by the Pharmacists' Defence Association

Consultation

General Pharmaceutical Council - Draft Standards

May 2010

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pda the pharmacists' defence association

The Response of the Pharmacists' Defence Association (PDA)

The Pharmacists' Defence Association is a not for profit organisation which is a defence association and 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 risks 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.

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Consultation on Revised Standards

Reprise

When the first consultation on draft standards was conducted the PDA submitted a comprehensive and detailed response. We made twelve firm recommendations which we believe are essential in developing a regulatory framework that is fit for the future, fulfils the regulator's duty to protect the public and provides a basis for development of the profession of pharmacy. These recommendations are repeated in Annex A and a full copy of the report is available on request.

Response

This latest iteration of the standards is an improvement on the previous standards in that they are written in a more consistent format and are better drafted. We welcome the GPhC's commitment to further development of the standards, in the longer term, for Continuing Professional Development and owners, superintendent pharmacists and pharmacy professionals in positions of authority and we look forward to full and open involvement in the process.

However most of the concerns we raised in our previous response remain; the re-drafting has failed to address the fundamental issues. Although we recognise that these are interim standards, we are concerned that none of our recommendations appear to have been adopted and we stand by our original recommendations.

We believe that all of the standards need more work and we believe that all areas should be subject to further long term development.

The opportunity for the GPhC to signal a different approach and to inspire the profession through setting new and innovative standards that create the framework for development of the quality of patient centred services will be lost if ultimately the old standards set by the RPSGB are promulgated.

While we understand that the Council for Healthcare Regulatory Excellence is seeking to provide consistency in the regulation of professions we believe that GPhC can and should set an example in how a modern regulator can fulfil the values set by the CHRE;

fairness by applying more equal weighting to the duties of the employer as well as the individual.

patient and public focus by recognising the pace of change and the move from the supply of products to the provision of services in the practice of pharmacy and facilitating progress while ensuring safety and quality.

proportionality by fully considering risk to and impact on patients, the public, professionals and their employers.

transparency by making all of the decision making process open to public scrutiny.

agility by having a thorough understanding of the profession and responding quickly where regulation needs to be modified.

adding value to regulation by focusing on the broader aspects of value to the public and the profession rather than the economic value to pharmacy owners.

Summary of Recommendations

We made twelve strong recommendations in our previous response. We hold to those recommendations.

In considering our response to this consultation it has become clear that a more fundamental review of the regulatory framework is required. For that reason we have added to our list; the following 14 recommendations to further strengthen our recommendations made in the last consultation.

1. The GPhC should carry out further work on standards with a view to facilitating the new roles for pharmacists.
2. Standards for the supply of medicines and the delivery of services should be considered separately.
3. The GPhC should consider how it will create a regulatory framework that will deliver the standards of patient safety embodied in the ECJ ruling
4. An urgent professional debate to establish the professions view on supervision needs to be supported by the GPhC and the resulting view needs to be fed into the regulatory frameworks.
5. The development of the Supervision regulations must also include a fundamental review of the Responsible Pharmacist regulations and the standards that underpin both.
6. Provisions within the RP regulations that allow short absences from the pharmacy should be carefully reconsidered to ensure that they can be operated for the benefit of the public and not for commercial gain.
7. Consultation on and development of better standards of Clinical Governance should be initiated.
8. The GPhC must ensure that it takes a balanced view on the inputs of all stakeholders; all have a view in the vision for pharmacy but no view should be given disproportionate weighting.
9. The GPhC should look towards creating standards that shape a different model of healthcare delivery for pharmacy.
10. The GPhC should undertake a fundamental review of how regulation is used, to ensure that it is primarily to promote the interests of patients rather than to protect the profitability of the corporate multiples.
11. The GPhC should consider how it could support the development of a pharmaceutical care model to complement the supply model.
12. The GPhC should have regard to contractual issues in as much as they impact upon the development of standards and/ or the delivery of standards.
13. The GPhC must develop standards that unambiguously support pharmacists to enable them to exercise professional independence for the benefit of patients and should consequently issue guidelines to owners and directors of pharmacy companies indicating to them what their responsibilities are in this respect.
14. The GPhC should consider the registration of non pharmacist owners and directors in order that they can be required to comply with standards and that people exercising their delegated authority can be held to account.

Strategy for Patient safety – The Pharmacist as Practitioner

The separation of the regulatory and leadership functions of the RPSGB and the creation of the GPhC are significant developments in the process of change for pharmacy in the UK. These are exciting times with the profession developing at a pace and scope that we have not seen before.

The drivers of change are many and varied and we are mindful of the investment that individuals, professional and academic organisations, commercial companies and other stakeholders are making in driving that change. Investment encompasses intellectual and emotional capital as well as finance and it is important that the right balance is struck between different interests.

Although we as the PDA act as a representative of individual pharmacists we believe that a balanced approach must be taken that allows for compromise between the needs and objectives of all stakeholders – no matter what form of capital they have invested.

It is our view that the historical supply function of pharmacy is largely reliant on capital investment and that those who invest financial capital should enjoy a satisfactory return on their investment. However, we believe that the provision of primarily clinical services for patients, rely increasingly on the intellectual and professional investment of individual pharmacists and that this too must secure a proper return on that investment.

We believe that it will be necessary to properly reflect these dynamics for the maximisation of patient benefit and safety. We believe that it is necessary to create a model for pharmacy that allows the supply function to sit alongside the provision of quality services and that we need a regulatory framework that supports that concept.

1. Consistency & differences of regulatory frameworks

While a consistent regulatory framework may be desirable across the professions it is important to recognise that they do not all operate in the same way because their respective business models are differently structured. This results in the professionals involved interacting with the patients and the public in differing ways. The section 60 order provides a consistent framework for the regulation of the professions but also allows for differences. Standards for pharmacy must recognise the uniquely different style of pharmacy operation, because of that they will invariably need to be different from those standards seen elsewhere.

Superficially Opticians & Dentists for example have many similarities with Pharmacists in that each profession has extensive training requirements; is registered with a General Council; the healthcare professional leads a team some of whom may be registered and some of whom are not; and all allow bodies corporate to operate practices. On the surface, a general approach to regulation appears logical and we understand why there is similarity in the way that standards have been drawn up within areas which are consistent across the professions. However there are significant differences in the way that the professions operate which must be fully understood if the GPhC wishes to develop the "right touch" regulatory framework for pharmacy.

The Dentist or Optometrist sees a relatively small number of patients each day and will spend some time with each providing an individual service on which a care plan may be based. Other members of the team may then implement areas of the care plan, providing additional services or selling products that satisfy the requirements of the care plan.

The average pharmacy will service several hundred patients every day and traditionally the Pharmacist will have a direct interaction with very few of them. The majority of the contact with patients has come through other members of the team with the pharmacist intervening directly with the patient when there is need for him/ her to do so.

However the profession is changing with pharmacists increasingly providing services directly to individual patients or groups of patients. These changes are driven by the needs of patients, developments within the profession and the way that government wishes to use a valuable, accessible and underutilised set of skills and competences held by the pharmacist. The direction of travel is therefore for the pharmacist to take on roles more akin to those of, say, a dentist or optometrist providing clinical services to individual patients.

The GPhC needs to create a regulatory environment that recognises and enables pharmacists to provide more services on a one-to-one basis, providing sufficient flexibility for development while ensuring the pharmacists' vital role in ensuring the safe supply of medicines is maintained.

Sadly these standards do neither. They simultaneously reflect the traditional model of pharmacy while creating the potential for the removal of the pharmacist from the dispensing process altogether.

The standards as presented do not support development of new roles for the pharmacist. Paradoxically, they appear to allow registered technicians to take on more of the work of the pharmacist so that the pharmacist can be absent. Neither is in the public interest.

1. **The GPhC should carry out further work on standards with a view to facilitating the new roles for pharmacists.**
2. **Standards for the supply of medicines and the delivery of services should be considered separately.**

2. Learning from Europe

In considering these Standards we should take into account relevant and recent case law. The most important judgement, given as recently as May 19th 2009, are the cases heard in the highest European court the European Court of Justice (Case C-531/06 and in Joined Cases C-171/07 and C-172/07) regarding the ownership of pharmacies.

In these cases the judges concluded that the system that provides the safest system for the protection of the public is one in which pharmacists own their own pharmacy.

The Standards presented in this consultation have therefore to be considered against a background of a system in GB in which the majority of pharmacies are not owned by pharmacists and are thereby in the view of the ECJ not operated in a way that is the safest for the public.

3. The GPhC should consider how it will create a regulatory framework that will deliver the standards of patient safety embodied in the ECJ ruling.

3. Patient safety through professional centred practice

Healthcare needs continue to grow ahead of the resources needed to meet them and the development of the role of the pharmacist is vital in improving access, choice and quality of healthcare services. Through significant professionally led 'ask your pharmacist' campaigns going back many years, the public have been instilled with the knowledge and the expectation that the pharmacy is a place that they can expect to consult a pharmacist without an appointment.

Removing the pharmacist from the pharmacy, devalues the vital services that pharmacies provide to the public and places greater risk on patient safety.

The model of pharmacy practice that supports the absence from the pharmacy of the pharmacist is significantly flawed. It does not secure the confidence of the profession, nor does it improve patient safety. Patients want and need services to be delivered from their pharmacy when they need them and this can only be done when the pharmacist is on the premises. Most importantly, as the person accountable for safety, the pharmacist must ensure that patients are not put at risk. We firmly believe that these objectives will only be met if the pharmacist is present in the pharmacy.

The Responsible Pharmacist regulations have already created the potential for a pharmacy to operate without a pharmacist – albeit for short periods of time. These regulations were written without the consideration of the regulations for supervision which we consider a mistake.

An urgent professional debate to establish the professions view on supervision needs to be supported by the GPhC and the resulting view needs to be fed into the regulatory frameworks.

The old RPSGB standards have been modified and adapted to take in to account the current Responsible Pharmacist (RP) regulations, but experience has shown that these (RP) regulations are significantly defective in a number of ways. In particular, the provisions within the RP regulations that allow short absences from the pharmacy should be carefully reconsidered to ensure that they can be operated for the benefit of the public and not for commercial gain.

Consequently, it is essential that consideration of the Supervision regulations also include a comprehensive overhaul of the Responsible Pharmacist (RP) regulations and the standards that are needed to support both.

The current regulatory framework and that which will be promulgated by these standards, results in a "tick box" approach with every action being driven by a centrally constructed protocol. There is little recognition of the difference in the needs of individual patients and operationally, through employment custom and practice, there is minimal scope for pharmacists to tailor their service according to those needs. This needs to change. The pharmacist must be enabled to practice with professional autonomy at the centre of the service with the needs of the patient as his/ her focus.

Nowhere is this more obvious than with clinical governance. Too often clinical governance is seen as an exercise in paperwork delegated to a junior member of staff with no power to require changes to be made. Worse still, the role of clinical governance lead can be allocated to an individual with no knowledge of pharmacy or of clinical governance. For the sake of patient safety the pharmacist must take a more central role.

4. **An urgent professional debate to establish the professions view on supervision needs to be supported by the GPhC and the resulting view needs to be fed into the regulatory frameworks.**
5. **The development of the Supervision regulations must also include a fundamental review of the Responsible Pharmacist regulations and the standards that underpin both.**
6. **Provisions within the RP regulations that allow short absences from the pharmacy should be carefully reconsidered to ensure that they can be operated for the benefit of the public and not for commercial gain.**
7. **Consultation on and development of better standards of Clinical Governance should be initiated.**

4. The impact of the multiples' business model on pharmacy practice

Multiple pharmacy operators have become increasingly influential as regards the pharmacy agenda in recent years. We are concerned that as a result, regulation now overtly supports their business model and even protects the value of their companies. They emphasise their size and importance in the market – between them they own the significant majority of community pharmacy contracts. Furthermore they multiply their voice through lobbying individually; collectively as the Company Chemists Association; as contractors through control of the National Pharmacy Association; and through being the strongest voice on the Pharmaceutical Services Negotiating Committee (PSNC). This year they also take effective control of Local Pharmaceutical Committees (LPCs) as LPCs adopt new constitutions.

It must be understood that whilst the multiple pharmacy organisations are an important stakeholder within the profession, they or their representative organisations are not the voice of pharmacy. Furthermore, it is evident that they are the voice of their shareholders and their capital.

In the traditional model of pharmacy the value of the business is enshrined in its contract with the NHS; value is driven by forcing higher prescription volumes through fixed resources – in particular the pharmacist. This places considerable strain and workplace pressure upon the pharmacist, a fact that in itself is now recognised as a serious professional issue.

The premises centred volume driven model inhibits the development and adoption of new patient centred services. The corporate multiples derive their profits from promulgating the traditional model of pharmacy and have funnelled funding for new services through a volume based mechanic at the expense of quality. Medicines Use Reviews (MURs) were designed as a service provided by the pharmacist to help patients get the most out of their medicines. The reality is that increasing numbers of MURs are conducted as a result of targets set by the head offices of the multiple pharmacy chains – targets that impact on the pharmacist and add to the pressure that they experience on a day to day basis. The impact on corporate multiple profitability of this approach is amply illustrated in the 2009/10 annual report of Alliance Boots, where a specific section celebrates the additional income derived through MURs.

This model has driven conflict between pharmacists who have invested intellectual capital in learning new skills and developing new competencies and employers who have volume driven targets. The result is that quality has suffered and patients are not receiving the standard of care that they need.

8.	**The GPhC must ensure that it takes a balanced view on the inputs of all stakeholders; all have a view in the vision for pharmacy but no view should be given disproportionate weighting**
9.	**The GPhC should look towards creating standards that shape a different model of healthcare delivery for pharmacy**

5. The individual pharmacist contract

The GPhC is required to regulate in accordance with the Hampton principles which include the statement that "regulators should recognize that a key element of their activity will be to allow, or even encourage, economic progress and only to intervene when there is a clear case for protection". We believe that the regulator must fully understand the business models that operate and changes that will result from development of the profession.

We would emphasise that the requirement is to *allow economic progress*; this is not synonymous with the protection of the profitability of big business.

We contend that the best value for the NHS and the best protection of the public would be for contracts for services to be provided for individual pharmacists. In this way more emphasis would be placed on the suitability of the pharmacists to deliver services; greater scrutiny over delivery would be achieved; and patient safety would be enhanced through clearer focus of accountability and speed of response.

In practices that are clearly led by a registered professional, such as dentists or optometrists, much of the value of the business is dependent on the skills and competences of the professional. It is the work of the dentist or optician to initiate care and additional value is created by providing higher value products and services that patients need and want. The relationship between the professional and the patient is developed over time and it is the trust in the skills of the professional that create the environment to add value.

As pharmacists become involved in the delivery of clinical services that are dependent upon the skills of the individual they will take on more of the characteristics of other professions; the value of the business will become increasingly dependent on the individual pharmacist. The corporate multiples may believe that a drive towards quality services delivered by individual pharmacists could result in a threat to their profitability. It is apparent that they continue to steer development away from quality services delivered by individual pharmacists and towards volume related protocol driven activities provided from the contracted premises.

This is not in the public interest nor does it promote quality or patient safety. High quality safe services will be delivered by pharmacists who are well trained, have time to understand the needs of the patient, tailor their service accordingly, and can audit their practice effectively. This will not be delivered in the volume based target driven business model operated by the corporate multiples.

A different model is required and we believe that this should be a pharmaceutical care model that sits alongside the supply function but in a way that is not dependent upon it. Both of these elements would be contractually recognised, one with the pharmacy owner, for the supply of products, the other with the individual pharmacist, for the provision of services. This would ensure that patients received the best pharmaceutical care while ensuring continuity of the supply process. It would also result in greater continuity of care and service provision as pharmacists providing the clinical services would be able to work within a framework that develops direct relationships with their patients and be rewarded according to the quality of the service they provide. This model would stimulate the development of professional "consulting pharmacists" – pharmacists who are contracted to provide services at a number of pharmacies. In this way continuity and patient safety would be further enhanced.

The draft standards support the current business model and do not create the environment for development and growth. The GPhC should undertake a fundamental review of how regulation is used, to ensure that it is primarily to promote the interests of patients rather than to protect the profitability of the corporate multiples.

10.	**The GPhC should undertake a fundamental review of how regulation is used, to ensure that it is primarily to promote the interests of patients rather than to protect the profitability of the corporate multiples.**
11.	**The GPhC should consider how it could support the development of a pharmaceutical care model to complement the supply model.**
12.	**The GPhC should have regard to contractual issues in as much as they impact on the development of standards and/ or the delivery of standards**

6. Owners of businesses employing registered professionals

Pharmacy is not alone in having a strong corporate sector; bodies corporate operate dental and optical practices. However there are notable differences in the way that body corporates are treated and operate between the professions.

Over 50% of pharmacies in the UK are owned by just nine companies. Of these four are supermarket chains for whom pharmacy is a small part of their business that is used to drive customer footfall; three are vertically integrated wholesale chains with pan European reach and very large scale; one is part of an Asian conglomerate; and one is part of a broadly based UK general retail chain. All seek to drive up the profitability of their pharmacies through volume and efficiency.

This is manifest through the imposition of multiple Standard Operating Procedures, tight staffing models and volume related targets. None can be said to be dedicated to the development of UK pharmacy and their primary corporate focus will not be that of patient interest.

In the dental profession a number of Dental Body Corporates (DBCs) operate dental practices. While corporate dentistry is not widespread controls on the DBCs are in place to ensure that they are professionally led and that the freedom of the individual dentist is not compromised. The GDC requires the majority of the directors of a DBC to be registered dentists or registered Dental Care Professionals (DCPs), or a combination of dentists and DCPs.

The GDC has also issued clear guidance to people in a management position which includes the following

> *2.1 As a director, owner or manager within an organisation, you are in a position to influence the way in which the organisation works and the way in which the people within it work. You have a responsibility not only to follow the principles in 'Standards for dental professionals' yourself, but to promote them to other people within your organisation.*
>
> *2.3 All members of the dental team who have to register with us are individually responsible for their own actions and for the treatment or processes which they carry out. Make sure you do not take any action that may affect the ability of any people you have authority over to follow the principles in 'Standards for dental professionals'.*

The opticians market has more prevalent chains and a greater degree of corporate identity than the dental profession but it is still somewhat short of the level of corporatisation that is seen in pharmacy.

However, with one exception, the optician chains are dedicated to optical practice and they are franchised; this means that the branding, marketing and buying are centralised but the running of the outlets is the responsibility of the optician who owns the franchise. Thus the impact on the practice of the professional of the actions of the body corporate is minimised. One large chain is owned by a large multinational which also operates pharmacies; however even in this organisation about a third of its outlets are franchised and the influence of the body corporate is less pronounced.

The GOC also enshrines the freedom of the professional in its code of conduct for business registrants as follows:-

> *Business registrants play an integral part in the provision of optical services and products to the public. Patients, consumers and professionals must be able to trust business registrants to maintain and support a good standard of clinical practice and care.*
>
> - *To justify that trust, a business registrant will take reasonable and proportionate steps to ensure that each person who undertakes activities regulated by the Opticians Act does so in accordance with the Act;*
> - *not knowingly act in a way which might contribute to or cause a breach of the Code of Conduct for Individual Registrants by any individual registrant employed or otherwise engaged by it to provide optical services;*
> - *ensure that individual registrants are always able freely to exercise their professional judgement in the best interests of patients;*

Furthermore the European Court of Justice considered the difference between the ownership and operation of opticians and pharmacies in its judgement 19th May 2009 *Case C-531/06* in which it stated;

> *Given the particular nature of medicinal products and of the medicinal-product market, and as Community law currently stands, the Court's findings in Commission v Greece cannot be transposed to the field of the retail supply of medicinal products. Unlike optical products, medicinal products prescribed or used for therapeutic reasons may none the less prove seriously harmful to health if they are consumed unnecessarily or incorrectly, without the consumer being in a position to realise that when they are administered. Furthermore, a medically unjustified sale of medicinal products leads to a waste of public financial resources which is not comparable to that resulting from unjustified sales of optical products*

Sadly the draft GPhC standards for owners and superintendents do not place similar restrictions on the corporate owners of pharmacies. Owners of pharmacies do not have to have any connection with the profession and there does not have to be a professional on the board. It is difficult to see how the GPhC could enforce even the meagre standards that it places on the board when board members do not have to be registered and no sanctions can be applied.

Reference to the ECJ ruling may indicate a way forward but in the interim we believe that the GPhC needs to consider the position of owners and directors as a matter of urgency.

Unlike the GDC and the GOC the GPhC draft standards do not seek to ensure that the individual practitioner is free to exercise his/ her professional judgement. Instead the draft standards tie down the individual pharmacist to follow centrally formulated policies and procedures even though (s)he will not have been party to their development and is unlikely to be notified of factors taken in to account or that influence day to day operation. This fact is of great concern to us and ultimately is not in the public interest.

Schedule 1, paragraph 6.2 of the 2010 Pharmacy Order gives the regulator the right to make guidelines for the (non pharmacist) owners of pharmacy businesses and we are concerned that up to now, the regulator has failed to use these powers. The GPhC must develop standards that unambiguously support pharmacists to enable them to exercise professional independence for the benefit of patients and should consequently issue guidelines to owners and directors of pharmacy companies indicating to them what their responsibilities are in this respect.

We argue that the powers should be extended to the extent that (non pharmacist) owners and directors should be registered so that they can be called to account should they, or people operating under delegated powers, fail to meet the standards or breach the code of conduct.

13. The GPhC must develop standards that unambiguously support pharmacists to enable them to exercise professional independence for the benefit of patients and should consequently issue guidelines to owners and directors of pharmacy companies indicating to them what their responsibilities are in this respect.

14. The GPhC should consider the registration of non pharmacist owners and directors in order that they can be required to comply with standards and that people exercising their delegated authority can be held to account.

7. Responsibility, accountability and control

The inertia and influence of the corporate multiples have significantly shaped current pharmacy practice and the impact of this is evident in the way these standards have been developed. As a consequence they are not serving the public to greatest advantage neither are they "right touch" or fit for the future of pharmacy.

In separating the functions of the RPSGB – a development that we fully supported – substantial changes to the regulatory environment have been made that adversely impact on the individual pharmacist while bolstering the position of employers and making them less accountable.

We argued for a delay in the implementation of the Responsible Pharmacists regulations and our fears have not proved groundless. Far from making the pharmacist "responsible" for the running of a pharmacy they have made him/ her accountable but have taken away much of the responsibility.

In the UK we have system whereby each pharmacist must be accountable for their own practice, a system where Superintendents are responsible for the actions of unregulated owners, a new law that states Responsible Pharmacists must ensure the safe and effective running of all aspects of the pharmacy they happen to be running at the time, no matter how short that time is, all of whom the European Court of Justice say may be subjected to unreasonable commercial pressure.

In the Standards for pharmacy owners, superintendent pharmacists and pharmacy professionals in positions of authority it states:-

"If you are a pharmacy professional in a position of authority in a retail pharmacy business, you must make sure that the standards are met where it is your responsibility and within your power to do so."

This paragraph appears to have been taken from the 2007 code of ethics where it was clearly associated with the duties of the pharmacist in control of a pharmacy. In that context it meant to the individual that:- "You are professionally accountable for your practice. This means that you are responsible for what you do or do not do, no matter what advice or direction your manager or another professional gives you. You must use your professional judgement when deciding on a course of action and you should use our standards as a basis when making those decisions."

"You" is clearly defined as the pharmacist in control and it is up to the individual to discharge his/ her duties as (s)he sees fit

In the context of the draft standards "*you*" may refer to the superintendent; the Responsible Pharmacist; a pharmacist who isn't the Responsible Pharmacist; or a registered technician. So "you" becomes an indefinite term. An additional level of complexity is added by the term "*where it is your responsibility".* Previously it was the responsibility of the pharmacist in charge but now responsibility may lie with the Superintendent, the Responsible Pharmacist; another pharmacist or a technician; often it is not clear where responsibility actually lies. Where Responsible Pharmacists seek to take on this responsibility it is often challenged and overruled by more senior management who may not be pharmacists.

The final part of the paragraph in the draft standards also seems to imply that you do not need to make sure that standards are met if you do not have the power to do so. This seems to be in conflict with the code of ethics but more importantly this revolves around who in reality has the power. Do Superintendents have the power to overrule Boards? Do Responsible Pharmacists have the power to overrule the Superintendent or non pharmacist Area Managers? Who in the UK in reality in many circumstances does actually hold the power; the Responsible Pharmacist or the non pharmacist owner?

Although these standards seek to provide a clear framework for safe practice they fail to do so; they provide a checklist to allow pharmacy companies to claim compliance without requiring them to take appropriate action or give the Responsible Pharmacist the authority to address issues directly. The RP is the individual who is held accountable if there is an incident in the pharmacy although (s)he may have had no influence on the design of the pharmacy, its operating procedures or staffing levels. In fact the RP has accountability without real responsibility – the worst possible combination of circumstances, one which inevitably leads to tension and stress.

We will not comment in detail at this stage, reserving our input for the further development of standards; however to illustrate just a few examples from the cases which arise on a daily basis:

Example 1

It is current practice amongst large employers to set pharmacists targets of achieving two Medication Usage Reviews (MURs) per day. Failure to meet these targets, reviewed often by non pharmacist managers, on many occasions, leads to performance review sanctions and disciplinary action. The pharmacist's professional judgement and their concerns expressed relating to the Code of Ethics are ignored by disciplining managers who can not appreciate the significance of their concerns for patient safety. Superintendent pharmacists tend not to intervene and are complicit in the way they are reluctant to become involved in the process. Further evidence is self-evident in the letter columns of the Pharmaceutical Journal during April and early May where there were unprecedented comments on the way pharmacists are being forced into completing MURs irrespective of quality or necessity.

Example 2

A pharmacist was dismissed from an large pharmacy multiple for not following the company SOP even though it was acknowledged in her letter of dismissal that in exercising her professional judgement "she had acted in the patient's best interest".

Example 3

A pharmacist was dismissed by a large supermarket chain when acting within her professional capacity as the Responsible Pharmacist, for failing to comply with her employers "respect for others" policy. She refused to accept a specific member of staff who the organisation wished to foist upon her as a trainee dispenser on the grounds that she believed that she did not have the competence to be able to perform to acceptable levels of competence and would compromise patient safety.

Example 4

On more than one occasion the PDA has dealt with pharmacists who have been victimised by their manager about whom they have grieved to the Superintendent pharmacist because they (the line manager) have operated outside their authority in respect of the RP regulations and forced their commercial imperative on the pharmacist. One such example was where the pharmacist decided to close down the pharmacy operation until they could be sure that it was a conducive environment in which to provide a safe service.

Example 5

The superintendent pharmacist of a large multiple informed all of the company's Responsible Pharmacists that they were to ignore the definition of 'retrospective sign-on' issued by the regulator and to use the definition proffered by the company. This enabled the abuse of the RP regulations in order to keep the pharmacies operational in the manner to which they had been accustomed before the RP regulations were introduced. This of course left pharmacists in the impossible position of whether to follow instructions of the senior pharmacist in the organisation and risk the wrath of the non pharmacist managers who did not know better or disobey the Regulators unequivocal guidance.

Example 6

The PDA requested that the Regulator investigate our claims that a large supermarket chain and its superintendent had (amongst other things) failed to respond to system failures or concerns, coerced pharmacists into long working hours without breaks, thereby affecting patient safety, and undermined public confidence in the profession. In response the Regulator refused to investigate and left the onus of further investigation on the PDA when they wrote

> *"…you anticipate that our investigation will resolve a number of broad professional issues regarding employer's responsibilities and good working practices. It is not denied that such issues are of concern and do need resolving but we do not believe that it is the fitness to practice processes are the right or appropriate instruments in achieving the outcome you are hoping for….."*

Response to Consultation Questions

Question 1

We propose to use the RPSGB's Code of Ethics for Pharmacists and Pharmacy Technicians as the basis for these standards. Do you agree?

Not sure. We believe that the proposal is to use the current code of Ethics until such time as a full review can be undertaken. We believe that these are regarded as interim standards and that a full review is carried out encompassing the objectives of the standards framework without delay

Question 2

We have revised the standards so that they are easy to read and use. Are the standards easy to read and use?

Not sure. The standards are more readable and, in that they follow the existing RPSGB standards, but we will not know whether they are easier to use until they are actually in use. However we contend that they are still not "right touch" and encompass many areas that are difficult to achieve in practice

Question 3

We propose to adopt the RPSGB's existing CPD standards for an interim period. Do you agree?

Not sure; we have no commitment to a timescale and no definition of what an interim period means.

Question 4

We propose to use interim standards that are based on the RPSGB current standards and policy. Do you agree?

Not sure. We understand that that these are regarded as interim standards and that a full review is carried out encompassing the objectives of the standards framework. However we would want to see commitment to a process and a time frame to achieve this.

Question 5

We have revised the standards so that they are easy to read and use. Are the standards easy to read and use?

Not sure. The standards are more readable and, in that they follow the existing RPSGB standards, but we will not know whether they are easier to use until they are actually in use. However we contend that they are still not "right touch" and encompass many areas that are difficult to achieve in practice

Question 6

The standards are outcome focused and less detailed than the RPSGB standards. Do the standards cover all essential areas?

No. We believe that in certain areas they are deficient while being more prescriptive and detailed than they need to be in other areas

Question 7

The standards apply to pharmacists and pharmacy technicians who are leading teams or managing the day-to-day business of a retail pharmacy. Is this clear?

No. We do not understand why they only appear to apply to "retail" pharmacy and in community pharmacy the responsibility for leading the team falls to the Responsible Pharmacist not a registered technician. It must be clear that a registered technician cannot take precedence over a Responsible Pharmacist

Question 8

We propose to adopt the RPSGB's current education standards and accreditation procedures for pharmacists for a transitional period to allow us to continue to accredit courses. Do you agree?

Yes

Question 9

We propose to adopt the draft standards of initial education and training for pharmacy technicians. Do you agree?

Yes

Question 10

We have the revised the standards so that they are easy to read and use. Are the standards easy to read and use?

Yes

Question 11

Should there be some flexibility within the curriculum requirements for competency based qualifications for pharmacy technicians to reflect differences in practice and the geographical locations within which trainees work?

Yes

Question 12

We have provided a single glossary for all the standards. Is the glossary comprehensive and easy to read?

Not sure. We believe that the majority is clear but additional clarification is required as to who "you" refers to in standards for pharmacy owners, superintendent pharmacists and pharmacy professionals in positions of authority; what "responsibility" means in this context; and what "power" means in this context

Question 13

Do you have any other comments you wish to make on the draft standards?

Our general comments precede this section

Annex A

Summary of PDA Recommendations (GPhC Standards Consultation Jan 2010)

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.

Further information is available from:

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