

Special Edition

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insight

The magazine of the Pharmacists' Defence Association



Responsible Pharmacist

Seeing the wood for the trees

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PDA mini conference
**Sunday
11th October**
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Chairman's letter

Protecting the interests of the Responsible Pharmacist.

During a series of meetings last autumn and spring, the concerns of the PDA about the unworkable proposals contained in the RP regulations were consistently raised with the RPSGB. We expected that these would be dealt with in the Society's RP toolkit when this became available.

However, the RP toolkit failed to deal with many of our concerns, and also completely omitted issues such as rest breaks.

A survey of members and a petition indicated that the profession would simply not be ready for the launch on October 1st. So we immediately called for a delay in the regulations. We wanted to use such a delay to try a dry run and work up some solutions to the current unworkability concerns.

A meeting with the Department of Health (DoH) to discuss the proposal for a delay was requested in mid July.

Sadly, in a move which would have undermined the hopes of many pharmacists, the RPSGB publicly refused to back the PDA's calls for a delay.

By the time we conducted our survey of members (August 2009), it became obvious that the profession, whether they were employees, locums or employers would simply not be ready for the implementation on October 1st. As a result, we launched a campaign calling for a delay in the regulations. We felt that should such a delay be granted, then we could all use the time effectively so as to try a dry run and work up solutions to the current unworkability concerns.

As we go to press, with now no time left before the October 1st deadline, the DoH have belatedly announced that following consultations with "pharmacy stakeholders" there exists "confidence in pharmacy's readiness to implement the responsible pharmacist provisions" and that therefore there will be no delay.

It is galling to note that the DoH listened to the RPSGB and disregarded the views being expressed by many thousands of community pharmacists. The PDA was joined in its calls for a delay by representatives of small contractors. Undoubtedly the multiples will also want these regulations in place as soon as possible, as they will take their Superintendents out of the firing line and place the RP in greater personal risk if something goes wrong in the pharmacy.

The delay would have meant that the PDA, employer representatives and the RPSGB would have been able to work proactively to sort out the state of confusion.

Instead, the RPSGB is now trying to get some last minute 'clarification' from the DoH around the perceived problems. We believe that what they are actually trying to secure is a last minute compromise – a fudge to try and hastily fix problems that they should have been fixing well over a year ago. We strongly suspect that their fixes will be beneficial to employers, but not necessarily for pharmacists!

Many of the professional and employment issues have not yet been resolved and as a consequence, the PDA has been forced into a defensive position in ensuring that our members are not disadvantaged or leave themselves liable as a consequence of the introduction of the regulations; it is no more than our members would expect.

So what next?

This magazine covers some of the main issues that pharmacists should be aware of and much more information will be provided on www.the-pda.org as the days and weeks go by. We will seek to publicise member experiences on the PDA website – good and bad as we move past the October 1st deadline for in this way, the experiences of some members may benefit others.

More responsibility – and what about remuneration!

Protecting the employment rights of pharmacists will be pivotal to the work of the PDA. The RP regulations will produce a new relationship between employers and pharmacists, this will require a consultation about a new contractual relationship and also remuneration. Letters have been sent to the HR directors of all the large community employers and also to the NPA asking how they intend to handle this. It is vital that pharmacists now register their desire to consult with their employers on a variation to their contract, if they do not do this, then they will be deemed to have accepted the new terms by implication and the opportunity will be lost. We enclose details on how to commence this process.

Meetings are being arranged between PDA and some of the large multiple representative organisations to discuss this and other matters.

Additionally, a considerable amount of behind the scenes work is also in train to support RPs in their practical needs – more details on this will follow.

Finally, we invite PDA members to an emergency national event to discuss the next steps with the RP situation on Sunday October 11th at the Pharmacy Show at the National Exhibition Centre in Birmingham.

I look forward to seeing you there!



Mark Koziol, Chairman, The PDA

Responsible Pharmacist Fact or Fiction?

Join the PDA at this emergency mini conference to learn what is fact and what is fiction and to discuss what support members will want from the PDA in becoming RPs.

- How to handle the new statutory authority
- How to approach the operational problems
- Employer/RP interface issues
- Panel Questions and Answers

Sunday 11th October 2009

2.00pm – 4.30pm

NEC Birmingham, at the Pharmacy Show

To book a place go to www.the-pda.org

Protecting your employment rights

Protecting the employment rights of pharmacists will be pivotal to the work of the PDA Union. Whilst many of the professional arrangements and new customs and practices need attention, (and PDA will be providing support in these areas) professional considerations will inevitably develop and even change over time as agreements are reached and both employers and employees and locums and their representatives become more experienced with the RP regulations.

However, protecting the employment rights of pharmacists working as RPs will need immediate attention. The reason for this is that employers are required to consult on any new work place procedures with their workers before they are instigated especially, if these procedures may result in a variation to the employment contract. Such a process enables the workers to discuss and either accept, reject or amend by mutual agreement the changes that the employer has proposed. Usually, any such variation brings with it an opportunity to discuss also a new consideration – a discussion about fair remuneration to compensate the workers for any new responsibilities or more onerous work practices.

Act now or miss out!

However, if changes are simply made by an employer and no consultation is held, then after a short period of time, the changes are automatically deemed to have been accepted by the worker and a new implied contract is created. This 'back door' method avoids any discussions about the rights and wrongs, takes away much of the say that a worker might have had and also avoids the thorny subject of fair remuneration for the new roles and responsibilities.

There is no doubt that the RP regulations will place substantially greater responsibilities upon the shoulders of the RP and this will result in a significantly different relationship between employer and employee. The new requirements will have an operational impact, and change the nature of the employment contract and

this will require a mutually agreed variation of that contract.

Not only are there issues under employment law, but there are also ramifications under Working Time Regulations and Health and Safety legislation in respect of training and risk assessments.

Our focus now must be on ensuring that pharmacists don't accept this change without due process, furthermore, they should not accept changes to their contract without taking advice.

We are concerned that some employers will want to handle the changes as a non-event as they may not want to alert their employees and locums to the fact that the new responsibilities bring with them new authority in the workplace and qualify for a consultation about additional remuneration. Already we are seeing signs that this may be a trend. We remind pharmacists that if they acquiesce to these changes without registering any objection, then they will be deemed to have accepted new terms without the need for any new consideration.

Consultation with employers

This can be done in one of two ways;

Instigated by the employer

As soon as the decision not to delay the RP regulations was made, we wrote to the HR directors of the following community pharmacy employers. Alliance-Boots, ASDA, Co-op, Day Lewis, Lloyds, Morrisons, Sainsburys, Superdrug, Tesco, Rowlands we also wrote to the NPA – the employers representative organisation.

Since the RP changes will effect many members, we have asked them how they would be seeking to initiate these changes to

their employees' contracts and what consideration they will be giving their employees and locums for agreeing to enter into the change. Because we are a Trades Union, we have offered to assist by discussing these matters with them directly if this was deemed to be helpful, but there would be no legal requirement for them to do so, unless certain conditions could be met (see below). It is too early to describe what will result from this correspondence, however, if a consultation with the employee is indeed instigated by an employer, then we suggest that pharmacists contact PDA for advice on any new contract that may be offered.

Instigated by the employee individually

Employees are entitled to instigate a consultation and this can be done by notifying their employer in writing that they wish this to be the case. We enclosed a template letter that may be used for this purpose.



Template letter sent by pharmacists in response to contract changes proposed by employer:

Dear

I write further to your communication of the giving notice of fundamental changes to my contract that have been brought about by the Responsible Pharmacist Regulations. I must advise you that I do not automatically accept these variations in my contract and I shall be seeking advice from the PDA Union. The RP regulations represent a very significant change in the statutory responsibility to be held by pharmacists in the pharmacy and they also provide the RP with considerable authority over operational matters resulting in a different relationship between employer and employee. Hopefully, these matters can be resolved; however should it not be possible to agree them to our mutual satisfaction then it may become necessary to undertake either a collective or individual grievance (or both) in this respect.

In the meantime I am prepared to work your proposed variations until such time as my concerns are resolved – this action should not be considered by you in any way as an express or implied consent to my acceptance of any or all of the proposed variations.

I look forward to hearing from you in due course.

Template letter sent by pharmacists to employers who have not discussed contract changes as a result of RP.

Dear

I write to you regarding the changes that will be brought about as a result of the new Responsible Pharmacist regulations which are due to commence on October 1st 2009. As you will know, these changes represent the biggest change in pharmacy legislation for more than 40 years. From October 1st a whole new set of statutory responsibilities and liabilities will sit on the shoulders of the Responsible Pharmacist and the RP will also be responsible under statute for securing the safe and effective running of the entire pharmacy (in so far as it relates to medicines).

There is no doubt that the RP regulations will result in a significantly different relationship between employer and employee. The new requirements will have an operational impact, and change the nature of the employment contract and will require a mutually agreed variation of that contract. This will be the case not only for employment or contract law, but also probably with the Working Time Regulations and Health and Safety legislation.

As you will know, employers should not introduce contractual changes without first consulting with those who will be affected by such a change. The purpose of this letter is to indicate that I am keen to enter into a consultation on this matter and in particular, that I would be happy for you to discuss these matters either individually or collectively with the PDA Union.

In particular, I am keen to ensure that you do not deem that these changes do not require any variation in the contract (for I am advised that they do), nor that you subsequently hold that I have impliedly accepted any potential variations in my employment relationship / contract simply because I have not raised any objections or concerns. I believe that it would be preferable that I indicate that until this can be resolved properly, then I am prepared to work the variations until such time as my concerns are resolved. This action should not be considered by you in any way as an express or implied consent to my acceptance of any or all of the variations.

I would welcome your response to this letter by the

The ICE committee

Employment law requires that employers must consult with their employees on any substantive changes that may impact upon their

employment. One way in which this can be done, is when one group of workers consults with their employer on behalf of other workers. This position is enshrined in law and provides for the establishment of an Information and Consultation of Employee's committee. This involves a group of employees getting together and discussing matters of concern with their employers – such as the impact of the RP regulations. To establish such a committee, pharmacists need to comply with the Information and Consultation of Employees (ICE) Regulations.

The ICE regulations apply to businesses with 50 or more employees. They give employees the right to request an information and consultation agreement. An employee request must be made by at least 10 per cent of the business employees, which must amount to at least 15 employees and the employer must start negotiations with representatives of the workforce for an agreement no later than three months after a valid request has been made. It is possible that such a committee may already be in existence and if so, employee pharmacists should contact them immediately and notify us at the PDA Union so we can assist you with the necessary dialogue.

The Grievance or Collective Grievance

We fully recognise that taking up such matters with an employer can be a daunting prospect and we fully understand how any pharmacists may prefer a more centralised approach.

Furthermore, a well prepared employer or area manager will always be at a considerable advantage in terms of commanding an argument.

One solution could be that if the employers consult, but the result of the consultation is not satisfactory from an employee's point of view, alternatively, should they refuse to consult at all, then employee's are entitled to instigate a grievance. Furthermore, should two or more employees have a similar grievance (whether this is two, ten or three hundred employees) then a collective grievance can be instigated. The advantage of a collective grievance is that it would be administratively much easier to undertake, furthermore the PDA Union would be entitled to take up such a collective grievance with an employer on behalf of its members.

Collective bargaining by the PDA Union as an alternative

Another way forward would be for an independent Union to engage in collective bargaining with the employer on behalf of pharmacists employed by him. Union legislation provides for such an approach, however, for an employer to be required by law to consult with the Union, at least 50% of all pharmacists employed by that employer would need to be in Union membership. Although the PDA has more than 15,000 members, this may not necessarily mean that more than 50% of pharmacist employees for any particular employer are in membership. We are currently undertaking steps to ensure that we satisfy these criteria. Clearly we urge all pharmacists who are not yet PDA members to join up without delay.

Act Promptly!

Irrespective however of which approach is chosen by pharmacists, the most important first step is to ensure that a consultation is instigated if one is not already being offered. Once a marker is put down and the workers concerns are noted, then even if a pharmacist initially works under the initial (unacceptable) terms, then these can not subsequently be deemed to be the new implied contractual terms. We urge pharmacists to use the appropriate template letter enclosed promptly.

So what will be the main negotiation points?



In communications with many PDA members we have become aware of the main concerns that are currently held and that are being discussed by some pharmacists with their employers. We provide some information about these issues for guidance.

Who is actually in charge?

Clearly, the master and servant relationship will still continue however, the RP will now have the statutory responsibility for securing the safe and effective running of the pharmacy. This puts the RP in a very different position as they did not enjoy this statutory role under the previous pre RP arrangements.

For those employees who work for employers who disagree that the new regulations are different, then we suggest that they study the feature on pages 6 to 8 to assist with their discussions. Any new contract of employment going forward must make clear who is responsible for what and this includes ensuring that the RP is given the authority to ensure the safe and effective running of the pharmacy.

Rest Breaks

The problem with rest breaks is significant and it revolves around the fact that the pharmacy must have an RP signed on to be able to operate. However, if one applies Health and Safety legislation and Working time regulation and also if one studies the relevant test case law, then whether a pharmacist is a locum or an employee, if they are to enjoy a rest break then they should sign off – hence rendering the pharmacy inoperable.

We became aware as to why this problem had arisen when PDA officials met with the DoH recently and were surprised to learn that when drafting the RP regulations, the DoH did not take into account the wider employment law as their focus was on healthcare legislation. The DoH expected that any operational matters that existed would have been picked up by the Society's consultation – the one that produced the RP toolkit. However, despite the fact that the position on rest breaks was consistently brought to the attention of the RPSGB by the PDA during their RP consultation, the RPSGB failed to take this problem into account. In reality, it would appear that the employment rights of pharmacists were not deemed important enough for anyone at the Society or the DoH to have wanted to have done anything about them in the RP regulations. The result is that many pharmacists will now be placed in a very difficult and unfair position.

The upshot of this important omission is that if rest breaks can now only be taken if the RP signs off, thus rendering a pharmacy inoperable then we believe that many pharmacists will be expected by their employers to forgo their statutory rest breaks so that the pharmacy can continue to operate, or alternatively, they will be pressurised into taking their breaks whilst still signed on as an RP using the two hour absence provision. This will cut through the thrust of Employment and Health and Safety legislation and may be to the significant detriment of pharmacists.

Make no mistake, if signed on, an RP will be held legally accountable if something goes wrong in the pharmacy whether they are present or not and irrespective of what they have agreed privately with their employer with respect of their work break.

“...RPSGB has failed to take the law on rest breaks into account.”

It gets worse!

If concerns about employers were not bad enough, the noises coming from the RPSGB about rest breaks are also very worrying. In September at the British Pharmaceutical Conference the RPSGB announced that it would now campaign for pharmacists to receive their rest breaks.

However, in a letter recently sent to the PDA from the RPSGB President Steve Churton he has stated;

***“I think that there are circumstances when it is very reasonable to remain as the RP during a rest break and times when this might not be considered appropriate. Furthermore, whether or not a RP takes the decision to ‘sign off’ during a break is a matter for the individual concerned and their terms of employment.*”**

Speaking personally, when I was Superintendent of Boots, I was content to remain the Superintendent and responsible for the activities of the company when I was on a rest break.

This statement is very unhelpful as there was never a requirement for any superintendent, Boots or otherwise to sign on when arriving at work and sign off when they went home. The simple fact is that the two hour absence provision should not be used to accommodate rest breaks not because it is professionally prohibited, but because it will represent questionable employment practice which will conflict with the law on rest breaks.

The RPSGB should be supporting pharmacists and helping to protect the health and safety of pharmacists, not encouraging practices that will patently undermine these.

A rest break must be a full physical and mental break away from the workstation, a person cannot be expected to carry any responsibility for the workplace while they are on statutory break.

“A rest break must be a full physical and mental break away from the work station...”

This means one of three things;

1. Another pharmacist must sign on to be a RP for the duration of the original RP's rest break.
2. The Pharmacy must cease to operate while there is no RP signed on.
3. A way forward is agreed, ideally between employee representatives and employers as to how this quandary can be best managed to prevent large scale problems for the public. This would need to be an agreement that does not disadvantage pharmacists nor one that would result in stress and fatigue through a lack of rest break.



Risk assessments

Whereas under the old pre RP arrangements, the pharmacist was required to work under protocol or SOP, these were largely professional or employment contract requirements. If under the old regime the pharmacist was unhappy about aspects of these protocols, then he/she would notify the employer and seek a change. However, under the RP regulations, it is the RP who will be

held statutorily liable for ensuring the suitability of any pharmacy procedure. It is the RP who is charged with the task of reviewing or amending an SOP either periodically, or in the event of a critical incident. This means that the RP must be able to complete risk assessments to undertake this task. Under Health and Safety legislation, if the worker is required to complete such risk assessments, then it is the employers responsibility to provide training. Any new contract of employment must make clear that responsibility for providing such training is that of the employer and that such training will actually be provided.



RPSGB Headquarters

Remuneration

Remuneration must reflect the new responsibilities for all RPs.

A superintendent pharmacist carries greater responsibility and is exposed to greater liability than an employee or locum pharmacist, consequently, the superintendent enjoys greater remuneration. A Responsible Pharmacist will from October 1st carry greater statutory responsibility and will therefore be exposed to greater liability than was the case when they were a 'pharmacist in personal control' for this added risk, the RP should enjoy greater remuneration.

What about Locums?

It is well known that unlike employee, self-employed sub contractors are not directly protected by much of the employment legislation. However, locums still enjoy significant protection through professional regulation, healthcare law and Health and Safety legislation. Additionally, locums are also protected by contract law and by the terms laid out in the contract for services that exists between them and their employer.

To this end, the PDA is currently updating its contract for services for use by locums, to ensure that it contains many of the new issues that spin out of the RP regulations. This can be downloaded

from the RP tools section of the PDA website. This document should be used instead of the existing locum contract for services and it should be served on the employers as soon as possible. Whether self-employed or not, under Health and Safety law, employers must ensure that they do not cause any of their workers (including locums) to suffer through the infringement of their basic Health and Safety rights – this is important in the area of rest breaks. Employers that are requiring locums to work straight through without taking a break could be exposed not only to liabilities under Health and Safety legislation, but also under professional regulation via the Code of Ethics. Locums will also now be protected by the RP regulations which make clear in law that it is the RP who is responsible for ensuring the safe and effective running of the pharmacy. This means that the behaviour of employers towards their locums must reflect the new realities and the new control that the locums will have over the pharmacy environment as RPs. If any employer seeks to question this, then they should be shown the relevant statute (which is also contained in the RP Tools section of the PDA website).



Watch this space

There is no doubt that the government's belated decision to proceed with the October 1st deadline regardless of the professions unpreparedness will lead to a general hiatus not only in the professional, but also in the employment sphere. This will be a fast moving situation and we ask that pharmacists keep a close eye on the PDA website as we will be publicising professional and employment developments as soon as they occur.

Responsible Pharmacist

Questions and Answers

We have received a large number of questions regarding the RP regulations from members and pharmacy owners, many more than space in this magazine would permit. We publish a sample of the questions and answers here and provide more Q&A's on www.the-pda.org/rpquestions

Question: I have been told that I can use my two hour absence facility to provide me with a rest break is this correct?

Answer: No this is incorrect.

A pharmacy may only operate if it has an RP signed on. The regulations do allow for the RP to be absent for up to two hours, but these are designed to cover situations where the RP is working away from the pharmacy e.g. visiting a local GP surgery, or residential home. In these instances, the RP remains signed on and as a result, the pharmacy is allowed to continue to operate a limited scope of activities e.g. sales of GSL medicines.

The two hour absence provision may not be used to accommodate rest breaks, not because this is professionally prohibited, but because it conflicts with the law on rest breaks. A rest break must be a full physical and mental break away from the workstation, a person cannot be expected to carry any responsibility for the workplace while they are on their statutory break. This means that the RP must 'sign off' if the full legal requirements of a rest break are to be observed.

This means one of three things;

1. Another pharmacist must sign on to be a RP for the duration of the original RP's rest break.
2. The Pharmacy must cease to operate while there is no RP signed on.
3. A way forward is agreed, ideally between employee representatives and employers as to how this quandary can be best managed to prevent large scale problems for the public. This would need to be an agreement that does not disadvantage pharmacists nor one that would result in stress and fatigue through a lack of rest break.

We are concerned that some employers will attempt to persuade pharmacists that they should remain signed on and simply use the two hour absence provision for their rest break – the effect of which will be that pharmacists will not in fact be getting their lawful rest break, they will effectively be working through.

Make no mistake, if signed on, an RP will be held legally accountable if something goes wrong in the pharmacy whether they are present or not and irrespective of what they have agreed privately with their employer with respect of their break.

Questions and Answers continued on page 15...



So who is actually in charge?

Who will now decide the operational standards in the pharmacy such as staffing levels, the range of services to be delivered and other such matters? Unsurprisingly, this is becoming one of the hot topics associated with the new RP regulations.

This matter is much more than one of passing intellectual or professional interest, because answering it may well have a substantial impact upon the operational costs of the pharmacy, particularly for the multiple operators. It will also fundamentally alter the nature and style of the relationship between employer and employee.

There is no doubt that employers have always been statutorily responsible and in control of the wider working environment and work place procedures e.g. Health and Safety procedures, a safe system of working, a safe working place, provision of contracts of employment, licensing, registration and many other matters. It is therefore the accepted custom and practice that pharmacists are largely obliged to follow company procedures for which their employers and superintendents are held accountable.

More specifically, what has also been custom and practice under the old regime is that employers/superintendents have generally produced the standard operating procedures for the pharmacy and although pharmacists had a professional duty to be satisfied that these procedures were safe and appropriate they had no statutory authority in this regard and consequently they have generally followed these procedures.

The new regulations however create a new statutory responsibility for pharmacists who become RPs in so far as they are now statutorily responsible for the safe and effective running of the entire pharmacy in so far as it relates to medicines. Furthermore, they are required under statute to ensure that they are satisfied with existing procedures, establish new ones (if they are not satisfied) and keep such procedures under review. They **will** be held accountable for such matters.

So far so good – it's pretty clear.

However, the 'conundrum' caused by the new RP regulations is the fact that at a cursory glance the new laws appear to be ambiguous and muddled in their thinking. As well as stating that it is the RP who is

statutorily responsible for the safe and effective running of the entire pharmacy in so far as it relates to medicines, they also state that;

A body corporate must have a superintendent pharmacist who has management responsibility for the keeping, preparing and dispensing of medicines and that the RP remains subject to the directions of the superintendent pharmacist.

It is quite likely that some employers may seek to exploit this apparent ambiguity by saying simply that the new regulations represent no change to the position as it has applied since 1968. For if it can be shown that these are indeed significant changes in the law which place much greater responsibility upon the shoulders of the pharmacist and give individuals much greater control – then that could lead to cost implications for employers; multiples in particular. The cost implications would occur when dealing with the demands of RPs to improve staffing levels and resolve workplace pressures so as they are able to ensure the safe and effective running of the pharmacy.

Change or no change in the law?

What the barristers say;

1. Failure to comply with the RP provisions is now expressly a matter of misconduct, further; the Act introduces a new sub section (record keeping) and provides that a breach of this is a criminal offence. There was no equivalent regulation prior to the new provisions.

2. There is now a positive obligation to secure the safe and effective running of the pharmacy business” as opposed to there merely being a requirement for the retail sale of medicinal products to be “under the personal control” of the pharmacist. The regulations state that the RP has to be in charge of the business in so far as it relates to medicines.

3. There is a clear obligation, which is set out in some detail as to the matters to be covered by the pharmacy procedure, which is now to be established, maintained and kept under review by the responsible pharmacist.

4. In my opinion, the amendments to the 1968 Medicines Act impose new and substantial requirements on pharmacists.

Lance Ashworth QC.

1. There is no doubt that the RP regulations will result in the biggest changes in pharmacy practice for more than 40 years.

Graham-Southall Edwards Barrister



Legal opinion confirms that the RP regulations do indeed result in significant changes which place a much greater onus

onto the individual pharmacist. We can dispel the myth that there is no change. In short, once the new regulations ‘go live’, RPs will carry new statutory responsibility and new liabilities that pharmacists did not have before.

The Control of the pharmacy

Having established that there are significant changes to the statutory responsibility and liability exposure, let us now examine what happens to the legal control that occurs within the pharmacy.

What the government says;

1. The Government is quite clear on this matter. We think that it is important to allow the pharmacist in charge (the RP) to meet fully his or her statutory responsibility for the safe and effective running of the pharmacy.

2. The RP will set out procedures to fulfill his statutory duty to ensure the safe and effective running of the pharmacy. This will include deciding which activities involving the preparation, assembly, sale and supply of medicines are to be delegated to suitably trained pharmacy staff, ensuring that they are competent to take these tasks on safely. These are important responsibilities which ensure the safe sale and supply of medicines and which safeguard the public.

3. The RP will be required to set down procedures and to determine the allocation of tasks to staff according to their competence, to ensure that patient safety is maintained.

Lord Warner Spokesman for the Government in parliament

What the National Clinical Directors for Pharmacy at the Department of Health say;

1. It is for the RP to decide on the procedures supporting safe working in the pharmacy for which he or she is responsible.

2. Although the pharmacy owner or superintendent can support the RP in providing ‘model’ procedures, the RP can rightly point out that they have the legal powers to ensure that these procedures meet the needs of the pharmacy.

3. All superintendents and pharmacy owners should recognise that they must not obstruct pharmacists from complying

with the law, which is now clearly set out in the RP regulations.

Jonathan Mason and Martin Stephens Department of Health

The RP is statutorily in charge of the Pharmacy

There is no doubt whatsoever, that when the government drafted the changes to the law, it was with the intention of placing the control of the operational standards of the pharmacy into the hands of the pharmacist – the RP. No matter what employers may prefer to be said on the subject there is no doubt that it is the RP that will now have statutory responsibility for the safe and effective running of the pharmacy in so far as it relates to medicines.

Those concerned about this position may argue that, the new regulations also contain the statement;

A body corporate must have a superintendent pharmacist who has management responsibility for the keeping, preparing and dispensing of medicines and that the RP remains subject to the directions of the superintendent pharmacist.

It would appear that many within the profession particularly the employer representative organisations have chosen to interpret this statement as suggesting that nothing has therefore changed as far as the statutory responsibility for the pharmacy operation is concerned.

This is patently not the case when one considers the preceding evidence. So what is the meaning of this superintendent position as described?

At the PDA we have no difficulty with the superintendent statement and we believe that the following simple logic unravels the confusion.

We believe that;

a) **The Body corporate and its superintendent are responsible for the pharmacy operation at a higher strategic level.** For example, it will be the company/superintendent who will decide how many pharmacies will be in the business, what services they will be providing to the public and what kind of corporate face the particular pharmacy business will have with the national media and the relevant regulatory bodies. The RP will be the subject to the directions of the superintendent pharmacist in so far as the superintendent will be setting the nature and style of the trading pattern of the pharmacies in the business e.g. the

opening times, the services to be provided and the overall direction of that particular pharmacy business. The superintendent (or his representative) will still continue to be the line manager to the RP in employment terms and so will still be responsible for remuneration and performance review. We also accept that it will be the company/superintendent who will have a substantial financial investment in the business and therefore they will have a legitimate interest in the business of the pharmacy. It will be their responsibility to provide the proper support to the RP to enable him/her to discharge their statutory responsibility.

b) The RP on the other hand will have the statutory responsibility for the safe and effective running of the individual pharmacy in so far as it relates to medicines. This means that whilst it is the company/superintendent who will set the direction, it will be the RP who will decide

how to deliver the safe and effective running of the pharmacy, the RP will have the full backing of the law to do this. This means that it will be the RP who should be instrumental in establishing what will be safe service levels depending on staff and other resources available. If the RP decides that he or she cannot deliver the services required by the company/ superintendent safely or effectively with the resources available, then the RP will have two options;

i) Require the employer to provide more resources whether they are more staff, more training or better central support and organisation.

or

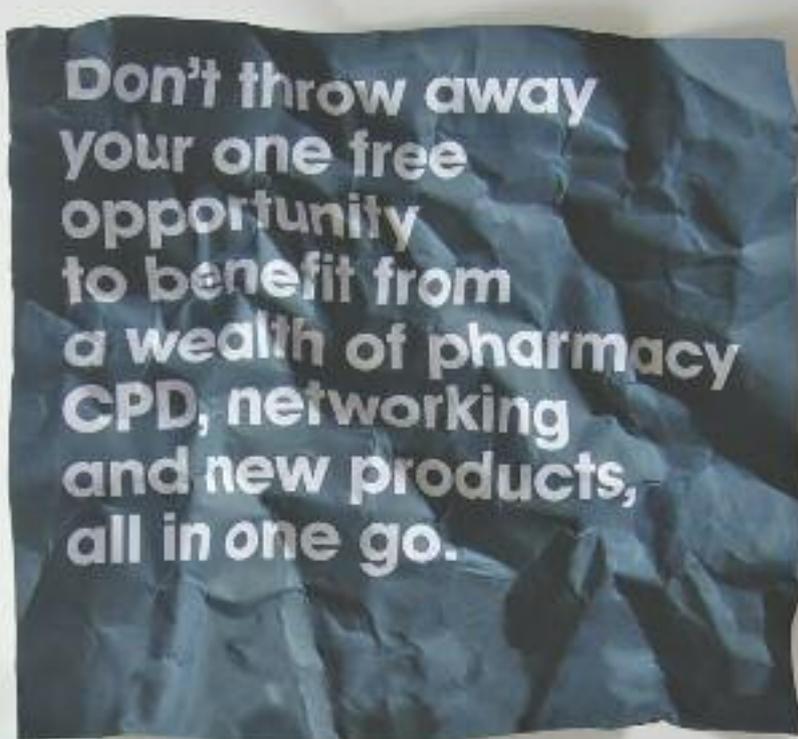
ii) Change or reduce the service level so as to ensure that the offering can be provided within the current resources that are available.

Support from the PDA

There can be no doubt that these are fundamental changes in not only the law, but also to custom and practice in pharmacy. Changes such as these may only realistically be made in incremental steps as otherwise the introduction of the entire concept by applying a 'BIG BANG' approach would be operationally overwhelming to all parties and undoubtedly detrimental to both patients and pharmacists.

The success of the transition from pharmacist to Responsible Pharmacist will depend on the time period over which the changes may occur – and this was the main reason why the PDA had been keen to see a delay in the formal roll out of the regulations, with a 'dry run' period being used to test out some of the new arrangements in an orderly fashion. The transition will also depend particularly upon what the employer representative bodies will be comfortable with saying to their members. Judging by the comments already being made by employer organisations – it would appear that the PDA needs first to agree the common ground and then discuss and negotiate the areas where there are differing points of view. Matters that cannot be agreed in this way may end up being the subject of test case law, which the PDA will seek to establish as soon as possible to avoid lingering doubts. These matters will all be areas of PDA activity going forward. In the coming months, we will be distributing materials to assist individuals and employers with the transition. We have also agreed to work with other organisations like the CPPE to disseminate supporting information and training materials. Additionally, we will seek to hold meetings for PDA members to bring these matters to their attention face to face.

The first such meeting will be at the Pharmacy Show on Sunday October 11th at the National Exhibition Centre (details opposite). Book online www.the-pda.org.



Don't throw away your one free opportunity to benefit from a wealth of pharmacy CPD, networking and new products, all in one go.

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So what next?

After a great many years of accepted custom and practice where employees and locums have largely been obliged to follow all the procedures of the employer (as described on page 6), it is easy to see how confusion may now prevail as a result of the RP changes. There is no doubt that employers have always controlled the working environment, it has after all, always been theirs to control. A position where it is now the RP who will have legal control over some aspects of the business (the pharmacy operation), and this power shift will inevitably produce tension which will need to be handled carefully.

We recognise that for employers, employees and self employed locums, this is a fundamental change and it is helpful to break down the issues into smaller 'bite sized' chunks. So let us examine the next steps that need to be taken so as to minimise the confusion and assist with the transition.

1. Instigating an intelligent debate within the profession to ensure that an appropriate balance between the interests of business owners and RPs can be found.

The PDA recognises that the owners of pharmacy businesses will have a legitimate interest in the way that their pharmacies are operated. Equally, it is also recognised that many pharmacies rely on Head Offices or the NPA for the provision of pharmacy material, to include SOP frameworks, practice literature etc. as well as employment procedures and dispensary management templates. These are important and useful resources. However, with the onset of the new regulations, the nature and tone of these materials must now reflect the new statutory position, and a way must be found to ensure that the RP can indeed have a significant say in the pharmacy environment.

In addition to instigating a debate around these matters to heighten awareness, the PDA will also be seeking to engage with the employer representative organisations to ensure that these matters can be addressed.

2. Ensuring that training materials are made available so that all parties truly understand the new RP position.

The criticism of the RPSGB's RP toolkit demonstrated that it is not only important to deal with professional matters, but also the awkward questions which pertain to more routine operational matters; these issues must not be avoided. As an example, the entire subject of the Rest Break situation was not dealt with by the RP toolkit resulting in confusion and frustration. More recently the RPSGB has publicised the fact that it will seek clarification from the Department of Health on the Rest Break situation. The news as we go to press is that no clarification/compromise can be found. The employment legislation is there to protect workers Health and Safety. This omission in the RPSGB's approach to the RP regulations is unforgivable. It has provided opportunities for some employers



to disseminate incorrect information. The PDA will be assisting members with these matters through conferences/training events and publications. We will host a Question and Answer section on the PDA website. This will specifically deal with the 'awkward' questions relating to employment issues. Beyond that, we will also seek to ensure that those who operationally manage pharmacists (particularly non-pharmacist area managers) also understand the new regulations.

3. Establishing new contracts of employment which include the new legal provisions.

The new legal powers being set out in the RP regulations will have an impact on the employment relationship between the employer and his employees. The very nature of the regulations call for the establishment of either brand new or at least amended terms and conditions and contracts of employment (or contracts for services if self employed). The statutory responsibilities and liabilities being placed upon the shoulders of RPs are much more substantial than before and this must be reflected in changed terms. We will seek to support PDA members through this process in several ways;

- Supporting members to approach their employers and by providing them with the materials that they will need to enable them to engage with them directly.
- Seeking collective agreements with the larger employers on behalf of PDA union members.

4. Seeking ways to enable RPs to comply with some of the operational requirements of the RP regulations.

Since the very start of the debate around the RP proposals, large numbers of pharmacists have registered their concerns about some of the operational matters that they refer to.

Examples include;

- Finding the existing SOP's, reading and digesting them, being satisfied that they are capable of supporting the safe and effective running of the pharmacy and then signing on as an RP – all before the pharmacy opens.
- Reviewing the SOP's for the pharmacy after two years.
- The issue of the two hour absence facility.

It should be possible to find workable solutions to most of these matters, however, these will need the benefit of time and consultation to develop. Despite the fact that no delay to the RP regulations has been given, the PDA will work with members and employer representatives to find operational solutions.



5. Producing materials to support RPs in their practice.

a) Signage

When the PDA was involved in the RPSGB's Responsible Pharmacist steering group, the matter of appropriate signage was discussed. Core to those discussions and a view that was widely shared by other representatives, was that patients deserve to know whether the Responsible Pharmacist is present, is on a two hour absence or

is not actually signed on at all. These considerations could make a significant difference to the patient. It was disappointing therefore that the RPSGB's RP Toolkit only contained one sign – the one that explains who the Responsible Pharmacist is. This leaves both the patient and the Responsible Pharmacist at risk. Consequently, two additional signs are contained on the adjacent pages which will resolve this problem. RPs are asked to carefully cut them out and they may then be used to support their practice.

b) RP tools section of the PDA website

A section containing numerous on-line tools will be available on the PDA website and what it contains will develop over time. Most importantly, it is intended that a regularly updated and growing Question and Answer and Practice Tips section will be provided. This will enable RPs to learn of situations that have already been faced by their colleagues elsewhere and what solutions were found.

c) A Contract for Services for locums

As we go to press, the PDA's new version of the contract for Services for locums which takes on board the Responsible Pharmacist changes is currently being finalized by PDA's employment specialist lawyers. It is anticipated that this will have been completed and be available in downloadable form from the PDA website.

6. Providing PDA members with reactive support

The PDA has extensive experience of supporting PDA members who find themselves in employment and professional disputes. We believe that no matter how many preparations are made, the RP regulations may result in a significant uplift in disputes in both of these areas. We will provide members with appropriate support in the event that such disputes occur. However, we believe that if the profession genuinely seeks to put fair and appropriate solutions in place then the number and seriousness of these disputes will be significantly reduced.

Responsible Pharmacist Fact or Fiction?

Join the PDA at this emergency mini conference to learn what is fact and what is fiction and to discuss what support members will want from the PDA in becoming RPs.

- How to handle the new statutory authority
- How to approach the operational problems
- Employer/RP interface issues
- Panel Questions and Answers

**Sunday 11th October 2009
2.00pm – 4.30pm**

NEC Birmingham, at the Pharmacy Show

**To book a place go to
www.the-pda.org**

No conference fee – but book early as spaces are limited!



**There is currently
no responsible pharmacist
on duty at this pharmacy**

**Responsible Pharmacist
Regulations**

**Under the law this means that there can be no sales
of medicines nor dispensing of prescriptions**

Medicines Act 1968



Responsible Pharmacist Regulations

**The responsible
pharmacist is
currently absent from
this pharmacy**

Questions and Answers continued...

Question: Certain activities are undertaken in the pharmacy before I get to work and also after I shut the pharmacy and leave to go home. Even though at these times the pharmacy is not open for business, are there any implications?

Answer: Currently, many pharmacy activities occur outside of opening hours e.g. preparation of MDS packs for residential homes, bulk stock preparations etc.

This has always caused concerns for pharmacists who, upon arrival at the pharmacy are often asked to check off large quantities of MDS packs without having been present when they were assembled or labelled. The good news from a professional and patient safety perspective is that under the new regulations, these pharmacy activities will be allowed to occur **only** if there is an RP signed on at the time that they are being undertaken.

Consequently, this may now mean;

1. The RP will need to start their work shift earlier or stay later than before so as to be physically present.
2. Pharmacy tasks are re-organised so that they are undertaken during normal working hours.
3. Another RP signs on for the unsociable extra hours.
4. An RP physically signs on remotely before arriving at the pharmacy at the time these activities commence at the pharmacy (max two hours absence allowed). This solution would only be appropriate in certain situations e.g. where an owner proprietor or regular manager is entirely familiar with the pharmacy procedures and is prepared to operate in this way. Before signing on remotely, the pharmacist would need to contact the pharmacy to check that all of the expected conditions are indeed in place and that nothing detrimental had occurred overnight that could affect the safe and effective running of the pharmacy. The RP may be asked to sign on in this way by an employer –but the decision to do this is strictly for the RP to make and only then if the RP is satisfied that he/she can secure the safe and effective running of the pharmacy. If the RP did feel comfortable with such a solution then they would need to consider an amended employment contract and remuneration arrangement.

This solution would not be suitable if an emergency locum was employed as it would be improper to expect them to take on such a responsibility without being in a position to be comfortable with the additional statutory responsibility in absentia. Similar considerations should be made for activities undertaken after the pharmacy closes.



Please Note; at the time of going to press, the RPSGB was seeking 'clarification' from the DoH on this matter it will be very important that this clarification does not lead to these useful safety measures being diluted.

Question: My employer has told me that because I am now able to be absent for up to two hours and remain signed on – he wants me to go and visit local residential homes during this time. What is the position?

Answer: Since the RP regulations do provide for absences of up to two hours, then the employers request is lawful and a refusal to comply with a reasonable request may lead to employment disciplinary consequences.

HOWEVER; It is the RPs statutory responsibility to ensure the safe and effective running of the pharmacy while signed on as RP. This means that it is for the RP to decide whether they are satisfied that they can establish procedures that can deliver the safe and effective running of the pharmacy in their absence. If the RPs professional decision is that through operational concerns, they do not feel that the safe and effective running of the pharmacy can be secured in their absence, then a refusal to leave the pharmacy whilst signed on will be an entirely legitimate response for which they have statutory authority to make and this would be a strong defence if an employer decided to instigate disciplinary action.

Question: My employers require me to meet certain MUR targets. I believe that these are unreasonable and that even trying to meet the targets causes safety issues for patients due to understaffing. Can the RP regulations help in this regard?

Answer: The RP regulations provide RP with new statutory powers, the RP is now charged with the responsibility for ensuring the safe and effective running of the pharmacy. This means that if the RP feels that the safe and effective running of the pharmacy is being compromised by unreasonable impositions of workload by an employer or because of staff shortages then the RP can use these statutory powers. The following options are available;

1. The RP explains to the employer what resources would be required so as to enable the RP to deliver the MUR targets; such as additional staff, or trained staff or a second pharmacist so as to still be able to ensure the safe and effective running of the pharmacy.
2. The RP decides what services it is possible to operate within the existing resources available and this may mean that a discussion is held with the employer so as to discuss how this will impact upon the business to include the possibility that MUR's cannot be delivered or if they are, then at a reduced level.

In both these cases, the RP should always notify the superintendent pharmacist so as to ensure that the superintendent has been warned of any potential deficiencies in the pharmacy. At best, this may result in support being provided through the superintendent's intervention. At worst, it means that the superintendent can be joined in, in the event that the situation escalates and results in untoward consequences.

UP WITH THIS WE WILL NOT PUT!

Responsible Pharmacists must stand up for their rights

Who's defending yours?

The Responsible Pharmacist regulations ensure that it is the RP who now holds the statutory responsibility for ensuring the safe and effective running of the pharmacy. This gives the RP a much greater say in how a pharmacy is to be run and could be good news for pharmacists and patients alike. The RP is now in a statutory position to insist on safe staffing levels, appropriate work loads and much more besides. This should naturally result in revised contracts of employment and also additional remuneration. However, not all employers will welcome this new reality and may argue that these new responsibilities deserve no additional recognition.

Although many employers will be keen to get this development right, it is inevitable that some tension may emerge and that conflict may result; be this of a professional or employment relationship nature.

Because employers will have large Head Offices or the NPA to fall back on – they will have their interests well covered but will you?

The PDA has supported many thousands of pharmacists in their professional and employment needs and now seeks to ensure that pharmacists are supported in this new and significant challenge.

If ever there was a time for pharmacists to have their rights protected – then that time is now!

Will your employer provide additional pay for your new role?

- ✓ More than £500,000 compensation already secured from employers who have treated their pharmacists unfairly or illegally
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- ✓ Union membership option available

now more than 15,000
~~12,000~~ pharmacists have already joined the PDA.

→ have you?

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