and C-172/07). Exert from judgement summary:

"restriction can nevertheless be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality.

Where there is uncertainty as to the existence or extent of risks to human health, it is important that a Member State should be able to take protective measures without having to wait until the reality of those risks becomes fully apparent. Furthermore, a Member State may take the measures that reduce, as far as possible, a public-health risk, including, more specifically, a risk to the reliability and quality of the provision of medicinal products to the public.

In this context, the Court draws attention to the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods.

Those therapeutic effects have the consequence that, if medicinal products are consumed unnecessarily or incorrectly, they may cause serious harm to health, without the patient being in a position to realise that when they are administered."

The Supreme Court for EU countries in making this judgement has deemed that medicines ***are not*** ordinary items of commerce and therefore individual states could put in place "protective measures" to ensure the public and patients safety. i.e. allow the regulator to prohibit the self-selection of P medicines.

Exploring some perceived positives to self-selection of P medicines

1. Patients will be able to access information about the products by reading the box.
   It is already legitimate to display empty packaging on self-selection so there is nothing to stop those that think this is a benefit doing it now. In the commercial world we live in labelling on outer packaging is there to stimulate sale and not to provide patients with balanced information.
   Patient representatives and groups have continually said that what they need is access to trusted product information and this is available through every pharmacy by speaking to the pharmacist. There is also nothing to stop pharmacies having products' patient information leaflets (PILs) available or unbiased fact sheets freely available to the public.
2. Anecdotally it is reported that some patients do not wish to be "hassled" by being questioned when purchasing a P medicine. There should be the same standards in place for POM and P medicines as in both cases the medicines are obtained from the pharmacy and are potentially dangerous if taken inappropriately. There is an absolute need for this questioning to take place in order to allow the pharmacist to perform the professional role of identifying red flag symptoms that may require intervention of the sale and further referral.
   Further messaging may be required to members of the public questioning the need for the supplier of medicines to put in place mechanisms to ensure that all supplies are safe and appropriate. At the same time questioning at the point of sale should be at an appropriate level in all pharmacies and conducted by suitably trained persons.

Background Summary

The proposal in the GPhC consultation on standards for registered pharmacies creates a situation that would allow for the self-selection of P medicines. This would fundamentally change the dynamics of the interaction between the customer and the pharmacy staff. It allows customers to see, handle and choose pharmacy only medicines without needing to ask a member of the pharmacy staff. This would be a huge retrograde step as it would further commercialise the supply of medicines and the support for self care. While this could be seen as giving patients more choice, the RPS believes that members of the public do not have the knowledge to make an informed choice and having the P medicines on open display raises the publics' expectation that they can self-treat without the associated required knowledge to do so safely.

This whole debate must centre on public safety. Despite the fact that self-selection of P category medicines will probably lead to an increase in sales the vast majority of the profession are against it. The reason for this attitude is, predominantly, due to the increased risk to the public: for example, customers may choose a medicine that is inappropriate and not be easily dissuaded from purchasing the product once they have it in their hands. Equally, having more powerful medicines on display could lead to theft or to children picking them up off the shelves unnoticed. The risks of harm may be increased by the more powerful nature of the medicines on display when compared to GSL products.

The RPS position

We believe that the reason for maintaining the prohibition on the self selection of P medicines is to ensure patient and public safety. We believe that the public will be put at risk if the GPhC move ahead with the proposed changes outlined in this consultation. If self selection of P medicines is enabled then there will be inconsistency across Great Britain as it will be up to the individual superintendent or pharmacy owner as to how they implement this. This will cause confusion for the public as some P medicines may be on open display in one pharmacy but not in another.

If the placement of P medicines were left to the discretion of each organisation we would consider this a significant risk to patient safety. In fact a review of the overall categorisation of all medicines could be implemented to ensure patient safety is paramount. For example, certain GSL medicines also have a significant impact on patient safety. We would ask GPhC to clarify where the evidence to justify a change from the current system of self-selection has come from.

The 'P' category is crucial to the extended roles of pharmacists and to enable formerly 'POM' medicines to be made accessible to members of the public. For every sale of a so-called 'POM to P' product, a visit to the GP may be saved. This represents a significant time saving for the individual and a saving of around £30 to the NHS. We would like to see more 'POM to P' switches but within an environment that is safe for patients and the public.

Before the GPhC make their final decision, following consultation, we would seek additional assurances that the GPhC have looked at all aspects relating to:

1. Some P medicine products
    - Abuse potential of the product
    - Consequences of an inappropriate choice
        - Side effects
        - Interactions
        - Untreated symptoms/condition
        - Whether the product would normally be recommended by the pharmacist
2. Dangers associated with **P** medicines for self selection
    - Security
        - both deliberate theft and the potential for children to pick up a product should be considered
    - Whether pack design, etc clearly shows what the product can be used for
        - Any lack of clarity could lead to inappropriate selection
    - The ability of staff to deal with difficult situations

Appendix B

Veterinary Pharmacy Forum response

The Veterinary Pharmacists Forum (VPF) is a Royal Pharmaceutical Society online sector group with over 1,000 members that is growing daily. There are approximately 20 veterinary specialist pharmacists in the UK responsible for a significant proportion of the veterinary prescription medicine supply in the UK. Veterinary Pharmacy is the main stay in the rural sector and due to changing legislation is increasingly important in the community sector. The Veterinary Medicines Directorate (VMD) has taken on the licensing and regulation of veterinary medicines but pharmacy, regulated by the GPhC (formerly the RPSGB), is still recognised by the VMD as a first class choice for dispensing of all medicines. A Memorandum of Understanding was drawn up between the VMD and the RPSGB to address this.
The VPF wishes to comment specifically on the proposal by the GPhC not to register pharmacies that sell only veterinary medicines and will make its comments under Question 1 of the Consultation.

Q1. Do the proposals provide sufficient clarity about the premises that need to be registered with us as a pharmacy?

We find it unacceptable the GPhC will not register premises where the service consists solely of the sale or supply of medicines for animal use and we would like to understand the rationale for this decision. We are aware that the Pharmacy Order, under which the GPhC was established, does not specifically cover animal medicines but neither does it specifically rule them out. The Veterinary Medicines Regulation (VMR) clearly state that registered pharmacies are able to sell and supply animal medicines and that pharmacists working from such premises can dispense animal medicines. If the pharmacy was not registered as such, this would require changes in the VMR and these practices would need to apply to the Royal College of Veterinary Surgeons to be registered as veterinary practices in order to dispense POM-V animal medicines.

1. General

- We believe that The Medicines Act definition of a pharmacy does not in any way exclude registration of pharmacies supplying veterinary medicinal products. We also believe that if specialised veterinary pharmacies could no longer be registered, then the veterinary monopoly would return losing the public some of its right of choice with veterinary POM prescriptions.
- Veterinary medicines sales through pharmacies are tens of millions of pounds. Some pharmacies that sell only veterinary medicines have done so for many years. The commercial impact of removing the pharmacy status would be considerable for them. In the years since the implementation of the VMR their premises were registered with the RPSGB. We must recognise that their resources, training and investment have been allocated in the supply of veterinary medicines. Rebranding has considerable financial as well as professional costs. We are happy to supply financial information to underpin this statement if requested.
- It is illogical that pharmacists that have developed skills in the supply of veterinary medicines, in the drawing up of animal health plans or in the giving of advice about the control of zoonosis, may not be able to do so as pharmacies. It could also result in the ridiculous situation where a veterinary pharmacy would be unable to register and therefore unable to dispense veterinary prescriptions, whilst a typical community pharmacy with less expertise in veterinary pharmacy would continue to dispense and supply veterinary medicines.

- We are concerned about the political message that would be given out by the GPhC refusing to register veterinary only pharmacies. Politicians, manufacturers and ultimately the European Union which is currently reviewing the distribution of animal medicines may read into this that pharmacy as a profession in the UK is inclining away from veterinary medicine. This is surely not the case as we are the acknowledged experts in the supply and use of all medicines. This would also be of concern to the VMD because pharmacy offers animal owners choice for dispensing of POM-V medicines in the market place.
- There are currently thousands of community pharmacies advising and supplying flea and worm preparations for cats and dogs (Frontline and Drontal). These pharmacies need proper monitoring by the GPhC to ensure that the premises are appropriately organised and that staff are trained to ask the right questions. We believe the VMD are not convinced that appropriate advice is being given in pharmacies.

2. Interpretation of the law

- The Medicines Act, since 2005 when the Veterinary Medicines Regulations (VMR) were conceived, does not include medicines for animal use and neither does the Pharmacy Order 2010 from which the GPhC was established. The Medicines Act definition of a retail pharmacy business is around the sale and supply of medicinal products and it defines medicinal products as medicines for human use. So, technically, the GPHC interpretation may be correct. We believe, however, that we need to look at the bigger picture including the VMD and VMR. The interpretation being made by the GPhC, we believe, does not reflect the spirit of the Medicines Act which is about ensuring a safe and effective supply of medicines. Many community pharmacies sell and supply both human and animal medicines so the GPhC is not limited and restricted to just human medicines.
- Under the Medicines Act the GPhC, as the regulator, can change the criteria for registering premises as pharmacies but only if it is for securing the safe and effective practice of pharmacy. Excluding veterinary pharmacies, far from securing this, will in fact have the opposite effect.
- The VPF feels that the law should reflect what should be and should always support best practice.
- The GPhC does not explain why the registration of premises where the service consists solely of the sale or supply of medicines for animal use is a problem. The VPF is not aware that registered pharmacies have ever been seen to be anything other than a positive influence on distribution standards.

3. Effect on public safety

- The opportunity for veterinary pharmacies to deliver education about the avoidance of zoonotic infections and to supply veterinary products such as anti-tick medication would be lost. It is beginning to be understood that the unquantified cost to the NHS of conditions that come from animals is large. The World Health Organisation (WHO) has stated that over 70% of new human infections originate from animals. Pharmacies provide an excellent platform from which to project the public health messages surrounding these infections and pharmacies specialising in veterinary medicine should surely be leaders. (See PJ March 24th 2012 p397 on Lyme disease.)
- Ensuring accurate use of medicines administered to animals is an important contribution to the safety of the food chain. Specialist large animal pharmacies are involved day and daily in advising farmers about the withdrawal periods of medicines and the avoidance of residues in food products especially meat and milk.

4. Professional issues

- The ability to break bulk by veterinary pharmacists as allowed by the VMR contributes to the safe and effective use of the medicine. Especially where flock or herd treatment are involved, the ability of pharmacists to supply exactly the amount of medicine required means the surplus medicine is not left unused. There is a real risk that such surplus will subsequently be used in the wrong animals or for the wrong purpose with its attendant risk for the food chain and for the animals. This process also ensures that farmers do not stockpile medicines that can be stored wrongly or pass their expiry date. Breaking bulk can only be done in a registered pharmacy. Non-pharmacy animal health suppliers do not have the ability to do this.
- Pharmacists are tuned into dosage and understand the need to ensure that the people administering medicines to animals are aware of the need for accurate dosing and ensuring that dosing equipment is properly maintained and calibrated. If a farmer administers an incorrect dose it will have an effect on the residue left in the meat. These activities need to be managed.
- Internet veterinary pharmacies can sell animal medicines (non POM-V) in Europe only by virtue of their premises being registered as a pharmacy. In 2003 EU legislation stated that you have to be a pharmacy to sell non- prescription veterinary medicines. Therefore, the veterinary internet businesses would have to stop trading in Europe markets, leading even to redundancies. Internet sellers from the EU into the UK would still be able to operate giving them a clear competitive advantage.
- Overprescribing in animals especially around antibiotics, some think, may lead to increased human resistance to medication and have an impact on treatment of human diseases. There is a concern that if vets prescribe and dispense there will be no checks in place. To ensure standards remain high and that vets are not over prescribing, some vets look for pharmacists for support, especially within the intensive livestock sectors such as the poultry industry. In Italy vets are not allowed to dispense veterinary medicines and in certain Scandinavian countries pharmacists dispense everything. There are vets involved in the large animal sector in the UK that believe, in time, vets here will not be allowed to dispense for the reasons previously stated. overprescribing and conflict of interest where they make money from prescribing. Pharmacists are the only non-veterinarians who can legally dispense POM-V (all veterinary antibiotics are POM-V) medicines and with respect to the supply of medicines for food chain animals specialist veterinary only pharmacies will be a prime vehicle in these circumstances.
- The GPhC Inspectorate needs to include companion medicines in their inspections of community pharmacies .
- Veterinary pharmacies are proud to be registered as pharmacies. Such registration ensures delivery of services to high standards, probably higher in certain respects than alternative routes of supply that the users of veterinary medicines may choose to access. The VPF believe it is safer for veterinary pharmacy to be registered and meet high standards as there are benefits for the consumer. The GPhC will need rules and best practice for veterinary medicines stocked in community pharmacies, so to exclude veterinary only pharmacies may not be a high resource saving in terms of inspection. Veterinary only pharmacies have special expertise so can provide the best possible service.
- The World Health Organisation has reported that a high percentage of new diseases are from animal origin. The NHS does not recognise the effect this has on patient costs. Veterinary pharmacy would have useful input into this research, including advising and educating the public on diseases originating in animals.