Modernising pharmacy regulation | A Response by the PDA

by the Pharmacists' Defence Association

Consultation

on the draft standards for registered pharmacies

May 2012

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Table of Contents

1. Introduction

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.

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.
- Pro-actively 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 PDA currently has more than 19,000 members and is one of the foremost bodies representing pharmacists. More than any other body we work hard to promote and maintain the interests of pharmacists and provide a counterpoint to the voice of commerce as represented by pharmacy owners.

As a defence association, we handle many defence episodes which emerge because things have gone wrong. During 2011 alone, we handled more than 4,000 such episodes and this volume of activity provides us with insights into their root causes that other organisations may not have. We are very confident that the standards of premises (in all aspects) and especially premises environments are at the root of a substantial proportion of incidents which cause harm to the public. This principle is one that should be ignored by the regulator at its peril.

This is why we ask that the regulator goes beyond its initially stated intentions in regulating pharmacy premises.

2. Executive summary & recommendations

We are generally supportive of the GPhC's broad approach to regulation and the principles set out in this document, however, we believe that in certain respects they do not go far enough. We are concerned that in finalising and implementing the new standards the GPhC must avoid mistakes made previously in pharmacy and in other professions. In particular we are concerned that the GPhC must be especially mindful of the following;

- The independence of healthcare professionals to act in the interests of the patient must be paramount; pharmacists, as healthcare professionals, must be free to act independently. The ownership structure of UK pharmacy militates against. The premises standards are a useful mechanism to ensure that such professional empowerment can be supported, however, we do not believe that the current proposals go anywhere near delivering the level of independence required. Furthermore, in certain areas, they have the effect of placing at further risk the professional autonomy of the pharmacist.
- We have always stated the truism that you cannot govern without consent. The GPhC must itself demonstrate consistency in the way that the standards are implemented, inspected and any alleged breaches are investigated and judged. This is essential if the standards and framework in which they sit are to gain the respect of the profession. However recent experience has failed to demonstrate congruence between the functional sections of the regulator – this issue must be urgently addressed.
- The new standards are an opportunity to address the current SOP led culture that has caused damage to the profession of late and which is beginning to harm the public interest. The GPhC says that it does not want to see a "tick-box" approach to compliance and we agree. However our experience is that more SOPs are the response to any change; this is a "lowest common denominator" approach that does not help develop practice and is used as a way to deflect criticism and accountability away from owners on to individual pharmacists. The standards consultation has stayed relatively silent on the issue of SOP's indicating perhaps that it too recognises limited benefits from such an approach to professional practice. However, we would have preferred the GPhC to have taken a more proactive stance in confirming the contexts in which SOPs should be relied upon and that in the vast majority of cases, the professional judgement of the pharmacist is where the true benefit to patients emerges.
- We believe that this is an opportunity for the GPhC to promote a different way of demonstrating good practice and compliance with standards.
- Risk based compliance assessment is desirable but must be based on appropriate risk assessment skills and management training. Risk is not synonymous with dispensing errors; a prescription dispensed correctly may still be a source of risk to the patient and thus a wider consideration of risk is necessary. Furthermore risk to the patient is most often a result of the system in which actions take place. This approach is a major foundation stone of the GPhC's proposals however, we are yet to be convinced that the GPhC has sufficient knowledge and experience of risk based assessment in pharmacy at the present time to be able to deliver and we know that it is inadequate generally in pharmacy. We believe that the move to risk based assessment must run concurrently with a structured programme of training and development of the necessary skills both within the GPhC and also within the wider profession.
- Moving from a regime that is heavily supported by guidance to one in which guidance is sparse will result in confusion and conflict as it has in other professions.
- Inspection of premises can be a positive force for improvement if results are published and the criteria for decision making are made transparent.
- Under the Responsible Pharmacist (RP) regulations the RP is taken to be responsible for all aspects of the pharmacy for which (s)he takes charge. However the majority of pharmacists have no control over the built environment, operational systems, staffing levels or processes and procedures. We believe that this is an opportunity for the GPhC to address this paradox.

Recommendations

In the further development of standards we believe that the GPhC should;

1. Strengthen those provisions that ensure the independence of the pharmacist
2. Ensure that commercial pressures do not take precedence over professional ethics.
3. Use the powers available to it under the Pharmacy Order to define and demarcate the limits of input and control of non-registrants. In particular it should curtail the power of non-pharmacist managers to change operational parameters to the detriment of patient safety.
4. Clearly separate those elements of the premises that are the responsibility of the owner from those which can be legitimately be said to be in the control of the RP.
5. Ensure that staff profiles are appropriate to the type, volume and profile of the services to be provided and that they are available for inspection at the pharmacy.
6. Provide guidance for pharmacists, owners and superintendents on how standards should be interpreted and met.
7. In particular ensure that certain standards – those that are at the route cause of conflict historically, continue to remain as specific unambiguous and distinct standards and do not become vague principles e.g. Requiring employers to make sure that staff are able to take appropriate rest breaks and that they are encouraged to do so.
8. Work with the profession to improve risk assessment and management skills through the undergraduate programme and post graduate CPD.
9. Seek more input from professional and representative bodies on what constitutes and contributes to risk.
10. Work with the profession on a phased introduction of the new regime.
11. Increase inspection frequency with an emphasis on providing support to improve standards rather than seek to identify breaches and punish individuals.
12. Publish the outcomes of inspection visits.
13. Work more closely with stakeholder bodies on communication with their constituencies of the new standards and compliance regime.
14. Protect the public by ensuring that P medicines are not supplied / sold via self - selection.
15. Create a senior 'accountable manager' within all businesses that provide pharmacy services so as to ensure that the regulator can enjoy regulatory traction, particularly within the large multiple operators.

More detail is given in the comments and observations below and in the responses to questions. We are willing to provide further detail if required.

3. Comments, Observations & Concerns

Subject to certain reservations as outlined in this document, we are broadly supportive of the GPhC's thrust to regulation and the principles upon which this is built. We are keen to work with the GPhC to reduce the impact of unintended consequences contingent on applying the new regulatory framework.

In our experience the development and implementation of new regulation often results in situations and practices that were not foreseen or planned for. As a result the regulations as implemented do not deliver the outcomes as intended at the outset of the process. The Responsible Pharmacist regulations are a case in point. We are concerned that a seismic shift in the approach to regulation will create such ambiguity as to allow certain pharmacy owners more latitude than the regulator intends. As some of these organisations can call upon resources more substantial than those available to the GPhC rectifying anything that the GPhC later deems undesirable will prove difficult.

For that and other reasons we are most concerned that a number of factors are given proper and adequate attention as the standards are developed.

3.1 Ownership structure & professional independence

A fundamental tenet of this consultation is that healthcare professionals operate in the interest of the patient; where potentially competing demands of patient care and commerce clash the assumption is that the healthcare professional will act to the benefit of the patient and will accept less than optimal commercial outcomes. At the level of the individual pharmacist we know that this is true; pharmacists as healthcare professionals are no less inclined to act to the benefit of a patient than any other healthcare colleague.

However community pharmacists are under tremendous pressure to meet commercial targets and comply with commercially driven operating standards. This results in actions being taken which are driven by employer pressure rather than patient care. Pharmacy, of all the healthcare professions, is unique in this respect; although there are commercial operators in other professions (e.g. opticians and dentists) their power over the healthcare professional is not as dominant.

UK pharmacy is like no other UK healthcare profession or any other European country in terms of its ownership structure. Less than 40% of premises are in the hands of independent pharmacy professionals. This means that the great majority of premises, and pharmacy professionals operating in them, are subject to overtly commercial pressures. The primary imperative of these organisations is to deliver shareholder returns equal to or better than those expected. Operating costs and market share are the major considerations. Patient care is merely an intermediate measure; primarily factors which may impact on patient numbers (waiting times, prescription collection & delivery) are considered important. Optimisation of outcomes and patient benefit are often not encouraged as these usually soak up pharmacist time and can even reduce item volume; avoidance of harm is given some consideration because patient harm can be expensive through litigation and impact on the brand.

Over a third of UK pharmacies are owned by companies based outside the UK and their commitment to the NHS and UK patients primarily extends as far as their profitability.

Over 30% of pharmacies are owned by vertically integrated wholesale groups whose main objective is to drive volume sales; they are principally interested in prescription item numbers and use targets and incentives in the drive for items. They treat services in exactly the same way and this has had the effect of undermining the quality and reputation of those services.

3.1 Ownership structure & professional independence *continued*

A further 14% of pharmacies are owned by general retailing groups; their motivation – aside from the profitability of the operation – is to drive footfall. The value of each visitor is much greater as a customer of the general retailing part of the store than their value as a user of the pharmacy.

Independent studies have demonstrated the impact of high prescription volume on patient outcomes; no amount of technology can make up for workload pressure.

Corporate chains will point to the (generally) high standards of fit-out of their pharmacies as evidence of high premises standards. They will provide evidence of the low numbers of dispensing errors; they will cite investment in systems and processes; they will demonstrate high standards of training of their technicians and support staff. But they will not admit to the constraints and pressure that they place on pharmacists to limit their professional independence.

Pharmacist Workload and Pharmacy Characteristics Associated With the Dispensing of Potentially Clinically Important Drug-Drug Interactions (DDIs)

This study found that pharmacist workload, as determined by the number of prescriptions dispensed per pharmacist work hour, was significantly associated with rates of dispensed potential DDIs. Other pharmacy characteristics, such as total pharmacy staffing levels and automation, were also significant predictors of dispensed potential DDIs. The findings are intuitive because pharmacies attempt to become more efficient in order processing once prescription volume exceeds existing capacity. Unfortunately, implementation of automation and other pharmacy staffing may not sufficiently compensate for the increased pharmacist workload, leading to an increased risk of dispensing a potential DDI. This finding is consistent with other reports concerning workload and medication errors

Medical Care : Volume 45, Number 5, May 2007

See also Sellers JA. Too many medication errors, not enough pharmacists.

Am J Health Syst Pharm. 2000;57:337.

Corporate chains are not owned or run by pharmacists; often the managers of pharmacists working in those stores are not themselves pharmacists. They do not understand the needs of the patient or professional considerations. They apply pressure to comply on the pharmacist in the form of targets; they make it more difficult for pharmacists to operate professionally and independently by controlling the support they receive from other staff; and they further compromise standards through the environment in which they operate. We see this daily through our work as a defence association and trades union. The professional independence of employed (and locum) pharmacists is routinely compromised at many levels. The choice of product to be used is often made by the company; standard operating procedures are imposed from head offices; staffing levels are imposed by head office (and often reduced by local management); pharmacy teams are often managed by non-pharmacists and often the pharmacist has little or no control over the people that they work with; targets are imposed on the pharmacist and on the team – any pharmacist taking any action that may impact on the team's ability to meet its targets comes under pressure not only from their manager but also from the team. As a defence association, we have even been involved in situations where pharmacists have been dismissed by their employer for not following the employers SOPs, even though they can demonstrate that they have acted in the patients best interests.

3.1 Ownership structure & professional independence *continued*

Acting in the patient's benefit is not synonymous with avoiding dispensing errors. Actual improvement in health or well-being may be achieved through a pharmacist professional intervention; optimising outcomes may require changes to a patient's medication regime to avoid harm or promote health. Patients may benefit by changing, reducing or avoiding medication and these outcomes may not be in the interests of the pharmacy owner.

We know that the GPhC cannot change the ownership structure of UK pharmacy but it can promote better patient care through how it regulates premises and how it interacts with owners.

The European Court of Justice has affirmed the right of member states to determine how they regulate pharmacy to ensure the professional independence of the pharmacist. In its 2009 judgement on the right to restrict ownership of pharmacies to pharmacists it stated that ***Member States may require that medicinal products be supplied by pharmacists enjoying genuine professional independence and Member States may take measures to reduce the risk that that independence will be prejudiced*** *(Judgments of the Court of Justice in Case C-531/06 and in Joined Cases C-171/07 and C-172/07)*

This judgement contains many fundamental recommendations which we believe give regulators the right – and we say a duty – to devise and implement a regulatory regime that ensures that pharmacists can operate free of commercial pressures.

The ruling was made in relation to the ownership of pharmacies and it considered the impact of non pharmacist ownership upon the safety of medicines supply. Increasingly, as we move towards more modern pharmacy practice through pharmaceutical care, pharmacists will be developing deeper clinical relationships with individual patients. Some of these will be through individual patient registrations and will be operated on an appointment led basis. It is apparent that the principles outlined in the ECJ are significantly more relevant when considering the provision of pharmaceutical care services directly to patients. The provision of pharmaceutical care is a role that requires the pharmacist to be able to act with a significant degree of professional autonomy, this places an even greater and fundamentally a more sophisticated regulatory requirement upon the GPhC.

We see the GPhC's intention to modernise the regulation of premises as an opportunity to address the power of the corporate owners and in doing so improve patient care through allowing greater professional independence for the pharmacist. We urge the GPhC not to squander this opportunity and to used its powers to best effect in supporting the professional autonomy of the pharmacist.

3.2 Consistency of regulation

We regard the GPhC as consisting of three parts; the body politic that sets policy, devises and drafts regulation; the enforcement function – the inspectorate that investigates and prepares evidence; and the judiciary – the fitness to practice committee that acts as judge & jury.

Too often there is a lack of consistency in the way that the enforcement and judiciary functions interpret and implement the philosophy of the body politic. The intentions of the regulation and the regulatory environment are often not followed in the way that the profession is policed and judged.

We can provide many examples but one recent statement by the chair of a Fitness to Practice hearing demonstrates the lack of congruence. The case itself is not the important factor here; it is the remarks made by the chair at the end of the case which illustrate the problem. He said that "A pharmacist is not competent to undertake a physical examination which includes the touching of a patient's body as part of a diagnostic procedure."

The GPhC claims to be creating a regulatory framework that enables practice to develop – to be capable of properly regulating pharmacy in all of its forms and pharmacists in all areas of practice. Touching a patient has always been required. A truss or elastic hosiery cannot be measured or fitted without touching a patient. New areas of practice positively require some form of diagnostic procedure and many require pharmacists to touch patients. The statement demonstrates how out of touch the chair of the Fitness to Practice committee is with modern pharmacy practice.

It is accepted that subsequently, the regulator, through its newsletter, sought to clarify the actual position of the GPhC – a position which is based on the reality of the situation, nevertheless, this episode caused confusion and demonstrates the point we make.

As premises regulations change it is essential that the philosophy and intent of the body politic is manifest in the way that the regulations are enforced; when the GPhC says "we" it must mean "we". We look forward to hearing how the GPhC will achieve such consistency.

3.3 Standards vs Standard Operating Procedures

We fully support the clear identification of standards and the guidance in the form of compliance indicators. We are however concerned that these should not be evidenced by more specific written requirements. However, what we would not support is the placing of a requirement upon a pharmacy to have written standard operating procedures for all matters.

Standard Operating Procedures were introduced some years ago as a means of assessing whether a pharmacy's working procedures were known and understood by the personnel working in that pharmacy; there were a small number and they covered only essential processes. Over time the number of SOPs has grown as they have been seen as a way of addressing issues identified by (often poorly executed) risk assessments and PCTs inspections and/ or new services.

The necessity for SOPs was enshrined in the Responsible Pharmacist (RP) regulations which require the RP to sign on when they take control of a pharmacy. We believe this to have been a significant fundamental error and have stated so on many occasions. The act of signing on as a RP requires that the RP declares that they have read and agree with the SOPs held in that pharmacy; if they do not they are required to write their own SOP and communicate this with the owner and the pharmacy personnel as necessary. However the list of SOPs has now extended dramatically such that many pharmacies have no fewer than 40 SOPs and others can have as many as 130. The majority of SOPs run to several pages; to read and fully understand even the most basic list of SOPs takes well over an hour and a fuller SOP manual could take half a day. It is inconceivable that the opening of a pharmacy could be delayed by a locum pharmacist reading and signing off the SOPs before commencing operations; patients, pharmacy staff, pharmacy owners and PCTs would make life impossible for any pharmacist who insisted on doing so. In practice the majority of locum pharmacists (up to a third of pharmacies may operate with a locum at particular times) sign on as RP without reading or signing off SOPs, trusting to fate that this will not result in a problem for them. If a problem does arise the company can fall back on the SOP and shift the blame on to the individual who is to be held accountable – the pharmacist.

Generally SOPs are written by people in Head Offices who often have little or no current experience of actual practice; they are usually then tailored by local management and then filed for reference at the convenience of local management.

SOPs often stand in the way of patient centred practice. By definition SOPs define what should happen in ordinary circumstances but it is when events go beyond the scope of SOPs that professional judgement needs to be applied in such situations SOPs can be a positive hindrance. In a situation where to do the best thing for the patient means going against a SOP a pharmacist is faced with a choice; does (s)he do the best for the patient and risk disciplinary action for acting outside the scope of the SOP?; or does (s)he avoid disciplinary action by staying within the SOP but risk harm to the patient by giving them less support than they need? Sadly it's often easier to re-direct the patient to another healthcare provider than to risk the employer disciplinary route.

The GPhC has stayed relatively silent on the necessity of SOPs and we take this to mean that it does not see SOPs as being central to patient benefit. However, we would urge the GPhC to be more proactive and explicit and make clear that SOPs are of limited value and in certain contexts if followed to the letter, they can cause more harm than good. We urge the GPhC to look for other ways of demonstrating compliance with standards.

3.4 Risk based compliance assessment

The shift to risk based inspection and assessment of compliance is a step forward and we applaud the GPhC's intent to draw upon more sources in assessing risk. We have considerable evidence of where risk lies and what factors add to risk and look forward to contributing to that process.

When considering risk to the patient we believe that the current paradigm needs to be altered significantly. Patient harm is considered primarily from the perspective of dispensing errors and reduction of harm is taken to mean the reduction of errors. Community pharmacy has worked hard at this and can take some comfort from the relatively small number of errors that actually occur. However, given prescription volume and medicines sales, some errors are inevitable and we believe that a more enlightened approach is needed in how these errors are investigated and prosecuted.

- Whether an error causes patient harm is a matter of chance; vigorously pursuing a pharmacist who was performing the role of RP at the time an error which caused actual harm is counter- productive as all involved seek to minimise damage to themselves rather than address the real issues which led to the error.
- Historically the regulator has concentrated investigations on the pharmacist as (s)he is the registered person who can be held to account. In future, the role of technicians, the wider pharmacy team, the management, the business and the role in the error played by the environment must be taken in to consideration. While the powers of the regulator are limited where non-registrants are involved, premises standards are an opportunity to make the duties and expectations of owners and their representatives clear.

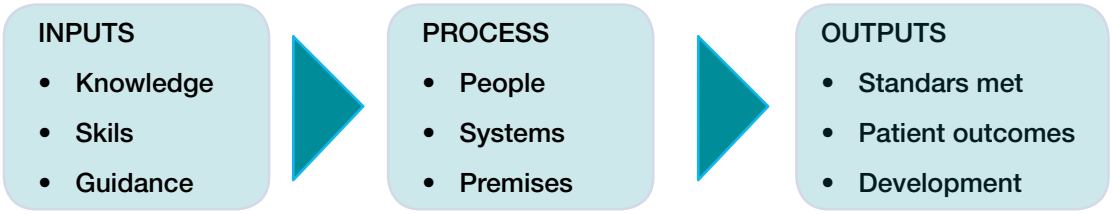
While we would not wish to see the number of errors increase we do believe that a broader consideration of patient harm is required. Patients should expect better outcomes from their medication; taking medicines inappropriately can result in lack of benefit or actual harm; unintended consequences through side effects or drug interactions are not uncommon. By enabling pharmacists to concentrate more on the patient better outcomes and less harm will result. Premises standards are a means of enabling this. Compliance should therefore consider factors such as:-

- Does prescription volume inhibit the pharmacist's ability to concentrate sufficient time on the patient? Is more pharmacist time required?
- Are there sufficient support staff to enable the pharmacist to spend time with the patient? Do they have the right skills, competence and experience?
- Are processes too rigid, stifling the opportunity to interact with the patient?
- Do systems help or hinder? Systems that flag up every possible drug interaction however unlikely or trivial result in such warnings being ignored.
- Are local management providing a supportive environment or are they making life difficult for the pharmacist?
- Are targets, incentives and performance measures applying inappropriate pressure or causing poor patient experiences?

We also note that the standards include the scope for "whistle-blowing"; this should allow greater input from employees at all levels. However we know that whistle-blowers are subject to very aggressive and intimidatory action by their employers and that over 90% lose their jobs. A locum pharmacist reporting his/her concerns is likely to find that (s)he is never employed by that company again. An employed pharmacist reporting concerns will find him/herself subject to disciplinary action; his/her career will be limited; and (s)he may be forced out.

3.5 Compliance and enforcement

Any system can be described as a series of inputs, processes and outputs.



If specific outputs are required it is advisable to define the inputs and – to a lesser extent – the process. Otherwise the system will fail to achieve what is intended or will produce the desired outputs with a high degree of waste. In this case we believe the "waste" could be pharmacists who are caught between the owner and the regulator and are either sacrificed by owners to deflect action against them or suffer excess stress in being held accountable for deficiencies for which they are not directly responsible.

We note that the GPhC intends to define the outputs – the standards to be met – but does not wish to be prescriptive over the inputs needed to achieve the standards or the processes by which they will be achieved. We believe that the GPhC must concern itself with inputs – particularly skills and guidance - and process as well as the desired outputs.

A good example of what happens when the full system is not given proper consideration is the Medicines Use Review. The output of the MUR was not adequately designed; in particular how this would fit in to the provision of other primary care services. Similarly the inputs to the process and the process itself were ill-defined. In order to maintain control of the MUR the corporate multiples forced standardisation of the service which resulted in emasculation of the MUR; the output is now a fee to the contractor rather than an empowered patient. Commoditisation of the MUR has led to it being discredited to the extent that it is a barrier to further pharmacy service development.

We are keen to ensure that the GPhC learns from the mistakes of others and avoids creating issues that it might have foreseen.

3.5.1 The importance of Guidance

Under Compliance Guidance the GPhC says "Recognising our desire to avoid an overly prescriptive 'one-size-fits-all' approach, it is not currently our intention to provide a comprehensive guidance document covering all the standards. We do not feel that this would be proportionate and could lead to a check box approach to compliance."

While we share the concern over a "check box" approach to compliance we do not agree that providing guidance would produce that result. Rather we are concerned that the lack of general guidance will result in confusion and conflict. Where will the responsible owner find guidance? The large multiples at least have head offices which will interpret standards and provide their own take on what is required; however if the GPhC later decides that these are inappropriate it may find it difficult to mount an effective challenge. But where does the responsible owner of a small chain, independent pharmacy or new pharmacy go to for guidance. Who, if not the GPhC?

We are concerned that moving straight from a situation where there is comprehensive guidance to one where there is virtually no guidance risks creating a void where no-one knows what is and is not acceptable. We have experience of the implications the two extremes. The legal profession recently went through a similar change in approach. The regulator failed to provide adequate guidance on how the new standards would be achieved; the consequence is that it is now very difficult to obtain a prompt view from the regulator on many issues as their own staff lack guidance and fear litigation.

Some guidance on general premises standards is essential to minimise potential conflict; where the inspector and the corporate pharmacy may be at variance over whether standards are being met it will be the pharmacist in control of a pharmacy at the time of the inspectors visit who will bear the brunt of that disagreement. We are confident that the GPhC would not intend that consequence. Through our work with pharmacists, companies and other pharmacy organisations we are confident that we can help the GPhC identify where guidance would be valuable and help to formulate it as appropriate.

3.5.2 Risk assessment and inspection

We note that the inspection will increasingly be based on an assessment of risk and that whether premises are suitable will depend on how well risk is managed, this is a fundamental change in approach. We are not convinced that the GPhC currently has the experience and knowledge to be able to move to a risk based approach to regulation, especially if it intends to do this in a short period of time. Furthermore, we are concerned that risk assessment does not currently feature in either the undergraduate education programme or the formal post graduate programme; one module is available from the Centre for Pharmacy Postgraduate Education (CPPE) but this is not compulsory and is of limited value. As a result we believe that the vast majority of pharmacists are unprepared for a risk based approach. We believe that a programme of education on risk is required ahead of the new regime being introduced.

We support a risk based approach to inspection but we do not think that using evidence from inspections carried out prior to standards coming in to force is an adequate way of assessing risk. Recent inspections have tended to concentrate on SOPs and compliance with Controlled Drug regulations. They have checked whether pharmacies comply with the technicalities of regulations and have not looked at the wider risks to the public. They have not concerned themselves with the interference with the safe and effective running of the pharmacy by functions or individuals who are not registrants and who are not therefore subject to the discipline of the regulator.

Inspection of company head offices could help address the wider risks and assess how they are managed. Such inspections would focus on the way that head offices develop processes, SOPs and guidance; it could further look at how well these are put in to practice. In particular, the GPhC should assess how superintendents are given the resources that they need and how they are supported in delivering the standards they aspire to.

We do not believe that less frequent inspection is required; on the contrary if a "right touch" approach is to be implemented successfully inspections may be required more frequently. In future, inspections should be part of a supportive framework designed to improve standards rather than to punish individuals where standards are not met. In this way the inspection becomes part of a learning and improvement process that informs the development of the GPhC and the profession. Observing the way that practice is developing, seeing changes to services and the skills, knowledge and mix are required to deliver them would allow the GPhC to respond to changes more quickly and appropriately.

3.5.3 Post-inspection reports

We believe that there would be considerable benefits to patients and the profession from publishing the results of all inspections of both pharmacies and head offices. Patients would be better able to choose between pharmacies in their area, would be better prepared for any issues that they may encounter and would be able to see for themselves if any systematic problems affected multiple pharmacies. Pharmacists would be better informed and in a stronger position to choose an employer based on their performance.

However we recognise that simply writing up and publishing of the results of an inspection would be unreasonable and that a number of factors would need to be considered in developing a publishing regime.

- The decision making criteria on which an assessment of compliance with standards are being made would need to be clear and freely available.
- A process for pharmacists/ superintendents/ owners to view and comment on a draft report before it is published for public scrutiny would be required.
- A process for receiving and acting on patient feedback would be required
- The process would have to be able to respond to action taken by the owner of the pharmacy to address any issues identified in the inspection report.
- The process would have to be responsive to changes in service mix.
- The process would have to be responsive to incidents and their outcomes.

Publishing the inspection report would greatly increase transparency and could impact beneficially upon patient safety, it is increasingly becoming a feature of modern regulation, not just of hospitals but in a wider sense e.g. in education.

The GPhC must be able to require any issues identified in an inspection to be rectified and the means to do this is through an enforcement notice. We believe that an enforcement notice needs to be specific in the action that is required; in order to do this the GPhC must have a very clear picture over what is and is not acceptable; it should therefore be able to issue guidance to all owners and pharmacies in how they should meet the standards.

The enforcement notice must be addressed to the party that is capable of effecting the action needed to rectify problems. It is essential that the GPhC separates issues with services, for which the pharmacist should be responsible from issues with premises from which those services are provided; factors such as staff levels, systems, processes and environment are matters for owners; any enforcement notice must be issued to the proper person; either the superintendent and/ or owner or the RP where appropriate.

3.6 Introducing appropriate corporate accountability; the accountable manager

In some respects the airline industry is similar to pharmacy. Both often have the significant commercial pressures on the one hand, leading to cost control and improved efficiency, and public safety factors on the other. However, we believe that historically the airline industry has been regulated in a way that is superior to that which has been the case in pharmacy. In the airline industry, when a critical incident occurs, the whole process is examined in a root and branch analysis, the actions of the pilot and that of his staff being examined as only one of the factors under scrutiny. This has led to a culture which allows for lessons to be learned by all of the airline industry. In contrast, in pharmacy, historically regulation has been all about seeking to identify the individual 'miscreant' and then to punish the individual who made the error or who was in charge at the time the error occurred. In the airline industry, there has also been a much greater recognition that often, it is the working environment and business behaviours that can lead to errors occurring. Sadly, this is not the case in pharmacy and it would appear that in recent years, the focus upon the involvement of the business operator in an incident has declined somewhat and this is demonstrated by the sharp reduction in regulatory episodes involving employers or their superintendent pharmacists.

Asked at a recent pharmacy conference , what single measure had improved the safety of the airline industry more than any other – a senior official of the Civil Aviation Authority (CCA) explained that it was via the creation of the 'accountable manager'.

The 'accountable manager' was a senior individual within the airline company; someone with significant authority. During the annual inspection of the airline, the CAA would spend at least a day in discussions with the 'accountable manager' to ensure that the business orientation lent itself to a good public safety profile. This was deemed by the regulator to be a very important step in ensuring that the airline was fit for purpose and yet in pharmacy such an 'accountable manager' quality check process does not exist.

In pharmacy, services are increasingly being provided by companies where pharmacy is not core to their business. Consequently, there is a danger that the regulator could easily lose regulatory traction in an infrastructure where pharmacy is a side issue. If the 'accountable manager' were to be established by the regulator, then this would provide a useful means to ensure patient safety was a top priority for any company involved in the provision of pharmacy services. It would also provide a more solid conduit along which the company could be held operationally accountable to the regulator.

This development would also assist in situations where some relatively inexperienced superintendents are appointed by some large multiple operators, or alternatively, the superintendent occupies a relatively humble position within the company hierarchy. This means that currently the superintendent may be unable to deflect the company from its commercial trajectory on the one hand whilst simultaneously be expendable and replaceable in the event that they were personally embroiled in a regulatory problem on the other.

We believe that company's operating a pharmacy service must be required to appoint an 'accountable manager'

We would expect that as in the airline industry, the GPhC would meet annually with the 'accountable manager' to discuss any patient safety issues and any relevant feedback from the routine inspections of pharmacies within that company.

The 'accountable manager' would need to be a person with significant authority and be able to commit resources if necessary. This could be the owner of the business or a board member of a larger company. Ultimately, as the title suggests, it would be the 'accountable manager' who would be held to account for establishing safe working environments and compliance with regulatory standards.

4. Response to the questions

In addition to our general observations outline above our comments on the proposals are set out in the required format below.

Registering a pharmacy

Question 1.

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

Yes

Question 2.

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

No

Question 3.

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

None

Question 4.

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

We note that hospital pharmacy departments are still exempt from the need to register their pharmacies. While we understand the historical context for non-registration of hospital pharmacy departments we fail to see why they are still exempt from registration. If the main function of the GPhC is to ensure that patients and the public are protected hospital pharmacy departments must be subject to the same standards as community pharmacies.

Standards for registered pharmacies

Question 5.

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

No

Question 6.

What is unclear?

The introduction to the standards says that responsibility for meeting standards lays with the owner of the pharmacy and in the case of bodies corporate with the superintendent pharmacist as well. In the first draft of these proposals the GPhC had included responsibilities for the directors of bodies corporate; we believe that the omission of these responsibilities for directors has weakened the proposals; directors of pharmacy companies must understand that they have responsibilities towards the public and the pharmacy professionals working for them.

Standards must cover not just the physical built environment but also governance, business behaviour, staff and medicines management. Some of the standards outlined overlap with the Responsible Pharmacist regulations and we have seen occasions where an RP has been held accountable for deficiencies in the built environment, governance or the standard of pharmacy employees.

We are in no doubt that responsibility for the built environment (principle 3), medicines management (such as where they are purchased) (principle 4) and the equipment and facilities (principle 5) must lie principally with the pharmacy owner and not the RP. It is essential that ownership of responsibility is synonymous with ownership of premises. The potential for the RP to be held accountable must be removed through re-consideration of the RP regulations and in the way that the GPhC implements those regulations.

Responsibility for governance arrangements (principle 1) and staff (principle 2) has the most overlap with RP regulations. It must be the responsibility of the owner to ensure that arrangements are put in place to deliver safe and effective governance and staffing levels. However on a day to day basis only the RP can determine whether governance, staff levels and staff competence are adequate and appropriate. It is not acceptable, for example, for local management (often non-pharmacists) to make decisions on staffing by referencing company standard operating models where doing so may compromise safety. The respective regulations need to be appropriately cross referenced to ensure that owners and RP s understand where responsibilities start and stop.

Question 7.

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

The document uses the term "staff" to mean employees, contract and agency workers; it is not clear that this also encompasses locum pharmacists and technicians.

Perhaps a more significant point is the extent to which the GPhC can make these standards apply to other staff that may be involved or employed in the pharmacy and are not registered with the GPhC and are therefore beyond its sphere of control.

Question 8.

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

Yes

Question 9.

How could it be improved?

Compliance indicators must be things that can be demonstrated and or observed; these things should not have to be written down or be the cause of more paperwork or tick box compliance.

Question 10.

Are the standards under each principle clear?

No

At this point it makes sense to treat questions 11, 12, 13, 14, 15 and 16 together and provide a single response under each principle.

Question 11.

What is unclear?

Question 12.

Is anything missing from the standards under each principle?

Question 13.

What standards should be added?

Question 14.

Are the compliance indicators clear?

Question 15.

What is unclear?

Question 16.

The indicators are examples only and do not represent a complete list of everything that might indicate compliance with the standards. What if any additional or alternative indicators would it be helpful for us to include here?

Principle 1

'1.2 The risks associated with providing pharmacy services are identified and managed

This implies that owners and their representatives are trained in risk assessment and management. We do not believe that this is the case or that such training that has been undertaken is adequate.

'1.5 The roles of individuals involved in providing and managing pharmacy services are clearly defined

There is significant potential for conflict between the RP and the owner or their representative over this standard. While we accept that the owner should define what roles may be required and in what proportion, only the RP can make a decision on a day to day basis as to whether the roles and individuals fulfilling those roles are adequate to meet the service demands as presented on that day. That responsibility is enshrined in the RP regulations.

The standard does not differentiate between pharmacists and non-pharmacists managing pharmacy services. While the GPhC cannot regulate non-pharmacist managers it can and should provide additional guidance to them and require that owners ensure that guidance is followed.

Guidance may be required on where services are deemed to have been completed as this will have an impact on what activities and personnel are involved. For example is delivery of a medication to a patient's home included within the definition of dispensing? If it does then delivery drivers should be included in this standard.

Principle 2

'2.1 Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training

While we agree that the owner must ensure that staff are trained appropriately and that their skills are developed, only the RP can decide whether an individual is competent to deliver services in a particular set of circumstances.

'2.4 Incentives or targets do not compromise patient safety or the professional judgement of staff

The ECJ is clear that Member States can choose to ensure that incentives and targets cannot be used to compromise the judgement of the pharmacist. We do not believe that this standard is expressed strongly enough or that it makes it clear that the professional independence of the pharmacists must not be compromised.

Under compliance indicators we believe that it would be appropriate to include:

- Employment contracts make it clear that staff are empowered to exercise their professional judgement
- Non-pharmacist managers have a clear understanding of their responsibility to protect the professional independence of the pharmacist and their duty to ensure that the pharmacy team can operate to the necessary standards of safety and effectiveness.
- Provide evidence that a full and proper assessment of the number, qualifications and experience of staff requirements to meet normal expected service demand has been undertaken and acted upon. (NB. On a day to day basis the RP has to decide whether this provides adequate staffing for the particular circumstances experienced on that day)

Principle 3

Under compliance indicators :-

"you consider the volume of work and work flow through the dispensary and develop procedures to reduce risks"

We agree that an owner should consider how a dispensary is laid out to reduce risk; however the RP is also required to make up his/ her mind as to the safety of the operating environment on any day.

Principle 4

Standard 4.2 states that "Medicines and medical devices that are sold or supplied are fit for purpose, of an appropriate quality and safeguard the health, safety and wellbeing of patients and the public". We are interested to see how that standard will sit alongside the duties of the Medicines and Healthcare Products Regulatory Agency (MHRA), particularly in respect of parallel imports, unlicensed medicines and specials.

Under compliance indicators there is no requirement for owners to prevent self selection of "P" medicines. The ECJ has made it clear that medicines are not items of ordinary commerce. By definition medicines in the "P" category require more care and attention to be exercised in their sale than GSL medicines. The public perception is that these medicines are "more potent" and potentially could cause more harm if not taken appropriately than other OTC medicines and this is often the case. More recent POM to P switches require that a certain protocol is followed and that certain questions are asked to determine whether the product can be sold safely and appropriately to treat a particular patient. As the compliance indicators stand we believe that the commercial managers, particularly those in corporate multiples will see this as an opportunity to market "P" medicines more aggressively and encourage self selection. This will erode the "P" category and limit the introduction of more effective over-the-counter medicines; the MHRA has already made it clear that allowing self selection of P medicines would hamper further POM to P switches in the future. The position is very clear, if P medicines are allowed for self selection, then this would be tantamount to disbanding the P category altogether and would allow the larger retailers to successfully argue that there remains no public interest in having such a medicines category at all. This could lead to hitherto P medicines being freely available on all supermarket shelves with no professional input whatsoever.

More fundamentally, we believe that the GPhC should play an important role in protecting the public interest, if it allows P medicines to go on self- selection, then that would represent a dereliction of its duty in its role as public interest guardian. Indeed the suggestion that P medicines should be on self-selection is an argument that we would expect to see coming from a large retailing lobby group and not from a health profession regulator which should have a better understanding of medicines and their danger to the public if supplied in the same way as say a normal item of commerce.

We urge the GPhC to think again about this intention as it will be met with significant resistance from the wider profession

Principle 5

There is no standard requiring that staff are trained in the correct use and maintenance of equipment.

Question 17.

To what extent do you agree or disagree that the standards and compliance indicators provide pharmacies with a clear and usable framework?

We believe that the standards and compliance indicators provide a good basis; however they require further consideration to ensure that the intentions of the principles and standards are carried through to implementation. Additional guidance will be required to differentiate between the responsibilities of owners / superintendents and the RP.

Question 18.

What, if any, further support tools or information would pharmacy owners or superintendent pharmacists need to be able to meet these standards?

The omission of responsibilities of directors and non-pharmacist managers should be corrected. As an absolute minimum they require guidance on what their role is in ensuring safe and effective practice and their duties in respect of ensuring the professional independence of the pharmacist.

The powers to allow the GPhC to do this were granted in legislation in 2007 and are to be found in the Pharmacy Order 2010. These powers should be used to provide the appropriate guidance.

Question 19.

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

Primarily we are concerned that the lack of detail will result in an employers charter – standards that may produce the intended outcomes, but using methods that are damaging to the patient and the professional interest. Furthermore, currently, the PDA is in many instances able to successfully use the interim standards and guidance to persuade employers to moderate their behaviour towards their pharmacists. A good example is interim standard 3.7 which places a requirement upon owners to not only allow their pharmacists to take rest breaks, but that they should actively encourage them to do so.

The very existence of this specific standard has enabled the PDA to successfully argue for rest breaks for hundreds of pharmacists in situations where hitherto, their employer has been unprepared to allow them to take a rest break due to their preference for the pharmacist to provide continuous cover. This is just an example, but should such regulatory detail be lost with the introduction of the new outcome based approach, then this would undoubtedly reduce the opportunities for limiting some of the more overtly commercial employment tactics. On that basis, we would urge the GPhC to retain regulatory detail in some of the most sensitive and key areas of practice.

Compliance

Question 20.

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

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

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

We agree wholeheartedly that guidance will be required in these areas; however we do not believe that guidance should be limited to these areas.

Question 21.

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

We firmly believe that guidance will be required in all areas. While we understand the regulator's desire to move away for an overly prescriptive environment we do not believe that it is sensible to move from a situation where detailed guidance has been given to one where no guidance is given. We know that having no guidance will lead to confusion and conflict. Providing appropriate guidance will not stifle innovation; on the contrary it will allow innovation within a controlled framework and will prevent excessive experimentation which may be contrary to the interests of the public and the profession. Furthermore, regulatory guidance will provide an important support tool to pharmacists who seek to achieve the right balance between the commercial imperative placed upon them by their employer and the professional and patient focussed imperative that they wish to observe.

Through our work with pharmacists, employers and other pharmacy organisations we have very clear knowledge of where clear guidance is required. Examples include;

- Staff profiles tailored to total workload and workload mix; guidance should include the publication of staff profiles for public scrutiny.

- Dispensing for residential homes; loopholes in the RP regulations have been used to allow preparation of monitored dosage packages outside the purview of the RP. These activities are not in the patient's interests and guidance should put limits around them.

- Hub and spoke dispensary systems where the dispensing is carried out in a central location and the dispensed medicines are then distributed to the patient via the local pharmacy.

However these are but three examples and we have other areas of concern which we will be pleased to discuss.

Question 22.

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

We are broadly in favour of the approach described. We have three key areas of concern.

Firstly we do not believe that it is sensible or prudent to move in one step from a system of regulation for premises where detailed guidance is given for most matters to one where no guidance is given except for two tightly defined circumstances. Our experience is that this will lead to impasse and then conflict; it is best avoided by recognising that some guidance is required and working with the various interests to define what guidance is needed.

Secondly we are concerned that in order for the approach to be successful, all parties need to have the right level of knowledge and skills and that these need to be applied consistently. This will require the GPhC to train its own personnel in risk assessment and management and ensure that the approach is applied consistently through all its functions. It will also be necessary to develop and deliver much better risk assessment and management education for all pharmacists, superintendents and owners. This will take time and in the process of implementation the GPhC will have to be mindful of the difficulties involved.

Thirdly we are most concerned that the GPhC separates the responsibility for the delivery of services provided from the responsibility for the premises. We have articulated our concerns in detail within this report.

Question 23.

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

Transition will be made easier and more effective through good communication. By that we do not mean the GPhC telling stakeholders what is happening and what they must do – although this is part of it. Rather we mean that key parties who have information that the GPhC will find invaluable must be part of the development of the final standards and be party to the development of the implementation plan. They must then be used to aid communication with the interests that they represent and the GPhC must be responsive to the feedback that they provide. We know that we have a substantial amount of evidence to provide to the GPhC which will guide the finalisation of standards and we have excellent communication routes to our 19,000 members; we wish to be part of the process.

Question 24.

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

Independence of the pharmacist.

We firmly believe that pharmacists will increasingly be involved in the delivery of pharmaceutical care which was defined by Hepler and Strand as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" . The judgement of the European Court is clear in stating that this level of care can only be delivered by an individual operating independently in the interests of the patient and not in the interests of a corporate body.

We are further concerned that the need for control demonstrated by the corporate multiples drives the proliferation of SOPs and the strangulation of pharmacy services which results in such services being turned in to commodities; the way that the Medicines Use Review has been turned in to a unit of commerce is a good example of this.

However we also recognise that community pharmacies in particular, are locations where services can be made accessible to patients and the public. Indeed there is very clear evidence of the value of the pharmacist remaining part of the dispensing process. Recent research revealed that for every 10,000 prescription items there are 22 near misses but only 4 errors; we are confident that pharmacist involved in the supply process is a key factor in ensuring that so few near misses turn in to errors. Thus there is a balance to be struck between the involvement of the pharmacist in the supply process and the delivery of services. The one must not be provided at the expense of the safety of the other.

Clarification of accountability.

An unintended consequence of the Responsible Pharmacist regulations was that the RP now holds accountability for all aspects of the safe running of the pharmacy. Furthermore the GPhC standards for pharmacy owners, superintendent pharmacists and pharmacy professionals in positions of authority promulgated this situation by not making it clear that owners and superintendents are accountable for the built environment, systems and processes.

The premises standards are an opportunity to address that error and correctly identify where accountability lies. A pharmacist must not be held accountable for that which (s)he cannot control. This means that that the physical environment, pharmacy systems, provision of support staff of adequate numbers, skills and experiences, and processes must be the responsibility of the owner and/ or superintendent. The day-to-day delivery of services to patients within that framework are the responsibility of the pharmacist. We understand that there will be areas where there is some overlap and room for doubt; it is in these areas that the inspectorate will have to use their observations in forming their own judgements. However we have considerable evidence for where the boundaries should lie and we would be keen to share these.

Appendix 1: The ownership structure of UK Pharmacies

There are over 14,000 pharmacies registered by the GPhC in the UK.

The ownership of these can be classified into the following categories

• Vertically Integrated European Wholesalers	31.4%
• American & Asian General Retailers	3.0%
• UK General Retailers	11.3%
• Non-corporate Chains (6 pharmacies and more)	15.3%
• Small chains (5 or fewer) and Independents	39.0%

A more detailed breakdown is given below

Nine companies (represented by the Company Chemists Association – CCA) own over 45% of all UK registered pharmacies.

Local and regional chains of 6 pharmacies or more comprise a further 15%; theses are partially represented by the Association of Independent Multiple Pharmacies (AIMp).

Notes to the numbers

According to the GPhC there were 14,124 pharmacies on the register of pharmacy premises on 1st March 2012.

This includes all pharmacy premises in England, Scotland and Wales but excludes Northern Ireland, the Channel Islands and the Isle of Man. The GPhC register includes pharmacies which do not have NHS contracts and/ or which are not open to the public.

For these reasons the numbers ascribed to each pharmacy company may be different to those claimed by the company. Such discrepancies are relatively small. However they do result in the impact on the market of those companies being under-stated.

The detailed breakdown of ownership of pharmacies on the register is as follows

Owner	Number	% of total
Asda [1] Wal-Mart Stores Inc (USA)	220	1.6%
Boots [1] Alliance Boots (USA/ Italy)	2327	16.5%
Co-Op [2]	850	6.0%
Lloyds [1] Celesio AG (Germany)	1614	11.4%
Morrisons [1]	115	0.8%
Rowlands [1] (Phoenix (Germany))	496	3.5%
J Sainsbury [1]	270	1.9%
Superdrug [1]	209	1.5%
Tesco [1]	360	2.5%
Non-corporate chains [3]	2155	15.3%
Small chains and independents [3]	5508	39.0%
Total Pharmacies	**14214**	**100%**

1. GPhC database search 03/03/2012

2. GPhC database search 03/03/2012. This figure includes all Co-operative societies with 5 or more pharmacies. A more detailed breakdown shows that that the organisation known as "The cooperative pharmacy" (comprised of National Co-operative Chemists Ltd and Co-operative Group Healthcare Limited) has 770 pharmacies on the GPhC register.

National Co-operative Chemists Ltd	484
Co-operative Group Healthcare Limited	286
West Midlands Co-operative Chemists Ltd	38
East of England Co-operative Society	8
Lincoln Co-operative Chemists Ltd	34

3. Non-corporate chains refer to regional and local chains of 6 or more pharmacies. Small chains and independents refer to pharmacies not in any form of group and those in groups up to five in number. The numbers here are calculated by applying the percentage of pharmacies classed as independent by the DH in the report "General Pharmaceutical Services in England 2001-2002 to 2010-11; Table 4: Number and percentage of community pharmacies owned by independent and multiple contractors in contract with PCTs at 31 March, England 2006-07 to 2010-11"

Appendix 2: European Court Of Justice decision on Pharmacy Ownership

In May 2009 the European Court of Justice (ECJ) passed its judgement on two cases on the right of a member state to restrict ownership of pharmacies.

The ECJ was asked to determine whether German and Italian legislation, which provides that only pharmacists may own and operate pharmacies, was compatible with EC law. It came to the conclusion that, although national legislation prohibiting non-pharmacists from operating pharmacies or acquiring stakes in companies operating pharmacies did constitute a restriction on the freedom of establishment, this was justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality.

The Court found that the very particular nature of medicinal products distinguished them from other goods. As such, the ECJ decided that the operation of pharmacies by non-pharmacists could represent a risk to public health and Member States should be able to take protective measures to ensure the reliability and quality of the provision of medicines to the public. It is therefore lawful for Member States to decide that only qualified, independent pharmacists may sell medicinal products in order to ensure that adequate safeguards are in place to protect the public. This was found to be particularly important with regards to the supply of medicinal products at the retail level as there is a serious health risk if such products are consumed unnecessarily or incorrectly.

The ECJ took the view that:-

- medicines are not items of ordinary commerce
- overconsumption of medicines may be harmful to the patient and represents a waste of resources
- Member States may require that medicinal products be supplied by pharmacists enjoying genuine professional independence
- Member States may take measures to reduce the risk that that independence will be prejudiced; this includes the right to restrict pharmacy ownership to pharmacists
- a pharmacist is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint.
- non-pharmacists lack training, experience and responsibility and do not provide the same safeguards as pharmacists.
- Member States may restrict ownership of pharmacies to pharmacists where they think that there is a risk that a non-pharmacist owners may compromise the independence of employed pharmacists by
- encouraging them to promote the medicinal products which they produce or market themselves
- encouraging them to sell off medicinal products which it is no longer profitable to keep in stock
- making reductions in operating costs which may affect the manner in which medicinal products are supplied

In more detail, the ECJ included the following statements:-

51 ...the protection of public health is one of the overriding reasons in the general interest which can justify restrictions on the freedoms of movement guaranteed by the Treaty such as the freedom of establishment ... and the free movement of capital.

52 More specifically, restrictions on those freedoms of movement may be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality ...

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

55 .... attention is to be drawn to the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods ...

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

57 Overconsumption or incorrect use of medicinal products leads, moreover, to a waste of financial resources which is all the more damaging because the pharmaceutical sector generates considerable costs and must satisfy increasing needs, while the financial resources which may be made available for healthcare are not unlimited, whatever the mode of funding applied ..... There is a direct link between those financial resources and the profits of businesses operating in the pharmaceutical sector because in most Member States the prescription of medicinal products is borne financially by the health insurance bodies concerned.

58 In the light of those risks to public health and to the financial balance of social security systems, the Member States may make persons entrusted with the retail supply of medicinal products subject to strict requirements, including as regards the way in which the products are marketed and the pursuit of profit. In particular, the Member States may restrict the retail sale of medicinal products, in principle, to pharmacists alone, because of the safeguards which pharmacists must provide and the information which they must be in a position to furnish to consumers .....

59 In this connection, given the power accorded to the Member States to determine the level of protection of public health, it must be accepted that Member States may require that medicinal products be supplied by pharmacists enjoying genuine professional independence. They may also take measures which are capable of eliminating or reducing a risk that that independence will be prejudiced because such prejudice would be liable to affect the degree to which the provision of medicinal products to the public is reliable and of good quality.

60 In this context, three categories of potential pharmacy operators must be distinguished, namely natural persons having the status of pharmacist, persons operating in the pharmaceutical products sector as manufacturers or wholesalers, and persons neither having the status of pharmacist nor operating in that sector.

61 It is undeniable that an operator having the status of pharmacist pursues, like other persons, the objective of making a profit. However, as a pharmacist by profession, he is presumed to operate the pharmacy not with a purely economic objective, but also from a professional viewpoint. His private interest connected with the making of a profit is thus tempered by his training, by his professional experience and by the responsibility which he owes, given that any breach of the rules of law or professional conduct undermines not only the value of his investment but also his own professional existence.

62 Unlike pharmacists, non-pharmacists by definition lack training, experience and responsibility equivalent to those of pharmacists. Accordingly, they do not provide the same safeguards as pharmacists.

63 A Member State may therefore take the view, in the exercise of its discretion referred to in paragraph 36 of the present judgement, that, unlike the case of a pharmacy operated by a pharmacist, the operation of a pharmacy by a non-pharmacist may represent a risk to public health, in particular to the reliability and quality of the supply of medicinal products at retail level, because the pursuit of profit in the course of such operation does not involve moderating factors such as those, noted in paragraph 61 of the present judgement, which characterise the activity of pharmacists .....

64 It is therefore permissible for a Member State inter alia to assess, in the exercise of that discretion, whether such a risk exists in the case of manufacturers and wholesalers of pharmaceutical products on the ground that they might compromise the independence of employed pharmacists by encouraging them to promote the medicinal products which they produce or market themselves. Likewise, a Member State may determine whether operators lacking the status of pharmacist are liable to compromise the independence of employed pharmacists by encouraging them to sell off medicinal products which it is no longer profitable to keep in stock or whether those operators are liable to make reductions in operating costs which may affect the manner in which medicinal products are supplied at retail level

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