GPhC Standards Consultation | A Response by the PDA

by the Pharmacists' Defence Association

Consultation

General Pharmaceutical Council - Setting Standards

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the pharmacists' defence association

Consultation Response Form

Health Care and Associated Professions:
Health Care and Associated Professions: Setting standards – proposals for consultation

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The response of the Pharmacists' Defence Association (PDA)

The Pharmacists' Defence Association (PDA) is a not for profit organisation which is a defence association and a union for pharmacists. The aim of the PDA is to act upon and support the needs of individual pharmacists and, when necessary, to defend their reputation. PDA currently has more than 15,000 members.

The primary aims of the PDA are to;

- Support pharmacists in their legal, practice and employment needs.
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist.
- Provide representation for its members.
- Proactively seek to influence the professional, practice and employment agenda to support members.
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care.
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists.

The views contained in this consultation were developed after an analysis of members views who were involved in surveys and focus group meetings. Additionally an expert group of pharmacists, lawyers and barristers were convened to ensure appropriate context.

Background

The Pharmacists' Defence Association is essentially a risk management organisation comprising of a Defence Association, Insurer and a Trades Union. Currently, with a membership of more than 15,000 pharmacists which continues to grow, the PDA works both reactively and proactively.

Reactively

PDA supports members in more than 3,000 incidents per year where members are facing some form of employment or professional dispute, a legal prosecution or a civil claim for compensation from a patient.

Proactively

The reactive experiences provide valuable insights and lessons into how and why things can go wrong. Consequently, a very important element of the activity of the PDA is to work proactively and seek to promote solutions within the broader profession which would have the effect of preventing problems for pharmacists and patients occurring in the first place.

With regards to professional regulation, the PDA is concerned that although there has been some recent improvement, the regulatory style of the RPSGB has been to focus on punishment, blame and retribution and on using draconian and burdensome processes to exact discipline upon many thousands of pharmacists. This has led to a widely held view in Pharmacy that the regulator is not a body that can be relied upon to support professional development, learning and innovation.

Expectations

Consequently, the PDA has been very supportive of the separation of the dual role of the RPSGB as this was a development which could simultaneously lead to the creation of;

- A strong professional leadership body which leads and develops the ambitions of the profession and which also provides pharmacists with the tools to enable them to deliver their service.
- A supportive modern regulator that strategically and operationally facilitates such professional development within a framework that is proportionate to risk and which is appropriately targeted.

Crucially, we believe that it is the right blend of these two thrusts that will be the most beneficial, indeed; this is a view that has also been shared by PRLOG.

Response

Sadly however, we believe that the proposals contained within the initial GPhC consultation fall short of these expectations. Our response to the consultation is provided in several parts;

1. Summary of recommendations
2. The strategic bigger picture analysis
3. Comments on important issues that sit at the strategic/tactical interface
4. Comments pertaining to specific annexes within the consultation
5. Additional concerns for consideration
6. Response to consultation questions
7. References

1. Summary of recommendations

1. The regulator needs first to agree a strategic vision for pharmacy with those it seeks to regulate and then to establish the relevant regulatory standards to support and underpin that vision.

2. We propose a regulatory approach that seeks to establish a coherent career framework in community pharmacy and which links the undergraduate degree to modern practice and lifelong development.

3. At undergraduate level, we recommend a better grasp and integration of, not only the realities of current practice, but also of the direction of travel.

4. We seek an explicit commitment by the GPhC to provide pharmacists with regulatory support on the issue of training and professional development.

5. We advocate a return to the professionally led approach to regulation; one which supports innovation and the taking of appropriate and responsible risks by pharmacists. This means that the standards should contain less prescriptive detail and allow a greater scope for professionals to make informed and professional decisions.

6. We encourage less focus on individual wrongdoing and more focus on institutionalised systemic abuse.

7. We would urge the GPhC to provide an anonymised whistle blowing system to enable registrants to express their concerns with reference to poor standards of practice. This would be a commitment that Inspectors will respond independently and objectively to any information received so as to establish the veracity of the complaint and establish an anonymised system of feedback for the complainant.

8. We promulgate standards of competency (and probity) for owners, area managers and managers who are not pharmacists in relation to practice standards, safe environments and workloads. It is unsatisfactory, in the modern era, that factors which impact upon patient care are determined by individuals who are not bound by any code or who are unaccountable to anyone but their employers.

9. We welcome the regulation of premises but ask that the GPhC implement these standards immediately and does not wait for 2 years as proposed.

10. We agree that support staff need to be regulated and would go one step further recommending that ALL support staff involved in the sale and supply of medicines should be regulated.

11. We are concerned that these standards for technicians have been assembled with the pre-emptive objective of implementing remote supervision without any correlating levels of suitable education or qualifications. We strongly recommend that the GPhC conducts an impact assessment on patient safety and follows an evidence based approach before adopting rules that enable the extension of technician roles.

12. A detailed discussion on the appropriateness of the prescriptive nature of the proposed CPD framework or other mechanisms to enable practitioners to demonstrate evolving competences within an educational and career framework is outside the scope of this response, nevertheless, we recommend that such a discussion should take place.

2. The strategic bigger picture analysis

What the modern GPhC was supposed to look like:

Professor Peter Noyce; professional advisor to PRLOG, the predecessor to the GPhC described a core aim for the GPhC:

"The General Pharmaceutical Council cannot simply "root out poor practice and behaviour", but must also enable the pharmacy profession to develop its practice" (12)

He further went on to add:

"We need to transform pharmacy into a coherent, clinical profession … and make sure the public know what pharmacists are capable of contributing [to patient care]." (12)

This focus was confirmed when Bob Nicholls, the new chair of the GPhC was appointed.

"We've got to be quite imaginative in terms of how regulation should be discharged," he added, emphasising that focus should move away from the punitive element of regulation — the element of "weeding out the bad eggs" — and towards the iterative improvement of standards, particularly in the face of rapidly changing pharmacy practice, with a view to raising overall quality constantly across the profession. (15)

It is our view that the proposed standards do not support these aims

The emphasis of the proposed standards, as defined in the consultations Executive Summary is focused upon:

- The establishment and promotion of standards for the safe and effective practice of pharmacy at registered pharmacies.
- The establishment of requirements by reference to which registrants must demonstrate their fitness to practise is not impaired.
- The establishment of standards and requirements in respect of the education, training, acquisition of experience and continuing professional development that is necessary for pharmacists and pharmacy technicians to achieve in order to be entered onto the Register or to receive an annotation in the Register and to maintain competence.

The focus is much more akin to the old fashioned approach which had been used by the RPSGB. It is one that stifles innovation and instead leads to defensive practice which is neither in the professional nor the public interest.

2. The strategic bigger picture analysis continued

Why has this drift occurred?

It is our view that the starting point for this consultation must be an agreed and ideally an 'aspirational' vision for the profession. The architecture of the regulatory approach must then support such a vision. If it does not, then it will not command the support of the profession and the broader more strategic role of modern regulation - to facilitate professional development within a structured regulatory framework - will fail.

A good example of this appears in Annex C which deals with the proficiency standards of registrants. Indeed item three within this Annex focuses principally on describing boxing proficiency standards into those intended for pharmacists and those for technicians.

This appears to be a naked attempt to facilitate the exit of pharmacists from the community pharmacy setting and supports the introduction of remote supervision. We would suggest that remote supervision is not a vision that many pharmacists, particularly those from the community setting, would aspire to.

Consequently, the approach taken not only fails to meet the shared vision requirement, but because it seeks to support the introduction of remote supervision it then becomes obsessed with minutiae rather than a focussing on the bigger picture.

The proposed standards appear to place too great an emphasis on the performance of individual practitioners and thus fails to understand that it is the structures and environments within which pharmacy practice is carried out that are the cause of many untoward patient incidents.

3. Issues that sit on the strategic/tactical interface

Beyond the issues of the lack of vision (the shared aim), are matters of concern which sit on the strategic/tactical boundary; some of these are a consequence of the vision deficit. We highlight three such specific areas:

a) The standards do not support pharmacist aspirations nor do they facilitate the development of pharmacy practice:

A lack of aspiration for the development of pharmacy practice goes against the grain of government policy in wanting pharmacists to play an increasingly clinical role within the community setting. Sadly, this consultation appears to dwell mainly on the career and professional developments for pharmacy technicians and very little attention is paid to the hopes and aspirations of pharmacists.

To develop their role in a risk-managed manner, pharmacists (particularly those in community) need to see a structured career framework. Hospital pharmacists have a defined career structure and this was embellished further in 2005 with the introduction of the "consultant" pharmacist post. Whilst the post was supposedly not exclusive for hospital pharmacists it is unclear how community pharmacists could ever engage in such a concept.

It has been stated in the Department of Health publication "A Vision for Pharmacy in the New NHS." 2003

"Pharmacists are successful in developing clinical and specialist roles in hospitals. We want to build on this success through the establishment of consultant pharmacist posts." (19)

Because community pharmacists have no real defined professional career structure, many face a cul de sac in terms of career progression. Indeed, upon qualification one can become an owner pharmacist and practise as such until retirement. Similarly one can become a locum pharmacist from day one of registration to the day of retirement. Usually in such instances, in terms of reward there are no tangible advantages in being a seasoned, experienced locum over and above being a newly qualified one. One can also become a pharmacy manager. Some long term serving community pharmacy managers find themselves actively performance managed out of their posts by employers motivated to reduce costs and are replaced by less expensive newly qualified pharmacists. The system fails to support professional development because of a lack of a defined career structure. Whilst community pharmacy is not unique in this situation, it is unique in that it is failing to address this structural deficit and successive workforce surveys have shown high levels of professional disillusionment within the community pharmacy sector.

3. Issues that sit on the strategic/tactical interface cont.

The Chief Medical Officer at the DoH, Sir Liam Donaldson recognised a similar problem with the career structures of many doctors.

"For too long the Non-Consultant Career Grades (NCCGs) have been regarded as a professional cul de sac. Although their creation, at different times, was in response to legitimate service requirements and their contribution to the National Health Service is undoubted, they are seen by some as lacking in status and recognition." (16)

The majority of practising registrants work within community pharmacy; consequently there is an opportunity to better exploit valuable intellectual capital for the benefits of the profession and the public.

We advocate a regulatory approach that seeks to establish a coherent career framework in community pharmacy and which links the undergraduate degree to modern practise and lifelong development.

An example of how important regulatory opportunities have been missed previously includes the introduction of the Responsible Pharmacist (RP) regulations. During the initial consultation, the government proposed that a RP would need to demonstrate additional competences before they could become an RP; furthermore, the register would be annotated indicating these additional qualifications. Had this occurred, then the RP regulations would have supported the introduction of a professional career framework since those pharmacists who felt less prepared to take on the added responsibilities could have remained as supervising pharmacists and they would have been able to work under the aegis of a more qualified RP. However, the government ultimately then failed to proceed with its own eminently sensible proposals.

b) The standards do not seamlessly link education with defined modern career pathways for registrants:

Tomorrows pharmacists will need to be equipped with skill sets that will help them to mould a modern profession focused on delivering clinical and pharmaceutical care. To facilitate this there has to be culture change in the way a pharmacy degree is taught and the weakness in clinical focus has to be addressed. There also needs to be a focused goal of creating a seamless framework from point of entry into university all the way through to leading edge practitioner level.

There needs to be at undergraduate level, a better grasp and integration of not only the realities of current practice, but also of the direction of travel.

At a joint conference held by the Guild of Healthcare Pharmacists and the UK Clinical Pharmacy Association, Professor Anthony Smith expressed his concern:

"There is currently a lack of communication between academics and clinical practice said Professor Smith. He was "ashamed" to admit that, at present, there is "frighteningly little discussion" between those who are involved with undergraduate education and those who are involved with delivering pre-registration training. "That has to change," he added. (13)

But the lack of integration does not stop with just the pre-registration year. Indeed at the European Association of Faculties of Pharmacy conference in 2008, Professor Ian Bates (17) observed the disjoint in creating a culture of lifelong learning in a presentation slide labelled:

3. Issues that sit on the strategic/tactical interface cont.

But then what?

- **Most educational 'policy' seems to stop at registration**
- **This being "Regulation" in most countries**
- **Except for "CPD" – is this really a policy? ...and does it work?**

He further noted that educational reform could not occur in isolation but had to occur in tandem with a career path for practitioners if modern age pharmacists were to deliver:

- **Better health care,**
- **Better patient experience,**
- **Better value for money**

BUT linked to better career pathways

Which means practitioner development pathways

Although work place training is seen in pharmacy, this is generally more common in hospital and primary care practice. In community pharmacy, much of the work place training is geared around supporting an employer's commercial agenda e.g. training on the new electronic till systems being installed or training around an employer's processes and procedures. As far as professional training and CPD is concerned, protected learning time is something that is rarely seen in pharmacy employment; instead pharmacists are expected to engage in CPD in their own time. This must change as it has the effect of ensuring that training is seen as a necessary but largely very inconvenient requirement and not a fully integrated pharmacy activity.

We would like to see an explicit commitment made by the GPhC to provide pharmacists with regulatory support on the issue of training and professional development.

3. Issues that sit on the strategic/tactical interface cont.

c) The standards do not inspire confidence in the Regulatory process:

It is not possible to govern without consent and this is why the thinking behind the reforms for all the healthcare regulators has been that regulation is proportionate to any particular risk and that it therefore has buy-in from registrants. In the final report "Enhancing confidence in healthcare professional regulators" Niall Dickson of the Kings Fund specifically addresses this issue:

"An effective regulator requires the broad support of those whom it regulates, and it is vital that the regulatory body is in touch with practitioners' concerns and aspirations. The aim should be to achieve a shared view about the standards expected of a good practitioner, accepting that this will change over time. It is probably fair to say that different professions regard their regulators in different ways." (18)

More than 50% of all patient facing pharmacist registrants in the UK are members of the PDA and we are aware that the majority of our members have little regard or confidence in the regulatory processes that have been used by the RPSGB. As a defence association, our extensive and operational experiences with the RPSGB's regulatory machinery have occasionally left us at a loss for words as some of its actions appear to be detached from reality. It is particularly relevant to discuss these matters at some length so that the GPhC can avoid the mistakes of the past. Currently, there may be a degree of latent goodwill that will exist towards the GPhC from grass root practitioners and pharmacy organisations and this must not be squandered.

In particular we have serious concerns about the following regulatory processes:

- **Referral to the Disciplinary Committee.**

  We have many examples where the registrant has felt bullied into agreeing wrongdoing and therefore accepting a warning for fear that a refusal to accept any wrongdoing will mean an appearance before the Disciplinary Committee, where their refusal will be construed as a lacking of insight. The annotation made on the register following the acceptance of a warning has potentially serious workplace implications for the registrant and the manner in which the RPSGB has conducted some of these matters is simply unacceptable and ironically, shows a distinct lack of insight on behalf of the RPSGB. What is worse is that if a registrant wants to put up an entirely reasonable defence, as is their natural entitlement, then they are additionally threatened with a costs order against them which in its own way could be even more difficult for the registrant to deal with than a disciplinary sanction.

3. Issues that sit on the strategic/tactical interface cont.

- **The time taken for cases to actually come before the Disciplinary Committee.**

  The current Disciplinary Committee has presently adjourned from November 2009 until July 2010 i.e. for 8 whole months. We believe that this is largely due to the mismanagement of allocated funds which has led to a shortfall of funding. Examples of such mismanagement may be where a simple case could be handled expediently in just a few hours before lunch, but where committees take full days or longer instead. Other examples include where the chair of a committee has spent most of the day writing the reasons for the adjudication whilst legal teams and other committee members are sat waiting at huge cost to both the regulator and registrant. In the past the decision has been given and the reasoning sent to all parties within 14 days. Other examples include where relatively large legal teams are used by the RPSGB which in our view adds nothing to the process apart from delays and costs. We are concerned that many registrants that encounter the current process come away with the impression that it has become a gravy train. Furthermore, because justice delayed is justice denied, then neither the registrants, nor the public can have confidence in how these matters are handled.

  Niall Dickson's report clearly understood the need to address this issue:

  "Given that it is registrants who pay the fees and given the move away from elected councils, there is a stronger need than ever not only to ensure that regulators do exercise their duties in a cost-efficient manner, but also that they are seen to do so by those who have to pay." (18)

- **The tick box approach that appears to pervade through the whole process.**

  We have numerous examples of inappropriate referrals to the higher levels of disciplinary process relating to dispensing errors of controlled drugs. This has been purely because a controlled drug has been placed in a tick box defined as a higher category of error when in fact there is no evidence that a dispensing error involving a controlled drug automatically poses a greater risk to the patient. In fact many cardio-vascular or anti epileptic medications pose a far greater risk because of their narrower therapeutic index.

We believe that the greatest benefit that the public derive from a pharmacist is their ability to make a professional judgement in the interest of the patient. This means that sometimes pharmacists, when balancing the risks and benefits, may circumvent the rules to ensure that they put the patient first. An erstwhile mantra of pharmacists was always that if they made such a decision, then they must be prepared to successfully justify it to their peers if challenged so to do. These last few years the RPSGB has not made allowances for this and has adopted a join-the-dots approach to regulation. This has had the effect of stifling innovation and any other more risk laden activity such as professional decision making. Indeed, because of the general regulatory regime faced by pharmacists today, we believe that pharmacists would prefer to steer clear of even the most basic professional excursions, such as emergency supplies to patients, for fear of attracting regulatory scrutiny.

Life is not black and white and it does not follow prescriptive rules, consequently a regulatory regime that attempts to do so will fail by definition and will simply appear forlornly detached from reality.

3. Issues that sit on the strategic/tactical interface cont.

We advocate a return to the professionally led approach to regulation, one which supports innovation and the taking of appropriate and responsible risk by pharmacists. This means that the standards should contain less prescriptive detail and allow a greater scope for professionals to make informed and professional decisions.

We advocate less focus on individual wrongdoing and more focus on institutionalised systemic abuse.

There is an argument that says that the current RPSGB showing such a tough and unwielding approach to so many registrants indicates that it is a fit-for-purpose regulator because it is protecting the public from unsafe practice. However, we argue that inappropriate regulation of individual pharmacists whose activities pose little or no actual risk to the public mean that the regulator fails to address other much more serious matters promptly. Moreover, the RPSGB appears hesitant to address the more serious systemic abuses of pharmacy regulations which may be carried out by some of the larger corporate entities.

Indeed, with the introduction of the Responsible Pharmacist (RP) regulations the historic regulatory failures of the RPSGB became apparent to the extent that Steve Churton, the then President of the RPSGB finally had to admit:

"What the RP requirements have done is to shine a spotlight on activity which is sometimes unlawful, and which I am sure none of us would condone." (1)

This stark admission, when understood in context, is nothing short of a disaster. A regulator admitting that despite having at its disposal an inspectorate and powerful regulations to prevent unlawful activity had instead focussed on the individual mistakes and human errors of individual practitioners and had consistently failed to deal with institutionalised wrong doing.

We welcome the fact that pharmacy premises will now feature more heavily in the regulators activities, however, we are concerned that the failure of these standards to adequately regulate the large corporate entities that dominate community pharmacy should not be underestimated.

A recent example of why this is a problem flows again from the introduction of the RP Regulations. The RPSGB provided clarification to the profession over what constituted making a contemporaneous record in the RP record. It would appear that one particular large corporate pharmacy company sent a memo that contradicted the RPSGB advice, leaving many pharmacists in a near impossible situation of having to decide what to do next.

We believe that such wanton displays of power pose a far greater threat to the safe delivery of pharmacy services than the actions of any one individual pharmacist.

4. Consideration of specific annexes

Annex A:

Standards for pharmacy owners and superintendent pharmacists to be met in connection with carrying on a retail pharmacy business.

This Annex fails to recognise the statutory role of the Responsible Pharmacist (RP).

It is telling that the significance of the statutory role of the RP and the change in dynamics because of the RP regulations (from a pharmacist working under the direction of a superintendent to the responsible pharmacist charged with a statutory duty to secure the safe operations within a pharmacy) has not been addressed by these standards.

Indeed, the term responsible pharmacist is mentioned on just 2 occasions in the course of all the annexes (and not even once in this Annex). Even when it is mentioned it is merely in terms of being a correct title rather than on its meaning or standard. We are confused as to why the role of the RP and the quality framework that the RP regulations were designed to install appear to have been marginalised.

Item (7) of the standards proposes that risk assessments of the activities conducted at the retail pharmacy business should be undertaken. On October 1st 2009, the RP legislation placed a statutory responsibility of securing "the safe and effective" operations within the pharmacy with the responsible pharmacist. So, whilst we agree that the risk-assessment should take place, the GPhC must specify that it is carried out by the duty RP who should have completed the requisite post-registration training (to a competency standard specified by the GPhC) in risk assessment.

Dealing with poor standards

Pharmacists, and especially locum pharmacists, often come across situations that would be considered as being worthy of requiring investigation by the regulator. Whilst the superintendent or owner should be informed of the risks and how the RP has mitigated against them, there is a clear public interest for the RP to inform the GPhC.

For registrants to have confidence to report such matters we would urge the GPhC to provide an anonymised whistle blowing system. This would be a commitment that Inspectors will respond independently and objectively to any information received so as to establish the veracity of the complaint and establish an anonymised system of feedback for the complainant.

This becomes even more important as almost 40% of community pharmacists now work as locums. Locums are especially fearful of being blacklisted. Many parts of the Great Britain are considered areas of local pharmacy monopoly (as defined by the OFT report in 2003), consequently, the mechanism must be able to protect genuine complainants.

Annex A continued:

The apparent ability for some large employers to act as they wish with virtual impunity has been one of the biggest perceived failings of the RPSGB which has undermined its credibility with registrants. This is a major and systemic risk that the GPhC needs to urgently address in order to demonstrate its proper credentials.

Whilst we accept that the RP is now in charge of securing the safe and effective operations within a pharmacy, the RP cannot make amendments to the physical size of the premises or to the layout even when he finds that this is increasing the level of risk in the supply of goods or services through the pharmacy. These are within the gift of the owner or superintendent pharmacist.

We would argue that there is an obligation upon the GPhC to set standards of competency for owners and superintendents. We accept that there may be a need to work with other authorities like PCTs (or PCOs) through 'memorandums of understanding' to discharge of these obligations, however, the need to set these standards in the first place rests with the GPhC.

The environment

The published evidence base clearly points to the environment in which practice is carried out as having a far greater influence on the safe and effective delivery of healthcare rather than focusing on poor practice by any individual registrant.

The chief medical officer at the DoH, Sir Liam Donaldson shows great insight into this:

"Current concepts of patient safety place the prime responsibility for most adverse events on deficiencies in system design, organisation and operation rather than on the negligence or poor performance of individual providers or individual products. Indeed, the level of harm arising from error in unsafe systems versus unsafe doctors is several orders of magnitude higher. Countermeasures based on changes in systems of care are, therefore, more productive risk reduction strategies than those that only target individual practices or products, though both are necessary." (2)

We believe that the focus of the current consultation is still the registered individual rather than the environment and structures that heighten the risk for the patient. No mention is made of the NPSA guidelines, which are evidence based, for dispensary layout. As dispensaries become busier and the logistics of supplying medicinal products become more complex the need for a concerted focus on environmental standards is paramount.

According to Dr Mullen:

"The shop area was small and stocked only health-related products. The dispensary was not necessarily small in size, but inadequate for the volume of prescriptions dispensed. Staff working in the dispensary were visible to the patients waiting in the shop area. Leading out from the dispensary was a small and overcrowded stockroom." (5)

Given that NPSA identifies environmental and system factors as posing the biggest risk to safe dispensing we are concerned that this consultation proposes a 24 month interim period before safe standards should start to apply to premises.

Appropriate standards should be set now and it should be incumbent on the owner/superintendent to deliver the requisite standard for their premises and systems with immediate effect.

Annex A continued:

The NPSA evidence based guidelines also deal with systems and process failures ('Design for patient safety; a guide to the design of the dispensing environment, Edition 1, 2007.' - The National Patient Safety Agency).

"Human beings usually make mistakes because the systems, tasks and processes they work within are poorly designed. Effective design can deliver products, services, processes and environments that are intuitive, simple to understand, simple to use, convenient and comfortable, and consequently less likely to lead to errors". (3)

The NPSA further notes 2 key components that are identified as the root cause of errors:

"The documents focus on the two aspects that have been identified as most likely to contribute to errors: The design and layout of the dispensing area and the design and presentation of information, particularly dispensing labels, placed on medicines given to patients". (3)

Clearly these are operational matters which have the potential to have serious implications for patient safety. Corporate pharmacy chains comprise more than 50% of all pharmacies in Great Britain and corporate superintendents discharge their duties via area managers and shop managers that are not pharmacists or pharmacy technicians (i.e. non-registrants).

It is of considerable concern that these proposed standards fail to set standards (of competency or probity) for owners, area managers or managers who are not pharmacists and therefore are not registered with the GPhC.

This is despite the fact both the Pharmacists and Pharmacy Technicians order 2007 and the Draft Pharmacy Order 2009 specifically allow the GPhC to make these non-registrants subject to regulatory processes.

"The Council may from time to time publish or provide in such manner as it sees fit guidance to registrants, employers and such other persons as it considers appropriate in respect of the standards for the education, training, supervision and performance of persons who are not registrants but who provide services in connection with those provided by registrants." (4)

The PDA has substantial evidence and the experience in dealing with the consequences of the fallout from the inappropriate actions of non-registrants such as area managers employed by several of the large multiple pharmacy companies.

We hope that the enabling legislation is used to capture the poor practises of non-registrants.

A letter published by the Pharmaceutical Journal from a candidate to the English Pharmacy Board election of 2009/2010 sums up the frustration experienced by pharmacists at the plain ignorant behaviour of non-registrants:

"I recently worked in a store where I dispensed 500 items on the day and yet had to argue with a non pharmacist manager for a 20 minute un-interrupted break." (19)

Annex A continued:

Workloads

It is unsatisfactory that in the modern era workloads that impact upon patient care are determined by individuals who are not bound by a code of ethics and who are unaccountable to anyone but their employers. Pharmacists are being placed in continual process of friction about workload and inadequate staffing. It should be a standards requirement that an independent assessment is made of the staffing requirement in each pharmacy by an externally validated entity. For far too long, pharmacists have been bullied into accepting working conditions that are from the Victorian era especially when working excessive hours without proper rest breaks.

We are concerned that the standards do not make any real contribution to the issue of appropriate staffing levels despite the substantial concern expressed by all stakeholders on the issue of workload.

The recent Elizabeth Lee case highlights the increased risk to the public when large corporate interests place commercial concerns above the paramount need to deliver a safe service. This is aggravated when poor or non-existent risk management processes are in place with non-registrants placed high up the command chain.

The commercial nature of community pharmacy means that pressures are placed upon pharmacies to deliver their services at a minimum cost.

This often leads to registrants being coerced into taking on responsibilities or undertaking tasks that they may not have the requisite skills or competences for. Whilst this is mentioned in passing in Annex D1 we feel that there is a broader underlying theme of pressure and coercion that exists within community pharmacy and that this often leads to pharmacists and their support staff working beyond the scope of their competency. The recent introduction of Medicine Use Reviews (MURs) has shone a spotlight upon this concern. (21)(22)

Member feedback has repeatedly confirmed the extent of pressure and coercion faced in delivering MURs especially when a line manager is a non-registrant area-manager.

Annex B:

Conduct, ethics and performance.

This Annex fails to recognise the statutory role of the Responsible Pharmacist (RP).

We were disappointed that Annex B had expanded to no less than 15 standards. The current Code of Ethics contains 7 distinct overarching standards. This current code was only introduced some 2 years ago after a process of consultation. It was widely welcomed when the profession had started to move away from prescriptive to ethics based standards.

Some of the proposed standards in this consultation appear to wish to re-introduce the tick-box prescriptive style of regulation, the very culture which we were hoping to leave behind. For example standard 7 which states "communicate effectively" or standard 12 which states "delegate effectively" or standard 15 which states "respond constructively to feedback". These are puerile statements not worthy to be top-line standards for professionals. Our firmly held opinion is that the inclusion of 15 standards is excessive and unnecessary.

Pharmacy has always been an over-regulated profession with little scope being allowed for practitioners to work under a broad set of ethical guidelines. As the profession moves towards being more clinically focused rather than supply focused the standards need to be less prescriptive. However, the GPhC proposed standards are the reverse of this.

If the proposed standards are compared to model standards in other clinical professions, then the ones in place at the General Dental Council (GDC) show how poor the proposed pharmacy standards are. The GDC addresses more detailed guidance in specific areas and in proportion to the risk that is being addressed. The following quote which comes from the GDC standards underlines the difference in mindset between the GDC and the authors of the current GPhC consultation.

"Many professions have a Code of Ethics and there's no doubt a few guidelines do help. That's why in 2005 the GDC produced and published its core guidance, Standards for Dental Professionals. This booklet, and the supplementary guidance booklets and statements which support it, doesn't tell you what to do or how to act. It simply lists the principles and values within which you should operate. This is, if you like, our Code of Ethics for you."

The rest of the document leads on from this starting point which is explicit, clear and straightforward. The follow on guidance is inclusive and not prescriptive and the mind-set is forward looking and progressive. We urge the GPhC to adopt this modern fit-for-purpose way of regulation and abandon the silly prescriptive tick box approach that forms the bulk of all the annexes.

Annex C:

Standards of proficiency for pharmacy professionals. (PROFICIENCY).

We acknowledge that the new GPhC is the regulatory body for both pharmacists and pharmacy technicians.

We are supportive of the fact that support staff need to be regulated and would go one step further in that we would argue that ALL support staff are regulated.

We would have liked to have seen this area explored with proposals to phase in such registration for anyone involved in the sale or supply process that is not registered with the GPhC. We would suggest the title of Medicine Counter Assistant which could be regulated by, for example, the Health Professions Council.

As one reads the standards it becomes clear that one major driver is a pre-determined agenda to deliver remote supervision arguing that skill-mix can be used to facilitate the absence of pharmacists from pharmacies.

Indeed Item 3.1 states that pharmacy technicians must be able to:

- **take responsibility for the carrying out of a range of activities in the pharmacy under non-directive supervision, where the overall goal is clear;**
- **take supervisory responsibility for the work of others and lead established teams in the implementation of routine work.**

Consequently, these standards have become very detailed. It appears that the author of this consultation recognises that technician registrants are less able to exercise judgement and discretion than are Pharmacists.

The prescriptive nature of the proposed standards have the effect of undermining what should actually be the professional judgement of the duty pharmacist (RP) and the level of activity that he/she feels comfortable in delegating. Professional judgement on team capabilities can never be replaced by tick-box criteria in the manner that these standards propose.

According to Dr Rachael Mullen from University of Manchester who published a report for the Pharmacy Practice Research Trust in 2004 entitled "Skill mix in community pharmacy: exploring and defining the roles of dispensary support staff."

"Decisions concerning which particular member of the dispensary support staff was charged with performing additional tasks were taken by either the Pharmacy Manager or the Pharmacy Owner. These decisions appeared to be based on trust, rather than on dispensing qualifications. In these cases, the dispensary support staff members were very experienced and had an established working relationship with the pharmacists. This helped to inform the pharmacists' judgement about the capabilities of dispensary support staff members." (5)

The European models, which are often used as good practice examples by the DoH, rely upon a significant level of investment both in safe systems of work and in the quality of education before technicians are allowed to work under indirect supervision.

Annex C continued:

Dr Rachael Mullen continued;

"A culture of developing safe systems of working within the community pharmacy sector across the three other European countries enabled these equivalent pharmacy technician staff groups to extend their role. A commitment to quality control was a feature underlying these safe systems of working. Prescriptions were more detailed and often included the clinical indication for the prescribed drug. The electronic transfer of the majority of prescriptions in Denmark and Holland allowed for the incorporation of a series of internal checks on the computer system. Also, original pack dispensing and barcode matching in all three comparator countries guarded against dispensing errors by the equivalent pharmacy technician groups." (5)

The role of technicians is a key role, however, the standards consultation fails to understand that this key role is working alongside and under the direct supervision (not indirect and not remote) of a pharmacist until such time as their educational development and the supporting IT solutions (such as bar coding etc) matches that of their European counterparts.

If the GPhC wishes to extend the scope of responsibilities for prescriptionists or technicians along a European model then it must first develop a higher level and quality of educational framework for technicians and prescriptionists.

In Sweden all community pharmacies are owned by Apotek. In this model of skill-mix prescriptionists (a lower level of University based qualification) outnumber pharmacists (a higher level of University based qualification) by about 4:1. Nevertheless over half of all Apotek employees are still University graduates as pharmacists or prescriptionists.

So Sweden has underpinned the development of skill mix with an appropriate level of education.

Dr Mullen adds;

"These equivalent pharmacy technician staff groups undertook longer periods of training, often comprising theoretical, college components and practice-based work placements. Indeed, the 'prescriptionists' in Sweden is currently trained to Bachelor degree level and are akin to the UK BPharm pharmacists." (5)

We are concerned that the proposed Standards did not address this and why none of the questions based around proficiency address the issue of the standard of technician education.

We urge that the GPhC follows an evidence based approach before adopting rules that enable the extension of technician roles.

To date there is very little evidence which would support extension of the technicians' role in community pharmacy from a low educational base as opposed to extending from a far higher educational base (the European model).

The extension of role for technicians envisaged in GB also seems to be based on the hospital experience and shows little awareness of the vastly different operating environments between the community and hospital settings. In particular there is no evidence to show that the multi-disciplinary and much more structured operating processes within a hospital pharmacy where technicians assume a fair degree of independence can be transferred to the community setting.

Even where systematic 'protocolisation' is in place, the nature of practice within community pharmacy means that either it is simply not followed, or that it breaks down on a routine basis because of 'real life' situations.
This is even the case within pharmacies operated by large companies.

Annex C continued:

According to a paper entitled "Patient Safety in Community Pharmacy: Understanding Errors and Managing Risk" (University of Manchester),

"One potential limitation of this study is that the numbers of different types of pharmacy (national chain, small chain, independent) were not evenly represented, and were weighted in favour of those pharmacies that were part of a national group or chain. However, this study also provides clear evidence that medicines counter assistants engage in all aspects of dispensing. Observations revealed that this was most likely to occur during busier shop periods, in an "all hands on deck" capacity." (6)

This "all hands on deck" mentality exists not only in the national chains but throughout community pharmacy and it means that often those who perform the tasks do not possess the required and skills. Independent research commissioned by the DoH and the RPSGB confirms this disparity between the tasks and the skills.

"With regard to the research literature that is relevant to the skill mix debate it is clear that most of it does not focus on 'skill'. Rather, much of it, particularly the work sampling studies in community settings, focuses on 'tasks'. (See appendix six for a list of tasks defined by some of the work sampling studies). Moreover, much of the work in this area fails to make the link between the task and the range of skills required to carry out the task. This makes it very difficult to provide evidence of what constitutes an appropriate skill mix for the community pharmacy." (5)

Without understanding the difference between tasks and skills it seems that this consultation has embarked on a one way trip to create a framework for remote supervision and absent pharmacists whose specific skills have been systematically reduced to a list of tasks.

The consultation becomes aspirational for technicians and a straight jacket for pharmacists. It seeks to facilitate the carrying out of tasks by technicians without any identification of the different skill sets that pharmacists and technicians bring to performing that task. The standards will systematically undermine the availability of pharmacists within pharmacy premises and their daily face to face contact with patients without understanding the risk that this poses.

This is further confirmed by the large areas of overlap in practice matters between technicians and pharmacists and the demarcation lines of roles and responsibilities are separated into little boxes. This would simply not pass the reality test in community pharmacy and is a fallacious foundation upon which an attempt is being made to support remote supervision.

We are unaware of any other regulator approaching standard setting in this manner. If we compare the approach taken by the GPhC to that taken by the General Dental Council (GDC), (which has also undergone a process of modernisation), the GDC sets high level standards with detailed lower level guidance. This targets regulation in areas in proportion to the risks posed and still facilitates collaborative working by dentists and their support staff.

Annex C continued:

For example items 2.2.1 and 2.2.2 and 2.2.3 in the proposed standards are very confusing because they introduce terms that are very subjective and open to systematic misinterpretation. The boxes treatment does nothing to aid outcomes or foster team working and is a potential dividing line with all the associated risks for patients.

The way that the boxes have been partitioned does not lead to satisfactory outcomes. E.g. validating a prescription (2.2.1) which can be carried out by technicians, applying a systematic legal and professional approach to dispensing (item 2.2.3) which can be carried out by technicians, and evaluating and advising of prescribed medicines(2.2.2) which can only be carried out by pharmacists.

These terms have no legal basis nor any defined meaning in the present day practice of pharmacy. They are not referenced to in any pharmacy law nor is any explanation given as to how they would be applied in practice with any degree of consistency. We would contend that this approach is a recipe for chaos and introduces a risk to patients.

The standards are striking in that they do not appear to develop a greater role for pharmacists in providing pharmaceutical care to improve patient care and outcomes. Indeed some of the proposals will diminish even the existing role of pharmacists which the recent report from the GMC found was "pivotal" in reducing errors relating to medicines (GMC Today, Nov/Dec 2009 issue).

"The report stresses that almost all errors were intercepted before reaching patients and causing any harm, which reflected the existence of well-developed safety nets. While nurses and senior doctors played important parts in preventing errors impacting on patients, the contribution of pharmacists was found to be pivotal." (7)

In providing a document that appears to be aspirational for technicians, the author may have failed to check what a vision is for the pharmacy technician. Furthermore, the author appears not to reflect the fact that technicians working in the hospital sector are different in a number of important respects to those working in the community sector.

In a recent civil criminal case involving a dispensing error, the technician was prosecuted alongside the pharmacist for technical breaches of the medicines acts.

There was considerable correspondence in the professional press regarding this development. The extract below of a letter written by one pharmacy technician to her professional body is not atypical of the attitudes that are prevalent amongst community pharmacy technicians (The Pharmaceutical Journal 27.11.2009):

"When technicians dispense, there is always the comfort of knowing that theirs are not the last pair of eyes on the item. However, when pharmacists dispense, they may double-check themselves and might "see what they want to see"…… So, where does this leave the convicted dispenser? Would she ever want to dispense again? I always thought that the onus lies on the pharmacist. They get paid more than technicians, so why should a technician have to pay when a pharmacist fails to do his or her job properly?" (8)

This attitude is not new; on more than one occasion this view has been discovered, by researchers, when investigating appropriate levels of skill mix into the community pharmacy setting. The attitudes of dispensers when discussing the role of the Final Accuracy Check seems to be just as unclear now as it was 5 years ago.

Annex C continued:

"However, the feeling more generally was that it was a good idea, but some dispensary support staff were reluctant to take on accuracy checking. This was because there was a fear of making a mistake and harming a patient and there was also some confusion about whether they or the pharmacist had overall responsibility ……I wouldn't like to harm anybody or I wouldn't like to be responsible for anybody, you know, for giving anybody the wrong things, I don't think I'd like to do that." (5)

It is clear from these recent letters and also the independent academic research that many technicians do not aspire to the added responsibility that their extended role would give them. We believe that the DoH policy of pushing technicians into performing more risky tasks whilst a "responsible pharmacist" is legally responsible and accountable is likely to introduce unnecessary risks to the public. According to the Pharmacy Order 2009;

"There is also a lack of consideration given in the literature to competence as defined in the Kennedy Report. Responsibility and accountability are what separate many professionals from their support workers, but views and attitudes towards these by different levels of staff are rarely covered." (4)

The standards focus upon the process of dispensing and fail to articulate in any detail that dispensing is but one component of delivering a package of pharmaceutical care in the community setting. Subliminal issues like patient comfort in knowing that the pharmacist is present to answer any queries advice on medicines and of course answer any questions about OTC or prescription medicines are not addressed.

Indeed, the standards fail to take into account strategic government policy to direct clinical care to the most appropriate care provider. Indeed the Minister with responsibility for Pharmacy recently confirmed at the All Party Pharmacy Group meeting in December 2009:

"Community pharmacies are an integral part of the NHS", he said. "We need to see the expansion of the role of pharmacies and the role of people getting a grip on their own health". (9)

In community pharmacy the interaction with patients, the ability to deal with complex one-off situations and other diffuse and immeasurable parameters occur on a daily basis. Advice cannot therefore, by definition be based on the 'protocolisation' that is predicated by the prominence given to SOP's. A pharmacist's advice cannot be based on a SOP. Whilst algorithms can help in the process, the whole patient picture requires the level of understanding (clinical and empathetic) that only pharmacy graduates with a Masters level degree have been trained for.

We do not therefore accept Item 3, 1 Annex C that technicians"… solve problems that are well defined but may be complex and non routine"

There is a failure throughout the proposed standards to recognise the lower level of skills of support staff and the lack of acknowledgement that pharmacy is part of the primary care team. If the pharmacy part of the team becomes a weak link, even maybe the weakest link when pharmacists are absent, then the implications for extra workloads for GP surgeries and A&E centres during weekends is worrying.

Annex D1/D2:

Education and training standards for pharmacists and pharmacy technicians.

Annex E1:

Continuing Professional Development Standards and Framework.

We have combined our response to both these areas to highlight that modern professional regulation should embed a culture of lifelong professional development within a career framework.

As a student

We are supportive that funding permitting, the pre-registration year may be incorporated within a 5 year degree so as to enable better, broader experience in all sectors of pharmacy practice. This is especially important as pharmacy evolves into a more clinically focused profession and we agree that the methods of assessment will need to change substantially to enable this to occur. We appreciate that there will be a period of transition as capacity building for this takes place but it will need careful co-ordination and guidance and of course must be adequately financed.

We are concerned that any undergraduate FtP processes need to be not only consistent but also must be applied uniformly whilst taking into account cultural differences. The focus should be on improvement rather than on sanction and they should be fair and transparent.

Given that the degree course will lengthen to 5 years, then we would expect that an undergraduate would be given a clear guide during the undergraduate FtP procedure as to whether their 'incident' would prevent them from being ultimately registered as a pharmacist. It would be unfair to the undergraduate who may still have several years of study to not know.

Upon registration

Upon registration we would wish to see newly registered pharmacists facing a structured career development. This means taking sole charge of a pharmacy premises as the Responsible Pharmacist (RP) after meeting certain additional criteria. This may involve competences such as being able to undertake risk assessments, or put in place practical risk management measures.

As part of the developmental process a newly registered pharmacist could assume the supervisory duties within a pharmacy without being a responsible pharmacist. This would help to develop the newly registered pharmacists' clinical skills with patients in a managed and structured environment.

As part of the career framework we would like to see the GPhC set standards for services such as MURs, vascular screening, minor ailments and such like. These standards could still be delivered by a variety of institutions as long as they met the standard for accreditation. Thus, standards set by the GB wide regulator should reduce the problems experienced with cross-PCT accreditation and such issues that act as a barrier in the development of pharmacists' clinical role.

Annex D1/D2/E1 cont:

Advanced Practice

We agree that all pre-registration tutors need to be subject to standards and an accreditation process and we see this as part of a broader more defined career structure for pharmacists. At present all tutors must have practised as a pharmacist for a minimum of three years' in the sector in which they work and this would form part of the career framework for community pharmacists.

The exact nature of advanced practise within a defined and structured career framework for the community sector is outside the scope of a response to this consultation. However, we believe that there needs to be a further consultation on this matter as soon as possible.

CPD or ?

We are generally supportive of the ethos that practitioners should focus their learning with a view to improving their practice to deliver a better standard of care. But is CPD the right mechanism?

According to Professor Ian Bates Head of Education Development, London School of Pharmacy, disengagement from the CPD process is an academically recognised concept because it is: (17)

Repetitive

Esoteric and useless diversion

(Zeichner; Hall)

Lack of pragmatism and "how to"

"Reflective practice" tedious, not practical (students, practitioners, professions)

And one possible solution is: (17)

Changing the relationship between practitioners and academia

Meet the needs of health services and support practitioner development

Recognise a career path for practitioners

The CPD framework as proposed is too prescriptive and a rather blunt tool for embedding a culture of lifelong competency based learning. For example, under standard 4 its states that:

"You should aim to think about your practice at least once per month and make some entries that arise from this and some that arise from events in practice."

Annex D1/D2/E1 cont:

A detailed discussion on the appropriateness of the prescriptive nature of the proposed CPD framework or other mechanisms to enable practitioners to demonstrate evolving competences within a career framework is outside the scope of this response, nevertheless, we believe that such a discussion needs to take place.

We are further concerned that the sanctions may be disproportionate to the risk posed to patients and patient outcomes for non-compliance. We would like to see full sight of the underlying sanctions guidance before any framework is adopted.

Standards for Checking Technicians

A substantial failing of this consultation is the lack of standard for accuracy checking. The "Nationally Recognised Framework for Final Accuracy Checking of Dispensed Items for Pharmacy Technicians" needs to be either adopted as a de facto standard by the GPhC or a separate standard established. Being silent on such an important public safety issue is not appropriate.

Currently there is a free-for-all within the pharmacy profession. The above mentioned standards that were developed for working in the highly structured environment of a Hospital Trust setting have been adopted and adapted for use in the community setting in a variety of ways with little consistency or evidence of safe practice.

The NPA, which represents all community pharmacies, markets a course that does not require the accuracy checker to have any formal qualification. We believe that this is entirely unacceptable and that the GPhC has a duty to rectify the current situation.

Given that some 40% of the community pharmacy workforce are locums, it is critically important that a pharmacist has confidence in the standards by which final accuracy checking occurs. This lack of uniform standards has been a major structural barrier and a major point of concern amongst practitioners.

Annex E2:

The return to practice policy.

We agree with the general thrust and logic that registrants need to be in practice to stay on the register and the requirement for a standardised return to practice format.

Maternity issues

However, we would suggest that because the demographics of the profession are such that women will be disproportionately affected and that women form the majority of the profession, we would advocate undertaking an impact assessment before this strand of the standards can be developed. We would recommend that the new regulator may consider more flexible alternatives to that which is proposed because the effect of the current proposal may well be detrimental to both the profession and the public due to the potential shortages of pharmacists that this could create.

The more flexible alternatives may include;

- **Participation in regular CPD (or its agreed replacement) as laid down by GPhC.**
- **Involvement in regular "keep in touch" days (for example, as practiced by some model employers for women on maternity leave)**
- **Involvement in CPPE and other such organisations clinical programme.**

Providing the registrant can demonstrate that they have complied with all the above then they should not be subject to the 30/60 day rule up to the period of 8 years. In effect the registrant, by virtue of having carried out all the above (as a proposed example) would have demonstrated that their knowledge and practise base is up-to-date to deliver a safe service for patients.

Health issues

Community pharmacy is practised in a commercial environment. The PDA has seen many examples where employers are not supportive of registrants that have health related problems, preferring instead to handle these as disciplinary matters.

It is therefore disappointing that despite the fact that the S60 orders being designed to address safe practise when a registrant had underlying health issues, the standards do not address or provide for a process of rehabilitation (following recovery from major illness) or remedial practise in health impaired registrants.

Additionally, more flexible arrangements like 'stay in touch with practice days' under the direct supervision of an appropriately accredited pharmacist would be a constructive way to support a registrant keen to re-enter practice. We would urge the new regulator to take a more supportive stance on these issues.

5. Additional concerns for consideration

- Standards are not proportionate to risk and in some aspects run counter to best practice and the published evidence base.
- Failure to underpin the roles envisaged of technicians with a suitable standard of educational attainment.
- Failure to establish a whistle blowing scheme.
- No understanding shown in the distinction between the skills needed to perform a task and the task itself.
- Lack of standards for the critically important task of accuracy checking or of the skills needed to perform the task.
- The failure to address the role of the responsible pharmacist and the competences required for risk-assessment.
- Lack of acknowledgement that pharmacy is part of the primary care team and how indirect supervision would impact on GP's and also on A&E resources.
- The need to regulate all support staff with an appropriate regulator.

6. Response to consultation questions

In the previous sections of this submission, the PDA has answered the very many substantive points that we believe need to be addressed by the GPhC and does not believe that justice will be given to its submission by answering these questions alone.

However it has often been noted in our profession that considering that such a large section of pharmacists perform locums that their viewpoint is not given sufficient weight in proportion to their numbers. The questions posed by the CHRE as part of the consultation were addressed by the locum membership group of the PDA union to reflect the grass roots views of its members.

Question 1.

Do you agree that the overall standards adequately reflect an outcome and patient focused, broad and flexible approach?

- ☐ Agree
- ☒ Disagree
- ☐ Unsure

Comments:

The GPhC is expected to act as a modern relevant light-touch regulator. Why this initial consultation finds it necessary to introduce additional standards without any reasoning as to why the present principles are inadequate, it is difficult to understand. This seems to be change for the sake of change, is it really necessary to alter things now and why? The overall tone and wording of the standards is rigid and overbearing. There is little focus on the patient experience or on patient outcomes.

Question 2.

Do you agree with the use and definition of the term 'patients and public'?

- ☒ Agree
- ☐ Disagree
- ☐ Unsure

Question 3.

The GPhC is committed to embedding Equality and Diversity at the heart of everything it does. Do you think the draft standards support this commitment?

- ☐ Agree
- ☒ Disagree
- ☐ Unsure

Comments:

See answers to questions 7 and 8

Question 4.

Do you think the draft standards for owners of pharmacies and superintendent pharmacists are proportionate to the benefit they bring and the risk they are guarding against?

- ❑ Agree
- ■ Disagree
- ❑ Unsure

Comments:

Although we welcome the fact that the need for such standards are recognised, as representatives of individual pharmacists we still have major concerns that require further attention.

Our concerns fall into three main categories:

1. That pharmacists, including locums, must always be encouraged to take breaks. It has been shown that error rates rise when pharmacists work continually without a rest period and it must be the duty of every superintendent to facilitate this safe working.

2. That standards of premises are reviewed in the light of the workload and services given to the public; that premises that are not acceptable to the profession are dealt with quickly and that the GPhC liaises with others to ensure the use of layouts and systems in pharmacies will promulgate improved practice.

3. That if a pharmacist has to raise a matter with the superintendent concerning the safe and effective running of the pharmacy, there is an obligation placed on the superintendent to respond in a professional manner, without causing any detriment to the pharmacist. If public safety is at risk, a pharmacist must be able to report their concerns to the GPhC and their confidentiality respected.

In general we are concerned that the GPhC may not be able to ensure adherence to standards which it considers are necessary for safe and effective practice. The very best consultations espousing the very best standards is a pointless exercise if it is not put into effect. We are bemused at the rationale for allowing owners two years grace to get their premises up to standard. We would wish to see interim measures proposed to reduce risks posed by current inadequate premises.

Question 5.

Should there be specific standards for the systems in place within registered pharmacies to control and prevent healthcare related infections?

- ■ Agree
- ❑ Disagree
- ❑ Unsure

Comments:

For example clear guidance over whether patients suffering from swine flu should have been allowed in pharmacies would have been helpful. Many GP surgeries took action to prevent potential carriers from entering their premises.

Question 6.

There is no explicit prohibition of pharmacies and superintendent pharmacists offering pharmacy medicines for self-selection. Instead there is a general requirement that 'systems are in place to ensure the safe supply of medicines to patient and the public, in a manner that promotes their safe and effective use and appropriateness'. Do you agree with this approach?

- ❑ Agree
- ■ Disagree
- ❑ Unsure

Comments:

This is a poor approach. Medicines are not normal consumer commodities and, no regulator, if acting in the interests of the patient should allow such signals to be sent out. Pharmacy medicines should simply not be on self-selection. The present system is clear and effective; any dilution of that control will be to the detriment of patient safety and the process suggested by the GPhC poses a public health risk. This will also add to pharmacists' and pharmacy staffs' tension and stress in their working lives by creating unnecessary confrontational situations whenever medicines are on self selection and pharmacists then have to refuse a sale. We are also unsure why this matter has come back just two years after the profession came to the conclusion that self-selection posed a public health risk.

Question 7.

Do you think the draft code of conduct, ethics and performance adequately applies to registered pharmacists and pharmacy technicians in all sectors of practice?

- ❑ Agree
- ■ Disagree
- ❑ Unsure

Comments:

Not fully. Currently there are different standards applied in different sectors and an independent audit needs to be undertaken to ensure that every sector is equally affected.

There is also some concern that community locums may suffer from unnecessary complaints to the regulator from employers. Management are less likely to make reports about and offer more support to their employee than they are the locum, escalating the incident. It is understood that how a complaint is handled differently initially can lead to differing outcomes.

Statistics should be collected to judge how often and in what circumstances, pharmacists from the different sectors appear before any disciplinary committee, to ensure equity.

There also needs to be independent audit of the fitness to practice processes and this was something that the RPSGB was asked to consider by CHRE in 2005. To-date the RPSGB has failed to consider an external audit for quality assurance of its fitness to practice procedures.

Also of concern is the disproportionate number of ethnic pharmacists that face the disciplinary process. This was noted by a previous Chair of the (old) Statutory Committee and he recommended that this issue needed to be investigated. To date the RPSGB has failed to address why its processes result in this inequity. We can compare the attitude shown by the GMC when this very issue had to be addressed by it. They commissioned an independent report to ensure that there was no inherent bias in its Fitness to Practice processes.

Question 8.

Do you agree that there should be provision within the Code which allows personal beliefs of registrants to prevent them from providing a particular professional service? (Subject to ensuring that patients and the public are referred to alternative providers of the service they require)?

- [x] Agree
- [ ] Disagree
- [ ] Unsure

Comments:

Although members individually had differing views on this subject, it was felt that we should support our Union members should they have difficulties with providing a particular service in light of their personally held beliefs. It is a strength of pharmacy that we embrace equality and diversity. This is of course subject to pharmacists giving appropriate direction to another service provider.

Question 9.

Do you think that the proficiency standards for pharmacists and pharmacy technicians are sufficient to ensure that they are able to practice safely, lawfully and effectively?

- [ ] Agree
- [x] Disagree
- [ ] Unsure

Comments:

The proposed standards propose a much higher level of autonomous working for technicians with no corresponding increase in their training standards or proficiency. We note with dismay the lack of standards for accuracy checking technicians. For locums to have confidence in trusting accuracy checkers we need to be sure that all accuracy checking technicians are trained to the same standard.

Question 10.

Do you agree that the standards of proficiency for pharmacy technicians should require a broader range of knowledge and understanding?

- [x] Agree
- [ ] Disagree
- [ ] Unsure

Comments:

Technician roles should not be extended until such time as this broader range of knowledge is attained. The current curriculum is simply not fit for purpose for the extended technician roles within the community setting.

Question 11.

Do you agree with the distinctions between the proficiencies of pharmacists and pharmacy technicians?

- [ ] Agree
- [x] Disagree
- [ ] Unsure

Comments:

The distinctions between the proficiencies of pharmacists and pharmacy technicians need to be defined in a better way. Generally speaking as long as the difference between both the education and responsibility of both parties is recognised and clearly defined, then each party can contribute well to patient service and safety.

However, the boxing off of proficiencies is an approach that is incredibly rigid. Delegation is based on trust and knowledge of specific individuals and how they work within a specific environment. For locums, it is especially important that this isn't merely reduced to a tick box set of criteria. We need to know the level of tasks that can be safely delegated and this can only be done by observing staff and then assess based on evidence as to how diligently they carry out roles.

General Comment

We dislike the term 'pharmacy professionals'. There are commercial businesses which refer to the 'pharmacy family' for their own commercial purposes. We would prefer to specify 'pharmacists', 'pharmacy technicians' or 'registrants'. There is a danger otherwise that the public will not understand the difference between the various members of the 'profession' or 'family'.

Question 12.

Do you agree that knowledge programmes for pharmacy technicians may continue to be delivered outside national frameworks provided that they have been accredited by the GPhC as delivering equivalent outcomes?

- ❑ Agree
- ■ Disagree
- ❑ Unsure

Comments:

Members have often stated that they have little confidence in the training of community technicians which is in stark contrast to that which is undertaken by hospital technicians.

All pharmacists have to rely on their technicians and, more importantly, rely on them knowing when to refer problems. Much of the lack of trust of these systems comes from the fact that there seems to be little external check on whether the trainee technician is actually producing their own work or whether they are being 'helped' in doing so by owners and managers. The same is true of counter staff who are often the first point of contact for the public within the community pharmacy.

There is now a nationally recognised framework for final accuracy checking of dispensed items for pharmacy technicians. A role nominated as an 'Accuracy Checking Technician' is developing in community practise. Our view is that the training, qualification and revalidation of any checking roles should be robust and standardised. The current lack of rigorously enforced, professionally regulated and nationally standardised, externally assessed training, qualification and revalidation makes it very difficult at present in particular for locum pharmacists like ourselves to be able to have complete faith and trust in delegation to an unfamiliar ACT; particularly when it is the responsible pharmacist who will be held to account if an error is made.

From a locum point of view a copy of an up to date portfolio containing current qualifications of ALL staff in each pharmacy would be preferential and available for scrutiny by the regulator.

Question 13.

Do you agree that pharmacy technicians must be able to apply a general knowledge of clinical and pharmaceutical science?

- ❑ Agree
- ■ Disagree
- ❑ Unsure

Comments:

The distinctions between the proficiencies of pharmacists and pharmacy technicians need to be defined in a better way than proposed. It is always beneficial for a job holder to understand the context of their work and technicians should be no different. However the educational standards for technicians will have to be significantly changed to accommodate this level of knowledge (particularly in the community sector) and on the understanding that such acquisition and application could only be under the supervision of a pharmacist.

Question 14.

Do you agree that undergraduate education and pre-registration should be integrated?

- [x] Agree
- [ ] Disagree
- [ ] Unsure

Comments:

We have no basic objection provided that the science base and funding of the degree course are not compromised and that such a fundamental change to pharmacist training is based upon sound evidence and is adequately resourced.

Question 15.

Do you agree that the standards should be based on an increased clinical role for pharmacists?

- [ ] Agree
- [ ] Disagree
- [x] Unsure

Comments:

The standards should be broad enough to encompass different roles not necessarily exclusive to patient facing activities; neither should it be assumed that pharmacists will lose their science basis in favour of unspecified clinical roles. The increased clinical role for pharmacists should still be underpinned by a strong science base. The standards should evolve with this increasingly clinical role but the proposed standards format because of their lack of aspiration will hinder this process.

Question 16.

Do you agree that delivering these standards will require changes to assessment at undergraduate level?

- [x] Agree
- [ ] Disagree
- [ ] Unsure

Comments:

Increasing the clinical component of the undergraduate degree will require a significant increase in resources (per student) and probably a reduction in the total numbers of students that are taught.

Question 17.

Do you agree that together, the standards and framework provide a comprehensive approach to CPD, in line with the Pharmacy Order requirements?

- ❑ Agree
- ■ Disagree
- ❑ Unsure

Comments:

This seems to be more concerned with the process rather than the value of CPD. The whole purpose of CPD is to ensure the continual lifelong professional development of practitioners. CPD should be an integral part of any role extension (for example new service development), but the standards fail to address this.

Question 18.

Do you agree that registrants, regardless of their scope of practice, should record some CPD that relates to their ability to practise according to the GPhC standards of conduct, ethics and performance?

- ❑ Agree
- ■ Disagree
- ❑ Unsure

Comments:

Standards of conduct, ethics and performance are fundamental to registrants' work but not a separate subject for CPD. We would also reiterate our concern that the standards have now changed from what was a widely understood and appreciated Code of Ethics for no apparent good reason.

Question 19.

Do you agree that there should be a return to practice requirement after two years out of practice?

- ❑ Agree
- ■ Disagree
- ❑ Unsure

Comments:

This is too rigid and does not draw a distinction between a registrant who has made every effort to keep up to date with relevant CPD and one who has not done any CPD during their period of being out of practice. Part of being a professional is knowing what you have to do to remain safe in practice.

If a rigid time frame must be imposed, we would want to see an evidence based approach as to how any rigid time figure is arrived at. This issue also needs to be approached with the knowledge that the majority of undergraduate students and new registrants are women.

Question 20.

Do you agree with the proposed return to practice and updating requirements?

- ❑ Agree
- ■ Disagree
- ❑ Unsure

Comments:

Whilst we agree that there needs to be a standards requirement before a registrant returns to practice we are concerned that the mechanisms proposed are too rigid and may be discriminatory against women pharmacists. More thought needs to go into alternative mechanisms. For example if a registrant can demonstrate that they have been practising under supervision for a minimum number of days during the period.

6. References

(1) Steve Churton, Pharmaceutical Journal (Online Only). 24.09. 2009 http://www.pjonline.com/news/rp_guidance_published?page=2#comment-1734

(2) Good doctors, safer patients, A report by the Governments Chief Medical Officer, Sir Liam Donaldson

(3) Design for patient safety A guide to the design of the dispensing environment, Edition 1, 2007. The National Patient Safety Agency

(4) The Pharmacy Order 2009

(5) Skill mix in community pharmacy: exploring and defining the roles of dispensary support staff. A report presented to the Pharmacy Practice Research Trust in 2004 by Dr Rachel Mullen, The University of Manchester

(6) Patient Safety in Community Pharmacy: Understanding Errors and Managing Risk, Darren Ashcroft, Charles Morecroft, Dianne Parker, Peter Noyce. School of Pharmacy and Pharmaceutical Sciences & Department of Psychology, University of Manchester

(7) GMC Today, Nov/Dec 2009 issue

(8) Extract from letter by a technician to the, The Pharmaceutical Journal 27.11.2009

(9) PJ Online (no printed version) 10.12.2009 ….. http://www.pjonline.com/news/pharmacies_ideally_placed_to_help_selfcare

(10) Which Investigation on Pharmacy 2008 http://www.which.co.uk/advice/pharmacists/undercover-operation/index.jsp

(11) Which Response to Pharmacy in England, Building on strengths - delivering the future DoH Consultation Response.

(12) Professor Peter Noyce, addressing the Guild of Healthcare Pharmacists and UK Clinical Pharmacy Association conference, 2008. Hospital Pharmacist 2008; 15:220-224

(13) Professor Anthony Smith, addressing the Guild of Healthcare Pharmacists and UK Clinical Pharmacy Association conference in 2008. Hospital Pharmacist 2008;15:220-224

(15) Bob Nicholls Interview, The Pharmaceutical Journal 2009;283:244

(16) Modernising Medical Careers for Non-Consultant Career Grade doctors. Department of Health

References cont.

(17) Professor Ian Bates Head of Education Development, London School of Pharmacy, New issues in Pharmacy Education, European Association of Faculties of Pharmacy, Lille 2008

(18) Enhancing Confidence in Healthcare Professional Regulators - Niall Dickson's final report and DH response to the recommendations, Department of Health 2008

(19) A Vision for Pharmacy in the New NHS. Dept Health 2003

(20) MR JAGJIWAN 'JAGGY' KHELA, ENB Candidate Dec 2009 http://www.pjonline.com/forum/workplace_pressure_0?page=#comment-2334

(21) The implementation of Medicines Use Reviews (MURs) in community pharmacy – Emerging Findings Gianpiero Celino, Webstar Health in a presentation to Primary Care Commissioning

(22) Determinants of the uptake of medicines use reviews (MURs) by community pharmacies in England: A multi-method study,
Health Policy Volume 88, Issues 2-3, December 2008, Pages 258-268

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