by the Pharmacists' Defence Association.

THE RESPONSIBLE PHARMACIST

A Consultation on Proposals for the Content of the Responsible Pharmacist Regulations

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the pharmacists' defence association

Introduction

The PDA's response to this important consultation is split into to several sections;

Section 1. Over-arching concerns

Section 2. Summary which highlights the most significant recommendations

Section 3. A section detailing specific important issues which do not naturally lend themselves to any one chapter of the consultation

Section 4. Responses to each chapter of the consultation, prefixed by general comments

Section 5. Potential loopholes in the regulations

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Section 1.
Over-arching concerns

It is felt that an opportunity should be taken in this introduction to register some over-arching concerns about the totality of this consultation and the general way in which it is being undertaken.

"Minister, if you must do this damn silly thing, do you have to do it in such a damn silly way"

Quote from the famous 1980s BBC sitcom 'Yes Minister'

It has been explained to the profession of pharmacy that the Department of Health (DoH) has decided that due to the practical consequences of what has been proposed in the Health Act, the Responsible Pharmacist (RP) consultation would be undertaken first and then some time later, the issue of Remote supervision would then be considered. Despite the fact that this was not an ideal scenario, those involved in the consultation thus far, by attending the national meetings and through involvement in other dialogue have proceeded on that basis. What is also apparent, is that as a consequence, the regulations on Remote Supervision are some way off. Consequently, whilst new regulations pertaining to the RP may soon appear, they have to reflect the Status Quo position of a pharmacist (either the RP or another supervising pharmacist) being present in the pharmacy **at all times**.

The PDA is concerned that in respect to the proposed staged approach described, this consultation appears to have lost its way in so far as it gives a strong impression that it simultaneously also wants to deal with Remote Supervision. Whether this has occurred because of poor draughting, or because of confusion in the mind of the authors, is irrelevant because it is essentially unhelpful.

Many of the answers to the questions would be different if being answered from a standpoint of 'Remote Supervision' as opposed to a pharmacist being present. Consequently, it is the belief of the PDA that the result of this consultation will have little value if indeed it was the intention to seek the opinions of the profession as it is no longer clear as to what this consultation is about.

For the avoidance of doubt, the PDA's responses are provided on the basis that no Remote Supervision regulations are in place and that a supervising or RP will be present in the pharmacy.

If what the DoH is trying to achieve is to persuade the public that it can place greater reliance on the pharmacist, then the PDA supports that concept. However, the PDA has some in principle and fundamental concerns about exactly how the Department is trying to achieve that end.

The public value a pharmacist because they have unparalelled access to a highly trained health professional. What adds even greater value is the fact that the pharmacist is able to make professional judgements based on their superior training and experience which will support the immediate needs of that member of the public and their family.

The problem is that the entire thrust of this consultation so far appears to place a worryingly large emphasis on written procedures and standard operating procedures. These will have to be emphasised even more when we consider the Remote Supervision concepts.

It is the view of the PDA that whilst there will always be a need for written procedures, these should merely be in place to supplement what is the most important factor, which is the pharmacists independence to make professional judgements.

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We are concerned that the level of reliance being placed on written procedures by this consultation is taking the profession in the wrong direction and this will be to the ultimate detriment of the public.

Finally, we are also concerned that the effect of this legislation will be to substantially change the relationship between the RP and the Superintendent Pharmacist. However, the thrust of the consultation document avoids dealing with this issue in the substantantive way that these proposals deserve. This will have the effect of storing up problems for the future.

Poorly thought through concepts based on the wrong basic principles can only result in bad regulations resulting in compromised working practices which will ultimately impact upon patient safety.

It is the view of the PDA that the DoH needs to revisit the basic principles upon which it is making these proposals and effectively go back to the drawing board.

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Section 2.
Summary of the main recommendations

a. It is the view of the PDA that the DoH needs to revisit the basic principles upon which it is making these proposals and effectively go back to the drawing board.

b. The PDA supports the updating of the current personal control and supervision requirements but not in the manner proposed by the DoH.

c The PDA urges the DoH to carry out an impact assessment of these regulations. The view being expressed by the DoH that the proposed changes will not result in significant changes to pharmacy practice is patently incorrect. Furthermore, the PDA urges the DoH to assess how these regulations may institutionalise poor working practices especially with respect to women and minorities who now comprise the majority of the workforce.

d. The PDA supports the concept of a "RP" (RP) but urges the DoH to look again at the issue of how the RP interrelates to the superintendent pharmacist. In light of the proposals, the view expressed by the DoH that the RP will be subject to the directions of the superintendent pharmacist is highly questionable.

e. The PDA proposes that all pharmacists must undergo a competency based assessment before assuming the role of the "RP". Such an assessment must follow suitable training which provides the RP with new skills and an understanding of the complexities of liability issues and also prepares the RP for a proper interface with the employer. The PDA recognises that whilst this is an important pre-requisite, the logistical, cost and practical implications may well mean that the introduction of the RP regulations would be many years away.

f. The PDA proposes the independent assessment of core procedures by a competent authority and an easy to understand "kitemark" for the generation of core written procedures. Such a kitemark system of validity, for the production of core written procedures would be especially relevant to locum RPs who comprise some 40% of the workforce.

g. The PDA is concerned at the lack of information contained in the proposed Statutory Pharmacy Record and proposes templates in the Appendix of additional information to be recorded.

h. The PDA argues that the idea of a 'sign off' of written procedures which run into hundreds of pages is unrealistic and asks the DoH to look again at this aspect of its proposal. The PDA makes some detailed recommendations in this respect in the relevant section.

i. The PDA strongly recommends that all pharmacy procedures and the pharmacy record must always be available in paper format and if desired in electronic form.

j. The PDA strongly believes that regulations should enshrine the right for regulatory bodies, competent Health and Safety organisations, trade associations like the NPA, PCOs' and the PDA to contribute to the Pharmacy Procedures for a specific pharmacy whenever asked by either the RP or the pharmacy owner.

k. The PDA advocates that regulations must stipulate a minimum review period and certain triggering circumstances for a review of the Pharmacy Procedures. In addition the name, registration details and qualifications of the individual who established the procedures must be recorded in the pharmacy record.

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l. The PDA proposes that the incoming RP is only liable for procedures that he has changed and that the RP that originally established the basic procedures is responsible for any inherent unsafe practices therein.

m. The PDA strongly supports the concept of One RP/One pharmacy

n. The PDA proposes that when an incoming RP decides that matters outside of the RP's control have rendered the pharmacy unsafe, then the RP must be able to 'sign off' from RP responsibility. When this occurs, the RP status must be able to pass to another pharmacist in a suitable position of authority such as an area manager or superintendent. At that point, the pharmacist present in the pharmacy would simply become a supervising pharmacist. The "emergency RP" would be allowed only a limited time in which to resolve any crisis. This would prevent this extra-ordinary measure being abused for cost reduction purposes.

o. The PDA opposes the general concept of an absent RP but appreciates the need for absence in four strictly defined scenarios.

p. The PDA suggests that the name of the absent RP should be prominently displyed in the pharmacy whenever that RP is absent.

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Section 3.
Specific Issues of Concern

Many of the concepts put forward in the consultation appear to be detached from a comprehensive appreciation of the operational realities of pharmacy practice where the collective wisdom does not support its view, or the requisite evidence is lacking. Worse still, in some cases there is substantial evidence to demonstrate that significant risks will be introduced for the public should these proposals go ahead. Many of these ideas will at best not deliver any of the additional value that is being proposed and are at worst potentially highly damaging or unsafe. Examples include;

Skill mix

The consultation states;

"The DoH's view is that the RP should check the pharmacy procedures when s/he becomes responsible for the pharmacy to assess the need for any changes. In doing so, the RP will use his/her knowledge of the pharmacy business and the skills and experience of staff working in the pharmacy to satisfy him/herself that the procedures in place support safe working in the pharmacy and that staff are working to these procedures" its own commissioned research published in 2002 and which forms the foundation for these regulations recognises that there is little research on "skill mix":

"This makes it very difficult to provide evidence of what constitutes an appropriate skill mix for the community pharmacy. There is also a lack of consideration given in the literature to competence as defined in the Kennedy Report. Responsibility and accountability are what separate many professionals from their support workers, but views and attitudes towards these by different levels of staff are rarely covered. " (Ref 1)

Tunnel vision

So keen is the will to introduce the idea of a 'signing off', that no attention has been paid to the fact that the 'sign off' process also produces a 'non signing off' scenario where an incoming pharmacist is unprepared to sign off procedures for professional or environmental reasons. The consultation appears not to want to consider the effect of a 'non sign off' and therefore has no idea on how this would effect the smooth operations of the pharmacy (or indeed its effect on patients).

Its expectations on how many pharmacists will actually read and consult the written procedures give cause for concern. The consultation states;

"Whilst a degree of consistency will help those wishing to consult pharmacy procedures .." (item 3.15)

This indicates that a genuine read through of the written procedures will be optional. This removes the concept of the conscientious "sign-off" of procedures in all cases and ignores the whole idea of a non-sign off altogether.

It is the firm view of the PDA that many pharmacists will refuse to sign off written procedures in situations where they are inadequate, or more likely, when they no longer suit the operational realities of the particular pharmacy. When this occurs, they will naturally seek and receive the support of the PDA.

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The extent of reliance on written procedures by support staff

Evidence from the Netherlands points to the inherent risk of relying on support staff to follow protocols. (Ref 3)

Research has shown that in the Netherlands where a pharmacist is allowed to be absent for periods of time (similar to the Remote Supervision proposal), the support staff left in the pharmacy did not observe the written procedures for over 40 per cent of the time. Even more worryingly the research found that for what is described as "pre-conditions for clinical care", SOPs were not followed for a staggering 66 per cent of the time.

Simply put, even the most basic SOPs relating to basic tasks before a repeat prescription was issued by a highly trained Dutch technician in the absence of a pharmacist were not followed.

It is the firm view of the PDA that the consultations reliance on the near universal adherence by support staff on written procedures represents yet another fundamental flaw in the whole approach to these proposals. This safety measure seems attractive in its theoretical application, in reality it will not occur and this will introduce significant risks to the public.

The expectation that support staff will accept the extra responsibility.

The DoH commissioned a workforce survey (Ref 1) which indicated that many technicians did not want additional responsibilities

"The overall consensus view is that the pharmacist should stay on the premises"

The research also noted :

"Whilst at a further point in the session some members of the group stated they enjoyed such aspects of their work because the responsibility was 'stimulating and a challenge', some of the group also felt that they are pushed into such duties. "

The overall approach taken by these proposals are based on the notion that the additional responsibilities will be widely welcomed by registered technicians. The evidence to support this appears to be lacking.

There is a real danger that the 'sweeping changes' approach taken by this consultation will result in registered technicians finding themselves shouldering the burden of new responsibilities that they would actually prefer not to accept.

Alternatively, the converse may be true, where registered technicians as a consequence of being at work, will not know that they are now to be held accountable for matters which they did not appreciate.

As a minimum requirement of the regulations, registered technicians must 'sign off' that they are happy to take such additional professional accountability, at the same time as an RP undertakes his 'signing off' as an RP for that pharmacy. At all times transparency must feature in any processes that are used.

Access to the Pharmacist in Context of Overall Benefit to Public Health

The pharmacist is the only healthcare professional that the public can consult personally without an appointment in easy and convenient locations. The consultation acknowledges this;

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" .. the pharmacist's ability to be absent from the pharmacy may mean that members of the public will be unable to rely on seeing a pharmacist when they visit a pharmacist." (item5.9)

Without even considering the wider aims of the DoH to ultimately introduce Remote Supervision (which we are not yet considering), there appears to be a rather worrying tendency for the consultation to infer that patients should be able to come to rely more on support staff because the RP should be involved in more important things. What would have been a more appropriate emphasis, would have been to use the support staff in such a way as to allow the RP to be even more available to members of the public wanting to speak to the pharmacist in the pharmacy.

This is important because the Consumers Association magazine, Which, (Ref 5) found that 30% of respondents would not trust the advice of pharmacy assistants. Even if only a few of these 30% could not see a pharmacist instantly and then decide instead to see the GP this would place significant extra pressure on GP's and on the NHS generally. If the GP surgery is closed the patient may be tempted to go straight to A&E department

A report on skill-mix commissioned by the RPSGB also made the following observation:

"Over the last decade, the Consumers' Association (who publish "Which") has repeatedly criticised deficiencies in the level of advice, questioning and referral of consumers to other health care professionals from community pharmacies, particularly if the sale is managed by a pharmacy assistant. "(Ref 8)

The Safe Supply of Medicines

The consultation acknowledges that: "Public safety is paramount" (7.4) but proposes regulations that at best will not enhance public safety and at worst could have a serious negative effect. For example, the DoH simply states that the pharmacist only needs to assess new prescriptions or any changes to prescriptions (some 80% of all prescriptions are repeat prescriptions.)

However, the professional body, the RPSGB recognises that:

"Prescriptions which 'have not materially changed' will be difficult to define and the fact that a repeat prescription has not changed may in itself indicate a problem " (Ref 6)

Similarly, in a research paper published in the British Medical Journal, (Ref 10) some 30% of Adverse Drug Reactions needing hospitalisation are caused by patients taking simple aspirin or NSAIDS. These simple items can be bought at petrol stations or the the local supermarket with zero involvement of the pharmacist. It is notable that 70% of ALL adverse drug reactions are preventable. The cost for these hospitalisations is hundreds of millions of pounds per annum. How has the DoH costed the potential extra overall burden of the absent pharmacist to the NHS?

The experiences of the PDA in handling many hundreds of dispensing error claims indicate that repeat prescriptions are just as prone to error incidents as are newly written prescriptions.

The consequences of many medicine supply non-interventions may take many years to come to light. The DoH has failed to consider the cost of the pharmacist not being involved in these assessments in the overall context of public health.

The PDA therefore strongly argues that whether this is the RP or the supervising pharmacist, an involvement in clinical assessments of all prescriptions is vital.

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Helping the Pharmacist develop Clinical Services

A recurrent explanation given in the consultation is that these proposals will enable the pharmacist to develop more clinical services.

We note that current personal control arrangements have not prevented Scottish pharmacies to take on many new roles such as a Scotland wide minor ailments scheme or a Scotland wide emergency supply scheme. Repeated requests by the PSNC and other bodies for simple measures which would truly make better use of the existing pharmacist workforce in England, such as pan-accreditation across PCOs have been repeatedly ignored. It is apparent that many other much more workable proposals could have been taken up by the DoH so as to make better use of the skills of the pharmacist.

Workforce issues

A fundamental assumption that appears to underpin these regulations is that there may be insufficient pharmacists to fully discharge clinical and supervision duties and perhaps also to develop the role of the pharmacist in the future. The PDA argues that the DoH should consider dealing with the causes rather than with the perceived symptoms. It is the view of the PDA that substantial pharmacist resource could be released if the issue of potentially poor employment practices in relation to both ethnic and female pharmacists were to be addressed. This may be contributing to significant numbers seeking alternative careers. (Ref 5,13 and 14).

If the DoH is unprepared to deal with these issues, then by developing new regulations to try and create 'more pharmacist availability' it could inadvertently be acquiescing to and hence institutionalising these problems. A detailed discussion on this is not appropriate in this response but the PDA wishes to stimulate further discussion on this subject.

The following is an extract from a study published in November 2007 by the University of Manchester :

6.2.1.2 Key finding

"Occupational segregation – along both gender and ethnic lines – begins as individuals choose or are prevented from choosing their preferred sector for pre-registration training. Given gender and ethnic differences in pharmacy practice patterns this segregation is likely to have serious consequences for workforce supply." (ref 14)

The report goes onto say

"Yet ensuring a closer match between expectations and opportunities may be difficult to achieve amongst some subgroups, given our finding of possible discrimination against Minority Ethnic (ME) students underlying the process of applying for and securing a training post.

We therefore advocate a programme of further research to explore the barriers and facilitators to career progression amongst ME members of the cohort which incorporates a thorough investigation of possible discrimination. This research should help to identify the relationships between structural aspects facilitating or restricting ME pharmacy graduates' career opportunities and explain the ways that ethnicity is implicated in the perpetuation of occupational segregation in pharmacy practice."

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Section 4.
Responses to each chapter of the consultation, prefixed by general comments

Pharmacy procedures (Chapter 3)

General comments

The review of written procedures, which may run to hundreds of pages, which the incoming RP (RP) is expected to undertake upon arrival at the pharmacy is a perfect example of the how authors of the RP proposal demonstrate a significant lack of insight into the realities of (particularly community) pharmacy operations. There is no possibility that a proper review of these procedures could ever be undertaken in the way described in a true life working situation.

Alternatively, if the proposal is that the RP simply signs off the written procedures without actually reading them (as seems more likely from reading this consultation), then this indicates that at its very foundation, the RP proposal is based on flawed and unacceptable principles, the consequence of which could result in unacceptable risks to the public and also to the RP.

If the review of written procedure is meant to be a 'risk management measure' then the way in which it is handled in the consultation indicates that it is likely to be a hollow exercise providing no worthwhile benefit to patient safety. Most certainly, it will not be the 'safety panacea' that the authors of the RP consultation may have wished it to be.

Furthermore, had the consultation involved an impact assessment, then this would have clearly demonstrated the issues of non feasibility.

The PDA strongly believes that the proposal for incoming RPs to review written procedures upon arrival in the pharmacy is not workable and consequently far from providing added safety for patients, it actually represents a risk to the public.

Chapter 3 acknowledges that the RPSGB has made it a professional obligation for pharmacists to adopt standard operating procedures (SOP's). However, what appears to have been missed by the DoH, is that in real life, the SOPs can only be entirely relevant in certain situations. In many other operational scenarios they can only be used as a general guide as in real life, situations routinely present which require pharmacists to override written SOP's with professional judgements which match the situation at hand. This concept is not only widely known to practicing pharmacists, but also to RPSGB Inspectors who routinely visit pharmacies and who have found that the overwhelming majority of pharmacists, support staff and pharmacy owners do not follow SOP's.

SOPs or pharmacy procedures can never act as a substitute for professional accountability and judgement. The PDA contends that what truly defines a professional is the ability to exercise that professional judgement, even when that may mean acting outside the accepted "norm", not in accordance with a written SOP or even outside the law, because these actions are justified in the patients' or the greater public interest. This is by far the greatest benefit provided to the public of having a pharmacist available at all times in a pharmacy.

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The PDA strongly believes that the reliance on written SOPs by the authors of the RP report is fundamentally flawed and that this represents the introduction of another serious and fundamental risk in these proposals.

The recent report by the Governments Chief Medical officer, Sir Liam Donaldson, made the following observation in relation to the contribution of poorly designed systems in causing harm to patients:

"Current concepts of patient safety place the prime responsibility for most adverse events on deficiencies in system design, organisation and operation rather than on the negligence or poor performance of individual providers or individual products. Indeed, the level of harm arising from error in unsafe systems versus unsafe doctors is several orders of magnitude higher" (Ref 7)

The PDA strongly supports this view. It is a major concern that many of the systems proposed by the RP consultation are deficient and it is therefore inevitable that if implemented, they will increase the chances of harm to patients.

3.1 The DoH believes there is a need for a balance to achieve some consistency in the content of the pharmacy whilst allowing the RP sufficient flexibility to ensure these meet the operational needs of the individual pharmacy

3.2 Q. Do you agree with this approach? If not, what are your reasons for this and what do you propose instead?

The PDA agrees that there is a need for consistency in the content of the procedures especially given the high level of locum working. Data from the pharmacy 2005 workforce census showed that in community (retail) pharmacy nearly 2 out of 5 posts were locum positions. (Ref 9)

The proposal is the procedures cover, as a minimum requirement, the areas specified in the regulations. Chapter 3 sets out what these minimum areas might be.

3.3 Q. Do you think the proposed minimum areas are the right areas?

3.4 Q. Are there any other areas that you feel the regulations should specify be covered in the procedures? If so, what are these and why should these be covered?

3.2 Answer

The PDA view is that the minimum areas are not adequate to secure the safe running of any pharmacy premises. The PDA has four major areas of concern. Incoming RPs, especially locums must be able to inspect key pieces of information described below. Thus the pharmacy procedures must cover how these matters are recorded and also how they can be inspected.

The sign off

As described before, although in theory the 'sign off' would be a good risk management measure, in real life it will be very difficult to deliver, and unless it is done dilligently, it will become a 'mere formality' exercise which does not actually result in a meaningful act of accepting the written procedures by an incoming RP.

We argue that for a genuine 'sign off' to occur, then the RP must be able to properly undertake this exercise. If this cannot occur then a 'sign off' must not be given. We would want to see procedures established which give the new incoming RP's a meaningful opportunity to examine the written procedures at the start of their period of duty.

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The staffing level

A critical feature of any pharmacy is the staffing level. Without having a model template of staff for that particular pharmacy, an incoming RP will find it difficult to decide whether the pharmacy has a suitable staffing profile. This model staffing template should also include who has initially established the staffing level, their name and registration number and the date when these levels were established. This template should also contain the qualifications of all staff and how long they have worked in that pharmacy. A proposed model staffing template is attached (Appendix A). We would expect that an up to date model staffing template would form an essential component of the written procedure which the incoming RP should inspect.

The original author of the written procedure

Since any incoming RP will have to review pharmacy procedures it is essential that from the Pharmacy Record it is possible to identify the pharmacist who originally established the procedures. This would include name and registration number and the date when the written procedures were established and /or last updated. In addition, any changes made by a subsequent RP should identify the RP and include the dates and times when these changes were made. A proposed template is attached in Appendix A.

Knowledge of any historic concerns or problems

Incoming RPs must be able to view any concerns or issues that previous RPs would want them to be aware of. This may alert them to potential situations that may need extra vigilance. For example, this may cover a factor to do with workload issue – say, a rush from the local surgeries at 3.00pm. Or may have more to do with messages about specific ongoing patient care scenario's. Currently, this is a widely accepted principle relied upon by good locum pharmacists when entering a pharmacy which stands up to the safety test. Consequently, the written procedures must state the need for such a record and also must provide for a vehicle in which these historic issues can be recorded e.g. a records or pharmacy issues book etc. A proposed template is provided in Appendix A

3.5 Q. Do you agree the pharmacy procedures should include arrangements for the sale of GSL medicines?

YES.

Patients expect pharmacies to have professional staff and to provide a professional service. Customers making GSL purchases from a pharmacy can expect to have a higher standard of care than when purchasing them from a petrol station or supermarket, even if they think that they may not need any additional guidance.

Given that one of the stated reasons for modifying the Medicines Act and the re-definition of personal control is to enable the SAFE sale of GSL medicines we believe that the pharmacy procedures should include arrangements for the supply of any medicine (GSL, P or POM).

The procedures must also deal with situations where a referral to a pharmacist is necessary.

3.6 Q. Do you agree that the inclusion of areas, over and above the specified minimum areas, should be a matter for the pharmacy owner/superintendent pharmacist and the RP? If not, what do you propose and what are your reasons for this?

We believe that these issues are matters that should also involve other players, the proposed list is not wide enough. The

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majority of pharmacists are employed by large companies with corporate legal departments whose role is to ensure the 'smoother and more efficient operation' of the corporate entity. The experience of the PDA indicates that many employee and locum pharmacists find it difficult to manage the corporate steamroller. It is suggested that when dealing with matters over and above the specified minimum areas, RP's must be allowed the option to formally involve outside parties such as those described below;

- Given the expertise of the PDA in dealing with operational and risk management issues it is felt that the PDA union, when specifically requested to by a member should be given a right to comment on specific individual pharmacy procedures. Individual pharmacists will otherwise find it difficult to ensure that they strike the right balance between employers needs, the patients needs and their own professional interests.
- The consultation acknowledges that clinical governance matters are a matter for within pharmaceutical services contractual framework. These are monitored by PCOs. Therefore, it is essential that PCOs are able to specify the records they may need in order to discharge their duties. This makes the local PCO one of the parties that should have an input.
- RPSGB inspectors may, with their substantial and wide experience provide a useful external third party contribution to defining minimum procedures relevant to that particular pharmacy. If necessary, and particularly if requested so to do by an RP, the Inspectorate should be able to provide an input and in certain cases should be able enforce procedures for that individual pharmacy.

The proposal is that pharmacy procedures may be set out on paper or electronically, provided these are readily available and accessible to those needing to consult them.

3.7 Q. Do you agree with this approach? Are there any other requirements (other than readily available and accessible) that you consider should be set out in the regulations? If so, what are these and your reasons for putting them forward?

The PDA has no objection to procedures being set out electronically but they should also always be available in paper format at each pharmacy. Thus the new incoming RP's can familiarise themselves with immediate issues and have at hand a copy for issues that may arise during the working day.

The majority of pharmacies have only one computer so an electronic only option could make it very difficult to consult procedures during the day. It is also extremely difficult to read long documents on a computer screen.

When downloading software one can only do so after having clicked a box accepting terms and conditions. Few individuals actually read the terms before ticking the "I accept" box? The PDA is concerned that an electronic only set of procedures may be used to create an automated short cut "I accept" tick-box electronic record i.e. a meaningless exercise which would do nothing to enhance safer working, but which would provide an electronic impression that all the written procedures have indeed been read and accepted by the RP.

The proposal is that regulations do not specify the format used for setting out the pharmacy procedures

3.8 Q. Do you agree with this approach? If not, what do you propose and what are your reasons for this?

3.9 Q. Do you agree with the view, set out in the consultation paper, on requiring the format used to allow the RP to "sign

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off" that s/he has checked the procedures and is content these support safe working in the pharmacy? If so, what are your reasons for supporting that view?

3.10 Q. Are there other matters that you feel should be included in the regulations in relation to the format of the pharmacy procedures?

The consultation cedes that

"a degree of consistency would help those wishing to consult procedures"(3.15)

This consistency should extend not only to the minimum information fields contained in the procedures but also to the format. If we genuinely want the RP's to feel professionally confident in signing of the written procedures then we need that process to be as universally accessible as possible. This means that the two components cannot be separated in the way that they should be treated presentationally.

3.11 The DoH's view is the RP should check the procedures on taking on responsibility for the pharmacy and assess the need for review and/or amendment as appropriate.

3.12 Q. Do you agree with this approach? If not, what do you propose and what are your reasons for this?

We fully support this approach as it is pivotal to the issue of taking responsibility by an incoming RP. However, we argue that for procedures to be meaningful they must be detailed. Given that level of detail which would be contained in these procedures it will be very difficult in a busy pharmacy for the incoming RP to meaningfully check all these procedures which may run to hundreds of pages and this is where the theoretical proposals which are beneficial become unworkable.

Furthermore, this is one area where the DOH's view becomes muddled, for on the one hand it wants incoming RPs to check and amend these procedures. On the other it indicates that not all RP's will want to read/consult these procedures;

It is stated that (item 3.15)

"a degree of consistency would help those wishing to consult procedures".

The consultation document goes further (in item 3.18) where it states;

"Any practice resulting in numerous, frequent, changes to procedures could result in unsafe working in a pharmacy where pharmacy staff have had insufficient time and training to gain an understanding of changes in the ways in which they are required to work"

We are very concerned about this collection of statements which give the impression that the DOH is altogether unsure about its policy. We either accept the concept of the responsible and consciencious 'sign off' and with that comes the likelihood of changes being made by an incoming RP, or we accept that the written procedures cannot be read in the time allowed, are rarely changed and act as no more than a badge of process which these new regulations have invented (much like the requirement of hanging of the Health and Safety Policy statement on the walls of all offices). For if that is to be the case then the incoming RP can not possibly ever 'sign off' and accept responsibility for it, unless it becomes a substantially slimmed down process covering no more than the most simple of operational issues.

Consequently, we are proposing the provision of the most basic information in the written procedures. Basic enough so

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as to be virtually universally applicable to all pharmacies. We also propose the use of standardised templates (see Appendix A). We argue that these should be produced as a 'kite mark' standard, and probably generated by a combined industry initiative body which can secure the support of practiitioners. This would enable incoming RP's to have read, understood and therefore accepted the written procedures at some time prior to sign off (possibly whilst undertaking CPD or at a training session specifically set up for this purpose). RP's could 'sign off' knowing that these written procedures where the industry norm.

Importantly, generation of the 'kite marked' written procedures would be a process that would demonstrably need to involve the appropriate representatives from the professional body, the employers and also employee representatives. Managed properly, such an initiative could even act as the focal point which could begin to deal with some of the unacceptable working practices that currently exist.

Subject to these arrangements, the incoming RP would now be largely following established industry norm general procedures which could more readily be 'signed off'

Any additional (employer specific) procedures could then be made additionally available, but these could be much shorter and could be designed in such a way as to allow a meaningful 'sign off'. This option provides flexibility in so far as it allows the RP to sign off standardised industry norm procedures with confidence and even if he is unprepared to sign off employer procedures, the pharmacy will still be able to operate. Ultimately, the RP would then only assume specific personal liability for the procedures he has changed.

The DoH is seeking views on the review and/or amendment of the pharmacy procedures

3.13 Q. Do you agree that guidance may be a more appropriate means of providing information and advice on the review of procedures? If so, what are your reasons for supporting that view?

3.14 Q. Are there proposal(s) that you wish to put forward in relation to the review of procedures? What are the reasons supporting your proposals?

We maintain that regulation rather than guidance would ensure consistency and help the timely review of procedures. We propose the following as a minimum:

1) An annual review of ALL procedures and declaration on the adequacy of the employer specific procedures signed by the superintendent or his nominated representative like the area manager. This could be similar to the annual declaration made for controlled drugs under the new clinical governance framework.

2) The PDA's experience shows that by the far the most significant factors that lead to incidents occurring in the pharmacy are quality and quantity of staff and workload, consequently we suggest that anything that impacts on these two areas should immediately trigger a formal review albeit one which may just deal with the affected parts of the procedures (a partial review).for example:

   - A long standing / qualified member of staff leaving
   - A certain level of errors occurring within a defined time-span
   - An unexpected increase in workload (new care home being supplied with weekly dosette boxes).

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The consultation uses 4 potential scenarios (item 3.20) and various changes are made to procedures in these scenarios. However, where would these changes be recorded? Medical errors and incidents may not come to light until many weeks or months after the event. Memories of staff hours etc may become hazy. This is why it is important that any changes to pharmacy procedures are properly recorded in written format.

The PDA provides a template in Appendix A for how and where the changes could be recorded. This audit trail would be critical in cases where incidents came to light many weeks or months from the date when the event took place. For example where a dispensing error has come to light or when negligent advice in absence of the RP has been given.

The consultation paper looks at the role of the RP, the pharmacy owner, the superintendent pharmacist, and the professional regulatory bodies in relation to the pharmacy procedures.

3.15 Q. What is your view of their role and what are your reasons for taking that view?

All these entities have a role. In addition, we also believe that there should be a role for the local Primary Care organisation and also the RPSGB inspectorate, especially if this is invited by the employer or by the RP. Importantly, since we feel that the agreement of procedures will inevitably involve a significant negotiation on cost between the RP and the owner, there should also be a role for the pharmacists union especially in relation to guidance on pharmacy procedures. An individual pharmacist needs adequate back up by a competent entity such as a Union.

Within this question we are concerned about several significant issues and these mainly involve the superintendent pharmacist.

1. The 'mere formality' superintendent

Currently, any pharmacist can become a superintendent pharmacist and often, hard pressed owners persuade short-term locums to sign the superintendents form simply to allow their pharmacy to operate legally. In many such instances, the locums sign this form more as a short-term exercise of expediency rather than because they fully accept the full legal responsibility that this position entails. Consequently, many such 'mere formality' superintendents resign just a few days later. The RPSGB too has alerted the DoH to the situation of temporary superintendent pharmacists. This was the RPSGB submission to the DoH on this subject.

"In some cases, a company will nominate a locum, with no real control over the business, as superintendent pharmacist of a body corporate and submit the relevant form to the Society. In all cases, the form must contain the signature of the nominated pharmacist, confirming that they have accepted the position. In the cases of 'locum' superintendent pharmacists, it is not unusual to find that they have resigned within a short timescale. In the past, prosecutions against companies have been dropped due to the fact that there was no superintendent pharmacist appointed at the time of the commission of the offences and the company has been dissolved by the time the case has come to court, which leaves no effective sanctions. "(Ref 4)

This consultation recognises that the "RP" is subject to the directions of a superintendent pharmacist. However, in reality, in many instances, this major building block of the DOH's strategy is flawed as there is no real superintendent pharmacist. This is a further example of how the building blocks of this whole proposal are far from solid.

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2. The RP is subject to the directions of the superintendent pharmacist

We are very concerned about the written reassurances given by the DoH (presumably to reassure current superintendent pharmacists concerned about losing control over their employee's), that the RP will be subject to the directions of the superintendent pharmacist. The notion that a pharmacist will agree to become a RP and take personal responsibility (and therefore personal liability) for what happens in the pharmacy whilst the environment is actually controlled by someone else (a superintendent) simply does not stand up to any kind of scrutiny.

Recent test cases such as the now infamous 'peppermint water' case saw the pharmacist facing criminal prosecution and then a professional disciplinary procedure for a dispensing error, whilst the superintendent of that company faced neither. More recently, in December 2007, a PDA member (locum) was held 100% liable in a civil court for an error which occurred despite the fact that a technician was involved and the superintendent was shown to have defective procedures in place.

These real life judgements indicate that the RP will indeed be held liable in every sense of the word and the DoH's proposal that the RP should be working subject to the directions of the superintendent is questionable.

The effect of this flawed hypothesis will (if left unchallenged) detrimentally affect the overwhelming majority of community pharmacists who are either employed or practicing as locums. Whilst these regulations require these pharmacists to accept the extra burden of signing off procedures and then to shoulder the responsibility if something goes wrong, the mistaken 'subject to the directions of the superintendent pharmacist' theory will continue to allow RP's to be coerced, bullied, process managed or simply asked to follow Head Office memo's by owners, superintendent pharmacists or their appointed area-managers (pharmacist and non-pharmacist) to accept working practices that the RP's may be unhappy about and which may be unsafe.

The PDA has clear evidence from numerous member incidents which show that a minority of Company area managers are deliberately mis-applying written company policy so as to reduce costs. When they do this, they deliberately hold informal meetings with their employee managers. No records or minutes are kept of these meetings and there are instances where potentially illegal advice and guidance is being given at these events. In other instances area meetings are taking place by conference calls and again no audit trail exists of appropriate or inappropriate advice which may be conveyed.

Furthermore, where pharmacists challenge such behaviour, threats of disciplinary action have been issued. In one recent instance this was done because some pharmacy managers failed to reach targets for MUR's set by area managers where it would have been near impossible to have achieved them without introducing unacceptable safety risks.

One can either address the symptoms by arguing that a grievance procedure exists or that the RP has the right not to sign off the procedures, or alternatively one can deal with the causes. To deal with the cause, there would need to be an understanding that the environmental conditions of the pharmacy (particularly staff quality, quantity and workload) are subject to the authority of the RP and not the superintendent.

We are particularly concerned at the lack of acknowledgement that registered technicians share the same code of ethics as pharmacists. Thus, in the pharmacists absence, there could be a real dilemma when a technician has to either follow his "professional" code or following a specific SOP. However, legally the liability for any untoward consequence of

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the technicians judgement will fall on the pharmacist. This is clearly an issue that needs further thought.

The pharmacy record: Chapter 4

General comments

The pharmacy record will be a statutory record with an offence being committed by the RP or owner for failing to complete the record fully. In addition, it will inevitably become an evidential source in the event of a regulatory episode or a civil claim if an error incident has occurred. As a consequence, the PDA is concerned that the DoH does not require a record kept for the reason for the absence of the RP.

In the PDA's submission there are only four scenario's where an absence should occur, (See Chapter 5) however, if the specific reason for absence is not recorded then an unexplained absence could cause problems for the pharmacist in the event of an error incident because the RP may not be able to convince a regulator or a civil court that the absence was appropriate. This could produce significantly worse regulatory or civil claim consequences for the RP. For example if a regulator or a civil court believes that the RP was absent because he was actually at the tennis club or maybe sent home by an area manager to save costs, then they are likely to view the RP in a poor light and consequently provide a harsher verdict.

This view is shared by other organisations such as the RPSGB when it states that :

"The pharmacist must be able to justify any absence from the pharmacy " (6)

This justification must be recorded.

The DoH proposes the regulations require the RP to include minimum specified information in the pharmacy record. Other information for inclusion in the record would be a matter for the pharmacy owner/ the superintendent pharmacist

4.1 Q. Do you agree with this approach and the proposed minimum information requirements?

4.2 Q. What are your views on proposals set out in the consultation paper for other information requirements in relation to the pharmacy record?

4.3 Q. Do you think there is a need for other information requirements in relation to the record? If so, what are these and your reasons for putting these forward?

The PDA supports the concept of a minimum record. However, we disagree strongly with what the DoH believes is a safe, sensible and workable minimum record. The PDA appreciates the need to balance unnecessary regulation with fit for purpose regulation.

The DoH proposes that the statutory record is one in which a RP accepts professional accountability for the proper running of that pharmacy.

The PDA suggests that the following additional minimum information is also recorded where appropriate. We attach a template in Appendix A:

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- Whether any changes were made to pharmacy procedures and why
- If the area manager or superintendent pharmacists' advice was sought before these changes were made
- The reason why the pharmacist was absent (see general comments section)

The PDA argues that a record of other staff including pharmacists working and at what specific time, is kept in the record.

In many cases an incident may only come to light after a delay which may be many months or even years. The situation where a pharmacist can be found liable because of an error made by support staff many years in the past is grossly unfair.

One recent civil case which involved a PDA member hinged on the fact that the employer alleged that the PDA member was present when the error occurred. After three years and at least two hundred thousand pounds worth of legal costs, two days before the case got to court, the employer accepted that their staff records had been inadequate and that the PDA member may not have been involved at all. The case against the PDA member did not proceed.

This scenario could occur again if proper records of supporting staff are not kept. It is especially important to record the details of the supervising pharmacist left in charge by the RP when absent and also of any registered technicians involved.

Another reason why a staff record would be helpful is to support an RP in the event that a poor staffing level is believed to be the cause of critical incidents in the pharmacy. This staff level would be particularly useful if it could be shown that a pharmacy routinely operates with sub-optimal staff compliments. Equally, such a staff record could identify quality concerns as it could establish which members of staff are routinely involved in dispensing or other errors.

Whilst the PDA accepts that it would be unwise to introduce "disproportionate burdens" on businesses, the right balance needs to be struck so as to ensure that the public can expect the safe provision of pharmaceutical services.

The proposal is the pharmacy record may be kept electronically or on paper, provided it is readily accessible and available to those who need to consult it. The DoH does not propose that regulations specify the format for the record – instead the regulations will specify the fields of information to be included in the record.

4.4 Q. Do you agree with this approach? If not, what do you propose and what are your reasons for putting your proposals forward?

We have commented already on the need for a paper record and the minimum fields that should be specified in the pharmacy record. Many pharmacies only have one computer and it may not always be possible to access this for non-dispensing purposes if needed during a busy day. A paper copy should always be available for reference.

The DoH proposes the regulations set out the minimum period that the pharmacy owner is required to preserve the pharmacy record and that the minimum period should be 5 years from the date of the last entry to the record.

4.5 Q. Do you agree? If not, what do you propose? What do you think should be the minimum period specified in the regulations and why?

We agree that 5 years is a reasonable time.

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Absence from the pharmacy: (Chapter 5)

General comments

We are concerned that despite being told that THIS WILL NOT BE THE REMOTE SUPERVISION CONSULTATION and that such a consultation will follow later, this section could give an impression that the Remote Supervision consultation has actually commenced – which it has not. We are even more concerned that despite this not being the Remote Supervision consultation, comments made herein will later be used by the DoH as some kind of statistical tool to support its Remote Supervision concept.

We await the consultation on Remote Supervision in due course and we will save our substantive comments on this subject for that consultation.

We clarify that since the current regulations which require the pharmacist to be present at all times are still in place, and that nothing in this RP consultation, nor the regulations that will immediately follow will introduce the concept of Remote Supervision, our comments in this section will deal with the 'Status Quo' as far as absence from a pharmacy is concerned.

For the avoidance of doubt, the PDA's position on absence from the pharmacy is that there are only FOUR defined scenarios where a RP may be absent:

- If a second pharmacist is physically present to supervise transactions
- In cases of a critical nature - for example to go to a patient's house or workplace when a critical prescription error which needs immediate attention has come to light
- For a mental and physical break when the risk of making a mistake outweighs the risk of a short period of absence.
- If the RP is holding a clinic in the consulting room where interruptions would create a greater risk (we consider working in the consulting room to be a de facto absence)

In these situations the RP should conspicuously display a notice which ensures that members of the public know who the RP is and also that at that particular time the RP is absent.

The DoH has stated the regulations specify the minimum proportion of time that the RP should spend in the pharmacy and this should be the majority of his/her time (ie more than 50% of each period when s/he is the RP and the pharmacy is operational).

5.1 Q. Do you support this view? What are your reasons for this?

5.2 Q What do you think should be the minimum proportion of time that the RP should be required to be present in the pharmacy? What are your reasons for this?

5.3 Q. If you do not agree, what do you propose and why?

Clearly, for lunch breaks and critical incidents, the time spent away from the pharmacy will be minimal. Where a clinical role beyond the pharmacy, or when a lengthy series of consultation room meetings occur, under the current regulations

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the pharmacist would leave the pharmacy in the hands of a supervising pharmacist. In this scenario the patient still enjoys having direct proximity and access to a qualified pharmacist.

To answer this question properly, we would ask that this is one matter that should be considered carefully in an impact assessment report as it would add valuable insights into the effect of altering the levels of responsibility and availability of the pharmacists in the team. Moreover, it would also help inform the forthcoming consultation on Remote Supervision.

5.5 Q. The DoH proposes the maximum time during any one period of absence that the RP may be away from the pharmacy should be three hours. The DoH seeks views on whether this period might vary in certain circumstances

5.5 Q. Do you agree the regulations should specify a maximum time? If so, should this be set at three hours?

5.6 Q. Do you think the maximum time might vary, subject to meeting conditions set out in the regulations? eg where another pharmacist or a suitably trained and registered pharmacy technician remain present in the pharmacy? If so, how might this vary and what are your reasons for putting that view forward?

5.7 Q. If you do not agree, what do you propose and why?

Our position on absence when a second 'supervising pharmacist' is made clearly above. The PDA view is that providing a second supervising pharmacist was present a RP may be absent from a pharmacy for any reasonable length of time. However, we would accept the DoH's proposal of requiring the RP to be present for at least 50% of the time IN THE EVENT THAT A SECOND SUPERVISING PHARMACIST WAS PRESENT. Our position on absence when no second pharmacist is available is also stated above in the previous question.

The proposal is the regulations specify the RP must be able to return to the pharmacy with reasonable promptness.

5.7 Q. Do you agree? If not, what do you propose and what are your reasons for this?

Implicit in this is the acknowledgement that some situations need the competency, qualifications, authority and accountability that only a RP will have.

A more detailed explanation of our position to the question above is combined with our response to the question below.

The proposal is the regulations require the RP to be readily contactable by pharmacy staff during any period of absence but do not specify the arrangements to be made – however, it may be appropriate to provide advice on this in guidance.

5.8 Q. Do you agree with this approach, including that guidance may be a more appropriate way of providing advice on arrangements for being readily contactable by pharmacy staff?

5.9 Q. If you do not agree, what do you propose and what are your reasons for this?

Ultimately, the interruption of RP's whilst they are busy providing alternative healthcare services and the consequent introduction of unnecessary risk to patients is a very serious flaw in the entire Remote Supervision proposal and this is why the PDA will be making a significant contribution to the Remote Supervision consultation when it occurs. However, we re-state that the scenario that we are dealing with in the current RP consultation is that for the RP to be absent, another pharmacist would need to be present.

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Consequently, with another pharmacist being present, the likelihood that the RP will need to be contactable will be remote, especially if the understanding is that the RP is called by the supervising pharmacist in a very limited number of emergency situations.

In this scenario, if the RP is to be actually present in the pharmacy for the majority of the time (see answers earlier in this section) then this risk manages the RP's absence even further.

We consider that the most urgent matters, those requiring immediate pharmacist input, will be those of a clinical / patient episodal nature. As such, with the supervising pharmacist being present, there should be no reason why this could not be handled immediately by the supervising pharmacist. We anticipate that those queries that may only be dealt with by the RP in this scenario, will be organisational or of a management nature and these matters could easily be dealt with by leaving a message on a voice-mail, or bringing the RP up to date during one of the RP's regular 'phone into the pharmacy' telephone calls. This means that no-one will need to interrupt the RP during any external clinic or patient service episode.

Under the circumstances, we would suggest that regulations need to stipulate that a procedure needs to be put in place which guarantees that the RP can keep in touch with the unusual developments of the pharmacy on a regular up-date phone-in or message on voice mail basis. Regulations would need to stipulate that such arrangements would need to be incorporated into the pharmacy's written procedures and also that all staff where made aware of the exact policy.

The proposal is that the RP is required to arrange for another pharmacist to be available to provide advice when s/he is absent from the pharmacy and is unable to be contacted by pharmacy staff. The DoH is also seeking views on whether the other pharmacist should also be a RP or eligible to take on that role

5.10 Q. Do you think that the regulations should require the RP to arrange for another pharmacist to provide advice where s/he is unable to maintain contact with the pharmacy? If so, should the other pharmacist also be a RP or eligible to take on this role?

5.11 Q. If you do not agree, you propose and why?

We are confused by this question which appears to be straying from the RP consultation to the Remote Supervision consultation although this is not yet underway.

We re-state our position, a supervising pharmacist will be present when the RP regulations become live. This supervising pharmacist should be able to deal with queries of a clinical or patient episodal nature. Anything else can wait for the return of the RP or for the regular 'call in' or voice mail message scenario described in the previous question.

The PDA position is that there is no justification for a complete absence of the pharmacist except in very tightly defined circumstances, which we have already described.

The regulations should not set out how the RP is to arrange for another pharmacist to provide advice during his/her absence. However, this might be a matter to be included in guidance.

5.12 Q. Do you agree with this approach? If not, what do you propose and why?

See points above

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Qualifications and experience: (Chapter 6)

General Comments

The consultation document says very little about the basic qualifications required by the RP. It is the view of the PDA, that the RP issue is not one that should be decided by length of time on the register, but more by some form of competency assessment. A higher level of responsibility is being bestowed upon this pharmacist and this requires a higher level of expertise. When considering that expertise, it is not merely a matter of whether the assessment of the pharmacist will show that the pharmacist currently has enough professional 'gravitas' to carry off the new role (an output), but it will also need to be an occasion where the potential RP can be taught the additional skills that currently may not be required of 'pharmacists in charge' (an input). These additional skills may include understanding the new liability issues, objectively signing off written procedures, understanding the impact on staffing levels, staff quality ,workload and environments on safe practice (The quality measures). The skills required will also mean that the RP knows how to manage properly, the new relationship between the RP and the superintendent / employer. Those who argue that there will be no change in this relationship are being disingenious.

The competency assessment approach is one that is also supported by other organisations who have contributed to this consultation.

Whilst it is the PDA view that the RP designation is a function of a competency assessment which is a process involving both inputs and outputs, for the record it is felt that the RP competency should not be designed into the curriculum of either the pre-registration year and the 4 year MPharm undergraduate course.

We would see the attainment of the RP designation being a post-graduate and post-registration further qualification. We believe that this would also entitle the holder to a higher level of remuneration which would compensate the RP for the higher level of personal liability involved in this role. We are concerned that if such additional training and remuneration is indicated, then this represents a very significant logistical challenge for pharmacy in the UK. This will mean that in reality the implementation of the RP regulations could take many years and have very substantial cost implications. The alternative is that RPs do not receive the additional training and are therefore inadequately prepared for this new responsibility. These considerations point at yet another very substantial oversight in the consultation.

The DoH is seeking views on an annotation to the registrar against those pharmacists with sufficient length of registration and experience to be a RP.

6.1 Q. What is your view and your reasons for this?

6.2 Q. Do you think there are other matters to consider in addition to those outlined in chapter 6? If so what are these and your reasons for putting them forward?

We disagree that the annotation should simply be a function of length of registration and experience. The only annotation which would be worthy of adding to the register would be an annotation that confirms the successful completion of a competency based assessment which followed some structured training to become a RP.

An RP annotation of the register will be required for a variety of reasons, not least is that the public rightly expects to be able to verify the status of a practitioner pharmacist.

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The online registers can be updated relatively easily and this is surely a basic function for any competent regulator.

Should there be a requirement that a pharmacist have a minimum period of experience following registration before taking on the role of the RP? In addition, could the period vary in specified circumstances?

6.3 Q. What is your view on a requirement for a minimum period of experience following registration before becoming a RP?

6.4 Q. Do you think the period could vary in certain circumstances? If so, what might these circumstances be and what is your reason for putting these forward?

As described in the previous point (inputs), RPs must have additional skills over and above those currently seen in pharmacy.

If, however, the DoH feels that a minimum period of experience is required then this should be in addition to AND NOT INSTEAD OF the completion of a competency assessment following training. As an added safeguard the CPD records of the RP applicant could to be assessed before any annotation is made.

The proposal is that regulations could specify a minimum period of experience in the relevant pharmacy sector and this, eg, could be expressed as 'x' period of experience in the last 'y' years.

6.5 Q. Do you agree with this approach? If so, what are your reasons for doing so?

6.6 Q. What do you think should be the minimum period and how should this be defined?

6.7 Q. If you do not agree, what do you propose instead and what are your reasons for this alternative approach?

There is no evidence to suggest that by merely serving a period of time in a relevant pharmacy sector a pharmacist will acquire the necessary skills to discharge the duties of a RP. Thus we disagree with this approach of period "x" in the last "y" years.

The PDA proposal based on competency and training is decribed above.

Views are also sought on a proposal for a required minimum period of experience before taking on the role of the RP where a pharmacist has not practised for three years or more.

6.8 Q. Do you agree that a minimum period of experience might differ where a pharmacist is returning to practise following an absence of three years or more? If so, what are your reasons for this? If you do not agree, what do you propose instead?

This would be an added safeguard, however, it may be an unnecessary one. If a competency assessment which follows the successful completion training is the route taken to produce an RP qualification, then the focus on 'years recently practiced' is much less important as a risk factor. Furthermore, since the demographics of the workforce are rapidly changing with the majority of new registrants being female it is clear that many more pharmacists may want to take career breaks to raise a family. Already, many female pharmacists are deterred from rejoining the workforce by the poor working conditions, disparity in pay with their male colleagues and scarcity of child-friendly employers.

The 'three year rule' would serve only to guarantee a workforce crisis in the future, whilst its impact on patient safety

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(subject to the training and competency assessment being the chosen RP qualification route) is insignificant.

One pharmacy/one RP: (Chapter 7)

General comments

The PDA can only envisage one scenario where the RP would need to be in charge of more than one pharmacy and we describe this below. We are encouraged that the 'rock concert' scenario and the medicines dispenser model initially argued by the DoH has now been demoted to being only a marginal idea.

The consultation paper sets out two examples of possible exceptional circumstances that might support allowing a pharmacist to be responsible for more than one pharmacy at the same time.

7.1 Q. What are your views on the examples given?

7.2 Q. Are there any other exceptional circumstances that you think should be considered?

The consultation itself acknowledges how marginal the temporary pharmacy scenario is. The PDA contends that an onsite pharmacist would be thoroughly useful at a rock concert as there are usually plenty of younger adults in need of urgent healthcare advice following de-hydration, poisoning, unprotected sexual activity / contraception etc.. We find it difficult to envisage how the RP would ever realistically arrive at a pop concert with reasonable speed, trudging through tens of thousands of revellers in muddy fields. Moreover, such a proposal nullifies the possibilities of preventative advice provided by the pharmacist.

The second example of a robotic machine may be appropriate in a sparsely populated country like Australia. However, in the UK it is a well known fact that very few members of the public are ever further than 20 minutes away from a pharmacy. Consequently, the delivery of medicines via automated machines with a remote pharmacist would result in the risks outweighing the benefits.

The DoH too appears to accept that there is no problem with access to a pharmacy because it continues to oppose the relaxation of control of entry regulations which prevent pharmacies opening. We see no evidence to suggest that there is any need now or in the future that cannot be addressed by the existing arrangements including the existing collection point regulations.

One RP, more than one pharmacy

Despite being a RP, there will be issues in a pharmacy that the RP will be unable to dictate. Examples may include, staffing levels, workload (increasing numbers of residential homes taken on by area managers) etc. In the event that these situations are getting worse and getting dangerously out of control, then it is likely that the RP will want to escalate these to higher management. However, in the event that they are not resolved the RP may well want to exit from the RP responsibility on the grounds that a continuation could represent a danger to the RP's professional reputation (by dint of an incident occurring for which the RP will be held responsible) and ultimately a danger to the public.

In this scenario, the RP will need to be able to resign the RP status with immediate effect and it would be appropriate to pass this on to the superintendent pharmacist, regional manager or owner for a short period until such time as the crisis has been resolved. This proposal would quite rightly place the responsibility in a place where it could properly be dis-

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charged, it would create an exceptional development which would be likely to cause the recipient of the emergency RP status to deal with the crisis immediately so as to persuade the original RP or replacement to take on the RP status. In this scenario the regulations would need to limit the amount of time allowed to the Superintendent or other to hold multiple RP responsibilities. The regulations need to require that the crisis situation is to be resolved promptly. Failure to make this stipulation in the regulations could lead to widespread abuse by employers.

It is conceivable that in some larger companies, the superintendent or area manager may well end up taking RP status for more than one pharmacy – however, this would represent such a risk to that individual that they would want to resolve matters promptly. Moreover, we would argue that a multiple RP arrangement as described would also involve a higher reporting protocol put in place where the regulatory authorities would be alerted as to these exceptional developments taking place. It may well be that this would help to notify them as to where problem pharmacy scenario's are occurring and would enable them to monitor the situation closely.

This kind of governance arrangement would bode well for public safety concerns.

To permit a pharmacist to be responsible for more than one pharmacy at the same time, there will need to be compliance with exceptional circumstances and certain specified conditions. The DoH is seeking views on what these conditions might be

7.3 Q. What are your views on each of the proposed conditions set out in chapter 6 and what are your reasons for supporting these views?

7.4 Q. Do you think the regulations should specify all or only some of the proposed conditions? What are your reasons for putting these forward?

7.5 Q. Do you think there is a need to specify other conditions? If so, what are these and what are your reasons for putting these forward?

Note our comments above (General comments Chapter 7).

Supervision by the RP in a pharmacy where s/he is not the RP: (Chapter 8)

General comment

The consultation does not provide any examples (exceptional or otherwise) when this regulation would be needed. However, this situation could occur in a Force Majeure scenario.

Force Majeure

Exceptional 'Force Majeure' circumstances are by definition rare and unique but they do occasionally occur in practice. For example, where a pharmacy in a village opens expecting its owner (or the locum) to attend but due to an accident they will be unable to. Often, the pharmacist from the nearest pharmacy will help out by 'popping in' to deal with emergencies before returning to their originating pharmacy. This process may even occur on several occasions in one day and often it occurs without any regard to competition or ownership matters. In such circumstances where a pragmatic 'non ideal' solution is deployed in a critical incident situation, it should be allowed to continue, however, even in this situation, we are not talking about one RP and more than one pharmacy, we are talking about one RP for the originating

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pharmacy, who will be temporarily absent due to a critical incident elsewhere requiring that RP's attention.

When arriving at the second pharmacy, this RP will become simply a supervising pharmacist. This is one of the four PDA absence permitting scenario's. In the event that the RP from pharmacy 1 arrives in pharmacy 2 to help out, it would be entirely unreasonable for that RP to take RP status for both pharmacies even in the case of an emergency scenario. Should this be the case, then it is very unlikely that the RP from pharmacy 1 would ever volunteer to help out in pharmacy and this valuable flexibility which currently exists would be lost.

This example is a further demonstration that shows why over-regulation through written procedures is inferior to a more flexible professional judgement regime made by pharmacists who face day-to-day prctical realities.

The DoH is seeking views on possible conditions supporting a RP's ability to supervising activities in another pharmacy where s/he is not the RP. Eg, such conditions (in addition to conditions set for the pharmacist's absence) might include that one or both pharmacies should employ certain staff (eg a registered pharmacy technician) and that both pharmacies have the same owner

8.1 Q. What are your views on conditions supporting supervision by a RP in a pharmacy where s/he is not the RP and the possible conditions set out in chapter 8?

8.2 Q. Are there other conditions that you feel need to be specified in the regulations?

8.3 Q. If you do not agree this approach, what do you propose instead?

Referring to the Force Majeure situation described above demonstrates why it would not be appropriate to load this solution with several pre-conditions. Either there is an exceptional crisis requiring a hands on pragmatic solution so as to enable the continued operation of a pharmacy for the benefit of the public or there is not. In this scenario, the proposed "additional safeguard" of stipulating that both pharmacies are under the same ownership is unhelpful.

More importantly, it will be necessary to ensure that this scenario which ultimately will always be a safety compromise is to be deployed only in a genuine emergency situation and nothing in the regulations should create a loophole that could be exploited by those motivated primarily by cost considerations.

Introducing the RP regulations: preparing for change: (Chapter 9)

General comments

The proposed regulations constitute a very substantial change in the working practices of pharmacies and pharmacists, moreover they very substantially alter the personal liability of pharmacists. The Medicines Act only dealt with conditions relating to the sale and supply of medicines, the new regulations are much more wide ranging as they additionally deal with taking responsibility for the entire operation of the pharmacy. This is substantially more than before and we are particularly concerned that the DoH feels that it does not need to carry out an impact assessment;

"The Government is committed to action to reduce unnecessary regulatory burdens and, therefore, has examined the need to carry out an impact assessment on these regulations. The conclusion is this is not required, as the regulations do not pose any additional burden for the sectors that are likely to be affected. The regulations do not introduce a new policy but continue to support existing principles underlying the Medicines Act 1968 that

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safeguard the public in relation to the sale and supply of medicines from registered pharmacies. The regulations clarify how the pharmacist is to exercise his/her responsibilities when in charge of a pharmacy to secure safe and effective working in the pharmacy." (item 1.45)

However, later in the consultation it contradicts itself by stating:

"These requirements extend beyond supervision – the RP has a legal responsibility to ensure that all aspects of the pharmacy's operation are safe and effective when these concern medicines" (item 6.11)

This view is shared by other organisations such as the RPSGB :

2. Risk Implications:

"The changes to the Medicines Act represent a fundamental change in pharmacy practice. There is a need to ensure that these changes enhance the culture of professional accountability, not detract from it, and patient safety must be the prime consideration. As the professional and regulatory body for pharmacists the Society needs to ensure that the new regulations are workable, proportionate and enforceable." (ref 15)

We cannot accept the DoH rationale not to carry out a thorough impact assessment. Concurrently, and as a bare minimum the Government needs to commission independent research on how these initial regulations may benefit public health. This independent research should inform the next steps on whether it is in the public interest to relax the supervision requirements and should also inform the next phase of the consultation which will deal with Remote Supervision.

The DoH is seeking views on the time needed to prepare for the introduction of the RP regulations. Firstly, the DoH proposes to introduce the regulations that provide a statutory framework supporting the safe and effective running of the pharmacy. That is, the regulations relating to

- The pharmacy procedures
- The pharmacy record
- Absence from the pharmacy
- Requirements relating to recent and relevant experience

9.1 Q. What are your views on this proposal and your reasons for putting these forward?

9.2 Q. How long do you think that pharmacy owners, pharmacists and others need to prepare for the introduction of these regulations? What are you reasons for this?

We agree that a period of preparation is essential for the pharmacy procedures and the pharmacy record and absence regulations to be introduced. Specifically, with regard to the Remote Supervision issues we again state that nothing in this consultation on RP should be mistaken as some form of tacit approval for Remote Supervision. We urge the DoH to work with all stakeholders and not just those who may stand to gain from these proposals.

The Company Chemist Association Chief Executive is on record as saying:

"We have enjoyed a constructive dialogue with the DoH over the past year on this issue." (Ref 12)

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As an association with 13,000 members and substantial experience of what happens to patients when working environments are inadequate, the PDA is disappointed that the DoH did not enter into a similar dialogue with the PDA.

Had it done so we would have strongly urged the DoH to consider the various practical issues which thus far have been neglected and which we highlight in this response.

A lead-in period of at least 12 months from the date the regulations are agreed should be allowed for the regulations to go into force. This will enable all stakeholders, employers, trade associations, regulatory bodies and the PDA union to develop protocols and properly risk-assess these.

There is a view more time is needed to prepare for introduction of other RP regulations - in particular, those linked to the pharmacist supervision regulations. In chapter 9, the DoH is seeking views on a phased approach to introducing these regulations.

9.3 Q. Do you think it would be helpful to take a phased approach to introducing further RP regulations? If so, what are your reasons for your view?

9.4 Q. What are your views on the option outlined in chapter 9 and your reasons for putting forward these views?

9.5 Q. If you do not agree with the approach outlined, what do you propose instead?

We support a phased evidence based approach. The evidence base would come from independent research and an impact assesment which should be commissioned by the DoH, however, it will inevitably have to come from other sources if the DoH will not commit to this.

We accept that the initial phase will not in any way change the requirement for a supervising pharmacist to always be present.

We also argue, that before any Remote Supervision consultation is undertaken, the new RP regulations should be substantially bedded in as the experiences so gained will inform any subsequent consultation on the Remote Supervision idea. Thus, the first step of establishing pharmacy procedures and the pharmacy record is sensible as is the recording of periods of absence together with reasons for absence (in the four absence scenario's described by PDA).

The DoH welcomes views on the need for guidance to support introduction of the RP regulations

9.6 Q. Do you think there is a need for guidance? If so, what matters should this cover?

9.7 Q. Who should provide this guidance? For example, is there scope for a joint approach to developing guidance by the DoH and the regulatory bodies

The PDA believes that guidance would be useful in helping to support the introduction of these regulations. This should help in delivering some consistency in the pharmacy procedures and the formats for the pharmacy record.

The guidance should be developed jointly by all stakeholders (including the PDA, the PSNC, the RPSGB and the NPA) so as to give a balanced, equitable and safe way for introducing these regulations.

In addition to this, suitable training (inputs) and competency assessment (outputs) must be designed so as to ensure that the new RP is armed with the appropriate skills to undertake the task.

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section five

Section 5.
Potential loopholes in the regulations

In drawing on its experiences of problems that occur in pharmacy practice, the PDA describes a number of scenarios that may well unintentionally occur if the regulations are not drafted carefully. Loopholes in the regulations could allow pharmacies to operate in ways which would be detrimental to the public interest.

Scenario 1

A company owns 124 pharmacies. On assessing various spreadsheets their accountants advise a review of staffing levels at certain branches. The superintendent pharmacist delegates this task to his 6 area managers. They convince one excellent clinical but potentially negligent RP, Mrs A, at one busy pharmacy to accept reduced staff levels.

They use this reduced staffing level as a template example for all their other pharmacies where they want to cut hours.

The area managers convene meetings for their managers in their respective regions. Using a Powerpoint presentation they show how Mrs A manages works so efficiently and so well and how well her support staff cope. Various motivational tools together with an element of bullying and performance management are used to coerce the managers to accept the reduced staffing levels. No records or transcripts are kept of these meetings.

The impact of this may not be immediate but the overall risk to patient safety would rise. The regulations must be drafted so as to prevent this downward pressure on staffing levels.

Scenario 2

Company B owns 666 pharmacies. Company B has recently undergone a management buyout which has been very tightly financed. Its newly appointed superintendent is persuaded by the owners to make use of the 3 hour absence rule for all its pharmacies. The company already has a policy of employing part-time pharmacy technicians at each branch.

They trial this arrangement for 1 month with some compliant "RPs" using selected stores only. Using this as "evidence" that the process works and is safe they decide to apply this policy across the whole group.

For the first and last 3 hours of the pharmacies opening times,(subject to satisfying the 50% rule), no pharmacist will be physically present at any of the companies' pharmacies. Even though the regulator and the PCO's, are not happy with the situation they have no power within the regulations to act. Company B puts in place all the procedures to satisfy the legal requirements of the "RP" regulations. So, the Company employed "RP" will still be so, except that they will not be at the pharmacy for the first and last 3 hours on each day. Any queries where a pharmacist is needed will be handled by an outsourced call centre staffed by pharmacists and paid for on a piecework basis.

The Company calculates that by not paying the RP for each of the first and last 3 hours for each day the company makes a saving of £ 130 per day per pharmacy. For their average 6 day per week pharmacy this equates to a saving of £40,000 per annum per pharmacy or £24 million for the group each year. The budgeted cost for the call centre backup is £ 5 mil-

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lion per annum. The net gain to the company is £ 19 million per annum.

In addition the pharmacy technicians that will be present in the absence of the "RP" are verbally told by the area managers of Company B that they must only contact the call centre if it's absolutely essential as the call centre charges Company B on a per call basis.

The proposed regulations must prevent this.

Scenario 3

Company Z owns Pharmacy A which employs a locum RP, Mr P. Support staff at the pharmacy fail follow the SOP and dispense a prescription without involving the RP in a clinical check a dispensing error occurs.

Mrs Y has suffered gravely as a consequence and now requires 24/7 care in the nursing home paid for by the local authority. Many years after the date of original dispensing, a law suit is brought against the pharmacist, Mr P, who is charged with having supplied an inappropriate dose of medication. Since the dispensing label has the initial of someone else on the check box – it is obvious that another member of staff was involved. However, the statutory pharmacy record cannot confirm who the support staff were on the days when drug TT was dispensed but can identify Mr P as the RP. Company Z has no statutory duty to keep time sheets and can only confirm the weekly hours that the support staff worked and were paid for.

The medicines act 1968 still makes a single dispensing error an offence and the RPSGB automatically refers to their Fitness to Practice any errors that lead to serious harm to the patient.

The employing pharmacy is facing a big civil claim, but it decides to pass this liability onto the locum Mr P.

Given that Mr P has fully discharged his duty but the technician has not how will blame be apportioned?

The regulations have not benefited Mrs Y and the pharmacist locum is now being held personally liable by the pharmacy owner.

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Section 6.
References

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5. Health Which October 2003
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13. A Longitudinal Cohort Study of Pharmacy Careers (2007) Manchester University
14 Are Women and Black and Minority Ethnic (BME) Groups Integrated in the Community Pharmacy Labour Market? Hassell, K.
15 RPSGB Council meeting 11 and 12 December 2007 PUBLIC BUSINESS Health Act 2006 – Content of the RP Regulations

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Section 7.
Appendices (A)

STATUTORY PHARMACY RECORD

Name of Pharmacist and Signature	Registration Number	Date of taking responsibility	Changes Made to Procedures	On whose authority changes made	Times of duty as responsible pharmacist	Time of Absence (if any)	Reason for Absence	Name of Second Pharmacist or Re-pharmacy technician absence	Registration Number	Names and timings of other staff	Signature of Second Pharmacist or Pharmacy ass	Comments by responsible pharmacist or pharmacist or technician comments)
adam gilchrist	78900	22-Feb-08	No		8am till 6pm	1-2 pm	lunch	cynthia turner	(technician) 12675	Cynthia 8 to5, M 8 to 12, An Lynn		company call centre pharmcist available for advice
bruce forsyth	23765	23-Feb-08	No		8am till 6pm	3-6 pm	Collect children a home	cynthia turner	(technician) 12675	Cynthia 8 to5, M 8 to 12, An Lynn		company call centre pharmcist available for advice
adam gilchrist	78900	24-Feb-08	YES	Adam made changes , check needed w manager	8am till 6pm	9-12 pm	running asthma c at Dr Patel's	cynthia turner	(technician) 12675	Cynthia 8 to5, M ILL . Anne Lynn		No second checker available during absence. Technician to and allow a mental break before prescript ADAM GILCHRIST
bruce forsyth	23765	25-Feb-08	No		8am till 6pm	3-6 pm	Collect children a home	cynthia turner	(technician) 12675	Cynthia 8 to5, M 8 to 12, An		company call centre pharmcist available for advice
anil patel	102667	26-Feb-08	YES	Superintendent	8am till 6pm	1-2pm	lunch	cynthia turner	(technician) 12675	Cynthia HOLIDA Mary 8 to 12 12 to 6		Changed page 8 and 11 as Pharmacy technician on holiday assistant working redcued hours compare agreed with superintend call ce

This document is only to be used to record concerns about existing procedures. All incoming responsible pharmacists must consult this document so as to be alert to any potential deficinies in the procedures which have already been spotted by their colleagues.

Name of Pharmacist and ignature	Registration Number	Position	Date when concern recorded	Superintendent or area manager nformed ?	Method of communication (email, hone, letter	Name of area manager or uperintendent	Nature of concern
Alan Jones	78900	Pharmacy Manager	11-Jan-08	yes	email	Rupert Murphy (superintendet)	As the new manager I wanted a copy of the model staffing schedule. This was sing from procedures and area manager unwilling to provide previous d schedule
Rakesh Patel	89056	agency locum	14-Feb-08	yes	letter	John Hawkeye (area manager)	Apparent that support staff are not following SOP in relation to handing out eat prescriptions. Apparently SOP's are not followed at this branch.
Anil Patel	102667	agency locum	16/7/08	yes	email	John Hawkeye (area manager)	Staff told that no prescriptions should be handed out during my lunch break on return from lunch break found 6 prescriptions had been given out.
Alonga Otisola	86789	Company employed elief harmacis	19/9/08	yes	email	Rupert Murphy (superintendet)	Staf not following company procedures in relation to sale of P medicines as procedures have been adapted by the branch manager. I cannot see any e of this change in the Company procedures. Staff unwilling to follow s which are consitent with the Company's procedures
Jacques Gdansk	1057896	agency locum	24/11/08	yes	phone	John Hawkeye (area manager)	Only one computer working and the technician is busy printing the 600 items have to finish by the end of today. I cannot check the SOP for ne at this branch. The branch has no printed copy. Request that a f all procedures is placed in the file.

This document is only to be used when ESTABLISHING procedures or when a pharmacist makes changes to procedures. These changes need to be agreed with the owner or area ger or the superintendent. This logbook must be completed fully and may be used in case of any incident arising.

Name of Pharmacist and Signature	Registration Number	Date Reviewed or Changed	Position	Changes Valid for	Changes Agreed or Made including reasoning
Adam Gilchrist	78900	11-Jan-08	Pharmacy Manager	Until Next full eview	First set of procedures Established
Adam Gilchrist	78900	24-Feb-08	Pharmacy Manager	Today only	Changed procedures for checking of prescriptions (pages 12-15 of procedures) no second cker available. Change agreed with area manager
Anil Patel	102667	26-Feb-08	Agency Locum	26 feb only	Changed page 8 and 11 as Pharmacy technician on holiday and counter assistant working cued hours compared to model staff hours. Change agreed with superintendent
Geougiou Veakrios	86789	11-Oct-08	Pharmacy Manager	Until Next full annual review	I am new manager so review of procedures triggered
Geougiou Veakrios	86789	11-Jan-09	Pharmacy Manager	Until Next full annual review	Annual review of procedures on anniversary of first review date

Workload grid							
Day	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Open							
Close							
Walk in items							
Monitored dosage							
Repeat collections							
Other							
Total							

Services - number of patients per day							
MUR							
Supervised consumption							
Methadone							
EHC							
PGD							
Other							

Additional notes:		Pharmacy Stamp
Signed	Date	

Statement of staffing levels, skill mix and working hours for Pharmacy

of

Superintendent pharmacist Tel:

Responsible Pharmacist Tel:

Working Hours	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	**Total Weekly Hours**
Pharmacist								
ACT								
Technicians								
Trainees								
Qualified Healthcare Staff								

Staffing levels, skill mix and working hours audit

Date **Deficit in hours per statement**	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	**Total Weekly Hours**
Pharmacist								
Accredited Checking Technician								
Qualified Technicians								
Trainee Technicians/ Dispensers								
Qualified Healthcare Staff								
Total hours shortfall								

Date **Working time audit**	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	**Total Weekly Hours**
Did the pharmacist have a 20 minute break for every 6 hours worked ***Y/N***								

About the Pharmacists' Defence Association (PDA)

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation and Pharmacist Union which aims is to act upon and support the needs of individual pharmacists and, when necessary, to defend their reputation. PDA currently has more than 13,000 members.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the views and concerns expressed by members
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist
- Seek to influence proactively 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 improve further the membership benefits to individual pharmacists

Contact Details

Further information is available from:

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