The PDA's proposals for better patient safety through a policy for staffing levels and working hours in the pharmacy.
what’s inside...

Summary of proposals 3
Setting the standards 4
Research-driven policy 6
The PDA policy 10
Written statement of staffing levels 14
Q & A’s 18
Superintendent Pharmacist letter template 22
Contact details 23
Working together to keep patients safe

...summary of proposals

The PDA will work towards ensuring that:

• A compulsory requirement is placed on every pharmacy to have in place a satisfactory staffing level policy

• The policy will outline the quantity of staff required to run each pharmacy safely

• The policy will include details of the quality of staff required in terms of the number of pharmacists, qualified technicians and unqualified assistants, as appropriate

• Details of the staffing level policy are readily available to all staff working in the pharmacy

• All staff have an absolute minimum of one 20-minute break after six hours’ non-stop working

• The regulatory authorities – that is, the RPSGB and the relevant NHS bodies – place these requirements on all pharmacies

{ Workload can reach a dangerous level where an error could occur at anytime – but we are expected to keep going with near misses occurring frequently. }
Setting the standards

The Pharmacists’ Defence Association (PDA) supports over 11,000 members who are predominantly employees and locums, often working in highly stressful environments.

Through its own research and experience of defending its members, the PDA has built considerable knowledge of the link between patient safety and inadequate staffing in pharmacies.

The PDA view is that inadequate staffing levels and long working hours, with no breaks, risk the safety of patients.

Staffing policy

To address these problems, the PDA has launched its policy on staffing levels and rest breaks.

This initiative has three aims:

1. To raise awareness of the issues and problems caused by inadequate staffing
2. To lobby for the acceptance of a national policy to address this undesirable situation
3. To provide a process that enables pharmacists to manage, individually, unacceptably low staffing levels

Current working practices

There are no nationally agreed standards for both staffing levels and working hours for pharmacies in the United Kingdom. Unlike in other industries, historically, the regulatory bodies have felt that staffing levels and rest-break issues are largely contractual matters between employers and employees. Consequently, they have not dealt with the specific practicalities of safe staffing levels and working hours in anything other than a very general way. Currently, the requirement placed on pharmacy owners, superintendents and pharmacist managers in hospitals, as stated in the Medicines Ethics and Practice Guide, Vol 29, page 86 A.2 (F), is:

To ensure that adequate support staff and information about the pharmacy are provided to enable all pharmacists including temporary staff and locums, to perform their duties effectively.

As a result, some employers have been able to develop policies that appear to be more influenced by cost-control strategies and less by a focus on patient safety issues and the avoidance of workplace stress. Moreover, the hourly rate of pay arrangements for locum pharmacists in particular have militated against a pressure for a widespread recognition of rest breaks. In the absence of a regulatory-led policy, what have emerged are a series of ‘accepted working practices’, which have been led predominantly by those who are concerned with the cost control and profitability of community pharmacy businesses.

Silent problem

Unacceptable staffing levels have been a silent problem in pharmacy for many years. However, with dispensing volumes going up year on year, there has been little in the way of a commensurate increase in staffing levels. From 2005, with the requirement of a new raft of services to be provided through new NHS contract arrangements, there is rarely a more
appropriate time to consider again the issue of safe and appropriate staffing levels. An opportunity exists to think about the issues in their broadest sense, not just from a quantitative point of view, but by considering staff profile and skill mix, to deal with these issues in a qualitative sense also.

The emergence of new working patterns

As a profession, pharmacists aim to provide a high-quality, well-managed pharmaceutical service for patients.

Traditionally, working patterns within pharmacy have been relatively standardised, with a focus on the sale and supply of medicines and the provision of advice to patients.

Recent changes in NHS policy in England, Northern Ireland, Scotland and Wales have created new opportunities for a move towards the provision of services. New arrangements for managing repeat medication, coupled with new opportunities for managing medicines and providing clinical services to patients, will further change the ways in which the profession works. However, these opportunities are emerging on the basis that the sale and supply of medicines and advice will still be provided from a community pharmacy setting.

It is envisaged that under new arrangements, the direct personal involvement of the pharmacist, will be replaced by a series of standard operating procedures (SOPs), which will enable much of the more routine supply operation to be handled by qualified staff working under protocol. However, all this will be undertaken under the direct personal responsibility of the newly designated ‘responsible pharmacist’.

The responsible pharmacist

Although innovation in pharmacy practice is welcomed, these changes will introduce new risks, both predicted and unforeseen. While these developments will expand the boundaries of the profession, they will introduce new and additional risks not only to patients, but in particular to the ‘responsible pharmacist’ who will be far more heavily reliant on the presence and the role of support staff in the pharmacy.

New risk management strategies

It is apparent that these new developments necessitate the development of new risk management strategies, particularly in the area of staffing levels and rest-break policies.

Importantly, the newly created designation of the ‘responsible pharmacist’ will change markedly the balance of power in community pharmacy. Previously, the environment of a pharmacy was usually determined by an employer; now, the ‘responsible pharmacist’ will need to be able to exercise a much greater level of influence over the working environment and, in particular, over the staffing-level profile of a pharmacy operating under SOPs that are the pharmacist’s direct responsibility. It is apparent therefore, that an open and transparent mechanism must be found to enable this to occur. Such a mechanism must not only be transparent, but, in the event that something goes wrong, must be able to provide an audit trail and a solid mechanism that can underpin the ‘responsible pharmacist’s decision-making in deciding to operate the pharmacy through SOPs.

It is against this background that the PDA believes that now is an ideal time to launch a national policy for staffing levels and rest breaks. The policy must provide a simple method that may be used to ensure that ‘responsible pharmacists’ are able to manage the risks properly. The policy will also need to lay down rules on staffing levels and rest-break policies. By so doing, patient safety will be enhanced and work-related stress reduced.
Research-driven policy

Evidence of inadequate staffing levels and rest-breaks in pharmacy

Two primary sources of evidence have been used to establish the link between inadequate staffing levels and rest-breaks and patient safety issues.

1. The PDA’s experience of defending hundreds of dispensing error claims on behalf of its members.
2. Research undertaken amongst the PDA membership to study the current trends on staffing levels and rest-breaks.

1. Lessons learned from handling dispensing-error claims by the PDA

Because the PDA has more than 11,000 members, it is routine for it to have an involvement in the defence of members who have been involved in a dispensing error. In the year 2005 alone, the PDA handled more than 250 such incidents on behalf of members.

When an error is reported to the PDA, an environmental survey is issued initially to the member. This requires the member to complete a wide-ranging environmental report that describes the overall working environment in the pharmacy on the day the error was committed. These environmental reports show a significant link between the commission of the error and the staffing level/rest-break scenario of the pharmacy in question.

2. Research undertaken by the PDA

An ongoing research programme is undertaken by the PDA to ensure its policy is underpinned by the realities of everyday pharmacy practice. Since 2003, the PDA has undertaken two surveys (one web-based and one postal) of members and has held four focus group meetings in the support of the establishment of this policy.

The working environment survey

In late 2003/early 2004, the PDA commissioned an independent study into the influence of the working environment on employed and self-employed pharmacists in community pharmacy. The research was based on a postal questionnaire, which was completed by 1,621 pharmacists. Results of the study were analysed and completed by an independent research institution, MEL, in Birmingham in April 2004. The findings formed the basis of the PDA’s work in producing the staffing levels/rest-breaks policy.

A pharmacist cannot dispense and check hundreds of prescriptions and also counsel patients properly.
Respondents
With 1,621 responses, the working environment study received a sizeable response from UK pharmacists. Among those who replied, 42 per cent were women, and 27 per cent of all respondents were aged over 56 years. 44 per cent were full-time self-employed locums, 33 per cent were full-time employees and 23 per cent had part-time status. The split between working in small independent pharmacies and working for the large multiples was approximately 50/50.

Working hours
The study found that:
• 51 per cent of respondents regularly worked more than 35 hours per week. 38 per cent worked between 35 and 48 hours, and 7 per cent more than 48 hours per week.

The study also found that respondents who worked longer weeks also tended to work longer days. The results showed:
• 65 per cent of respondents worked between 8 and 10 hours per day (excluding breaks) and 4 per cent worked more than 10 hours per day.

Conclusion
It is apparent that long working hours are prevalent in community pharmacy.

Workload and safety
With increasing dispensing volumes and growing demands to innovate service offerings, pressures on individual pharmacists are increasing. At the time of the study:
• 49 per cent of respondents thought their workloads too heavy
• 89 per cent believed that their workload affected their performance detrimentally
• 75 per cent believed that their workload had risked patient safety

Conclusion
These findings suggest that not only are pharmacists affected by large workloads, but detrimental effects could also be observed on the standard of work and patient safety.
Taking a break

Guidelines in most industries specify how often employees should receive a break during their working day. However, the PDA survey found that:

- 71 per cent of respondents work through the day without a break

Of these,

- 50 per cent were required to do so by their employers
- 26 per cent did so out of choice
- 24 per cent did so out of necessity

These results suggest that many pharmacists work without regular breaks, sometimes out of choice and others out of necessity. Importantly, the questionnaire also found that:

- 67 per cent of respondents thought that patient safety had been put at risk because of working without breaks

Staffing levels

The survey found that:

- 81 per cent of respondents thought that the quality or quantity of support staff that they experience in their pharmacy puts patient safety at risk.

Additional contributions from survey respondents.

As well as completing the survey, many respondents offered additional information and made general comments on the issues being surveyed.

Some of these comments have been reproduced throughout the main body of this document.

Synopsis

Currently, there is no industry-wide policy on support staff or working hours. However, it is apparent that such a policy will reduce risks to patients and will protect pharmacists and support staff from the dangers and consequences of overwork.

I left my previous job because I was expected to work a 14 hour day – this is the kind of thing that pharmacists are now expected to do.
Setting a national industry standard

In most industries involving predictable workloads, standards have been developed for governing the ways in which people work.

For instance, the TUC has produced standards for staffing levels for manufacturing and other industries to ensure the safety of the work force; the government, through legislation, uses the tachograph system to police the working hours of the drivers of heavy goods vehicles to ensure the safety of both the drivers and the public at large.

In the industries where they are introduced, national standards promote greater safety for both workers and the public.

PDA policy

Given the unique impact of medicines upon the public and, in particular, the harmful effects of errors if they occur, the PDA believes that a much more practical system of ensuring appropriate staffing levels and rest-breaks should be in place. Moreover, the PDA believes that the regulatory authorities should play a greater pro-active role in enforcing such safety standards.
The PDA policy

The issue of setting acceptable national staffing levels has dogged the profession for many years. Over the past 30 years, the Council of the RPSGB has periodically debated this issue, but with no two pharmacies being the same, the idea of a fixed national staffing-level standard has never been a workable proposition.

Opportunities offered by the new Health Act

In order to create a workable policy, the PDA has taken a new approach. Instead of seeking to set a national staffing level calculation method, the PDA wants to take advantage of newly proposed Health Act legislation, which proposes the creation of the concept of ‘the responsible pharmacist’. The PDA policy proposes a template that ‘responsible pharmacists’ can use so as to specify appropriate staffing levels at their pharmacy. They can use the template to negotiate and agree the staffing level with owners in a formal manner.

Since (because of Health Act legislation), safety issues stemming from staffing levels would fall under the aegis of the responsible pharmacist to a greater extent, such an approach, at the local level, ensures that local needs can be met by locally-agreed solutions. The key is that the resulting levels become transparent and can be used as a reference tool, not only by the staff employed and temporary locums, but also by the regulatory authorities, to ensure compliance.

We need some guidelines on realistic workloads and staffing levels.

The PDA will work towards ensuring that:

- A compulsory requirement is placed on every pharmacy to have a satisfactory staffing-level policy in place
  
  Each pharmacy should decide its own staffing requirements and this would be based upon current good practice. Ideally, this initiative would need to be led by the nominated ‘responsible pharmacist’ for a particular pharmacy, as this would be the person who takes ultimate professional responsibility. The policy would need to be informed by issues such as workload, hours of opening, additional services being undertaken, and the quality and experience of staff.

- The policy will outline the quantity of staff required to run each pharmacy safely
  
  The policy would need to be very specific, itemising the actual number of staff required and at what times/days. Importantly, this exercise should not be based on a minimum staffing level but more so on an appropriate level to support safe operations.
• The policy will include details of the quality of staff required in terms of the number of pharmacists, qualified technicians and unqualified assistants, as appropriate.

The internally-written staffing statement for each pharmacy should specify the number of pharmacists, qualified technicians and support staff the pharmacy requires to run safely.

• Details of the staffing level policy are readily available to all staff working in the pharmacy.

This information should be transparent to all pharmacy staff, and should be displayed openly for all staff to read. Importantly, the policy needs to be clear that it relates to staff required to ensure that the entire range of professional services provided by that pharmacy can be delivered safely. This means that the staffing policy relates to members of staff working in the professional/pharmacy areas of the pharmacy and does not involve staff who have been deployed to other non-pharmacy areas of the premises e.g. cash and wrap or helping with the re-design of the window displays (unless this is at pre-agreed and specified times of low pharmacy activity).

The PDA has developed a template that ‘responsible pharmacists’ may use to specify what will be an appropriate staffing level for their pharmacy that they are happy to agree with owners.

**An example template that may be used is provided on page 13 of this document.**

• All staff have an absolute minimum of one 20-minute break after six hours’, non-stop working.

In most industries where public and/or employee safety is at risk, standards exist for regular rest periods. For instance, drivers of heavy good vehicles must take regular breaks. Working-time directive legislation places an onus on employers to ensure that employees are provided with at least a minimum rest break opportunity.

Using this existing legislative standard, the PDA is championing the minimum standard of at least one 20-minute break every six hours in the pharmacy. Research has shown that many pharmacists are required to work through their breaks by either their employers or through circumstance. Often, this means that pharmacists will attempt to take breaks while still on the premises so that they can still be available to undertake any routine activities that may be required of them.

The result is, that in many instances, pharmacists simply do not take breaks at all, working through break times in the belief that they are acting in the public interest.

The break proposed in this policy must allow the pharmacist a complete physical and mental respite from the business of the pharmacy because such an arrangement will be more appropriate to the public interest.

• The regulatory authorities - the RPSGB and the relevant NHS bodies – place these requirements on all pharmacies.

While the position of the ‘responsible pharmacist’ will provide pharmacists with the legal basis to influence the staffing levels strongly, the acceptance of this policy by the RPSGB and other regulatory authorities such as local primary care trusts will ensure a rapid and wide take-up. This will assist with improving the safety profile of pharmacies and will ensure that a better standard of service can be provided.
Already, brand new NHS community pharmacy contractual arrangements in England and Wales do specify that minimum staffing levels are a contractual requirement. The PDA proposals build on these minimum levels by supporting the concept of a staffing level agreed between the responsible pharmacist and the employer. This level is not to be a minimum level, but more one that can properly support a safe and consistent service to the public.

The PDA will lobby the RPSGB and the Department of Health to ensure that staffing standards become nationally recognised and that they form the foundation of good practice throughout pharmacy in the UK.

Compliance

By pursuing the principles described above, it becomes possible to create an interdependent compliance triangle. After the staffing policies have been agreed, they are then publicised through the display of a template pro-forma. Once they are available for use as a reference point, it becomes much easier to establish whether the staffing policies are being adhered to, or whether they are being openly disregarded. Subsequently, the fact that a potential regulatory involvement exists means that the ‘responsible pharmacist’ has a workable tool. This will ensure that once appropriate staffing levels have been agreed, they can be monitored and enforced if necessary.

How it will operate in practice

In the event that a ‘responsible pharmacist’ — be that an employee or locum — becomes concerned that the staffing level falls below the pre-agreed levels, then he/she will be able to risk manage the situation by pursuing a number of different avenues. This could be as simple as accepting that for a short-term temporary period, because of sickness or temporary absence, special measures may need to be put in place to ensure that patients can rely on safety, e.g. by amending the SOPs. In other situations, such as the permanent resignation or long-term absence of staff through maternity leave or sickness, this may mean requiring the owners to provide extra staff. This may be done by writing to the employers formally and requiring them to rectify the problems. In the worst case scenario, such as a persistent disregard by the employers for concerns about routine staff shortages, it may become necessary to involve the regulatory authorities on the grounds of public safety.

It is felt that the adoption of the PDA staffing-level principles will lead to the creation of a compliance triangle. This solution will go a long way in delivering the staffing-level solution that has evaded the profession up until now.

My breaks have disappeared and staff shortages have become a big problem.
Synopsis

The PDA is committed to the national implementation of its staffing levels and rest-breaks policy. To this end, the organisation will strive towards ensuring that every pharmacy is required to have a statement of minimum staffing levels in place. This statement will outline the quantity of staff required to run each pharmacy safely, as well as their quality in terms of the necessary mixture of pharmacists, qualified technicians and unqualified assistants. The statement will also make clear the precise arrangements relating to rest-breaks to allow those taking professional responsibility for the operation of the pharmacy to have a complete physical and mental break from the pharmacy operation.

By making this information transparent and readily available, pharmacists, technicians and support staff will be more able to act in situations where staffing levels are routinely low or where rest-break policies are inadequate.

As a result, understaffing and dangerous working patterns will be easier to identify and rectify, with the following benefits:

• Improved public safety
• Reduced stress because of more appropriate workloads
• Better working conditions for pharmacy staff
Written statement of staffing levels

The PDA template

Once appropriate staffing levels have been decided upon, owners and pharmacy managers may record this information on the templates provided (overleaf). These templates give an example of a written record of the pharmacy’s staffing requirements. Staff may use this information to ensure that the correct workforce is in place. If actual staffing levels fall below the specified level, then further action may be required. For instance, by amending the SOP’s temporarily to add additional safety features, by writing to owners to request rectification or through regulatory inspection by RPSGB or NHS inspectors.

References

- Royal College of Nursing (2003). Setting safe nurse staffing levels: an exploration of the issues.
- Rest-breaks during the working day, Department of Trade and Industry
- The influence of the working environment on locum and employed pharmacists ; MEL Research and Service Development
- New EU drivers rules ; Freight Transport Association
- Securing our long term health, Wanless report
- Future pharmacy workforce requirements, Kings College, London
- Working time directive, Health and Safety Executive
- Working time directive, Department of Trade and Industry
- Recommendations for staffing and practice in departments of surgery, Royal Australian College of Surgeons
### Workload grid

<table>
<thead>
<tr>
<th>Day</th>
<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thu</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Close</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walk in items</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitored dosage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repeat collections</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Services - number of patients per day

<table>
<thead>
<tr>
<th>Service</th>
<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thu</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
</tr>
</thead>
<tbody>
<tr>
<td>MUR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supervised consumption</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EHC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PGD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Additional notes:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Pharmacy Stamp**

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

<table>
<thead>
<tr>
<th>Working Hours</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
<th>Sunday</th>
<th>Total Weekly Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technicians</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trainees</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Qualified Healthcare Staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td>Deficit in hours per statement</td>
<td>Total Weekly Hours</td>
<td>Date</td>
<td>Working time audit</td>
<td>Did the pharmacist have a 20 minute break for every 6 hours worked Y/N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>--------------------------------</td>
<td>--------------------</td>
<td>-----------</td>
<td>--------------------</td>
<td>---------------------------------------------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monday</td>
<td>Pharmacist</td>
<td></td>
<td>Monday</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuesday</td>
<td>Accredited Checking Technician</td>
<td></td>
<td>Tuesday</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wednesday</td>
<td>Qualified Technicians</td>
<td></td>
<td>Wednesday</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thursday</td>
<td>Trainee Technicians/Dispensers</td>
<td></td>
<td>Thursday</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Friday</td>
<td>Qualified Healthcare Staff</td>
<td></td>
<td>Friday</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Saturday</td>
<td></td>
<td></td>
<td>Saturday</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sunday</td>
<td></td>
<td></td>
<td>Sunday</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Questions and Answers

Q 1. The pharmacy superintendent seems to be a key figure in determining staffing levels, why is this?

A. The pharmacy superintendent has additional personal professional areas of responsibility relating to their important role, which are described in the Medicine, Ethics and Practice Guide (29th edition) on page 86.

Alerting the pharmacy superintendent to matters, which they may be unaware of, helps to flag up local issues as well as providing a more accurate picture of day-to-day reality in the pharmacy. When inadequate staffing levels are identified by the RPSGB as a contributory factor towards an error, it is likely that the pharmacy superintendent will play a more pivotal role in the investigation, if they have failed to address relevant issues previously notified to them.

Q2 What shall I do if my employer/contractor refuses to declare their staffing model?

A. There are some employers who already have staffing models based on workload and some of these are prepared to be transparent about them.

Regrettably there will be employers who may not have a logical staffing profile or will refuse to divulge it where it exists.

Frequently, large organisations budget for safe staffing, but this is not translated into correct levels at the coalface by (often non-pharmacist) middle managers. Neither does it reflect the fact that poor store and area management of staff resources on a day-to-day basis may result in inadequate levels when locums are in situ. It would be in their interests to understand the breadth and depth of the issues.

Although it is our intention to lobby all employers to voluntarily declare their staffing models we wish to also convince the RPSGB that it should be an ethical imperative to do so. Irrespective of the reasons for not doing so, a new transparent culture must be engendered in the interests of patient safety.

The PDA has always encouraged locums, in particular, to assess the staffing levels in pharmacies they visit. If an employer refuses to divulge the normal staffing levels then the documentation can be assembled by the employee or the locum whilst they are on duty. This can be kept as information to not only put the superintendent pharmacist on notice of the inadequate staffing levels, but also used as evidence and in mitigation in the event that an error occurs.

Remember, when the new Health Act is passed, the new position of ‘Responsible Pharmacist’ will be created. This will significantly change the dynamics of who decides what in a pharmacy. If you are a ‘Responsible Pharmacist’ then the employer will need to take account of your concerns and the prospect of an employee or locum pharmacist negotiating and agreeing the staffing levels with the employer will become much more likely.
Q3 What if I believe that the levels of staff are dangerously low on a given day – can I close the pharmacy?

A. Staff shortages may be caused by a variety of circumstances, the principles however are broadly the same whether it is unavoidable or not. You have a duty of care to your patients and you should not put their safety at risk. If you genuinely believe that you are compromising patient safety then you will have to go through a professional decision making process, including a risk assessment of the implications and risks of continuing the service. Acting outside the public interest by closing down the pharmacy and depriving them of the service may outweigh your judgement of acting within the public interest deeming the pharmacy to be unsafe.

If a pharmacy is ‘unsafe’ then a pharmacist reserves the right to close it down in the interests of public safety. However, if you do this, then it is likely that someone (either a patient or an employer) may report you to the RPSGB. It would then be difficult for you to justify your decision to the Society if you closed down the pharmacy on a ‘general issue’ or for an indeterminate amount of time. You would only be able to justify the closure in the event that there was a major critical issue; e.g. An indeterminate amount of errors had been made and because there were no other staff the pharmacist could rely upon to trace patients, or where some other major health and safety issue had arisen etc.

We would only advise pharmacy closure in the last resort and in taking any action whereby you will require the PDA’s support, you do not want to leave yourself open or vulnerable to charges that you acted contrary to the public interest. If in doubt, contact PDA for advice.

If you decide to keep the pharmacy open, our initial advice is to do the following:

• Establish the staffing shortages (via the Statement of Staffing and Working Hours if possible)
• Contact the ‘Responsible Pharmacist’/ Area Manager/Proprietor and request that he or she give you the required support. Make a written note of the conversation. If appropriate support is not forthcoming then elicit the reasons and include this in your written notes.
• Conduct a risk assessment. What are the issues that can be risk managed and what cannot.
• Brief the staff on what they can or cannot do and how you are going to manage the situation and the patient’s expectations.
• Do not compromise your standards or take short cuts in your protocols, sacrificing accuracy for speed. Do not be tempted to work throughout the day under extreme pressure without a mental break.
• Collate all the evidence you have on ‘near misses’ or errors.
Once you have negotiated the crisis

- Write to the superintendent pharmacist with your evidence (the ‘statement of staffing levels, skill mix and working hours’ would be one piece of evidence, the conversations you may have had with other employees and senior managers may be another). We attach a sample letter that you may find useful. Whether you choose to use our letter or not, you are strongly advised to put your concerns in writing and at the minimum, ask him/her to disclose the rationale behind the staffing levels.
- By writing to the Superintendent with such evidence you are escalating the issue, not only into the clinical, but also the professional and corporate governance arena.
- Ask for a RPSGB inspector visit, share your thoughts and evidence with him or her; listen and make a record of the conversation. Ask them their opinion on the issue regarding putting patient safety at risk.

Q 4 What if my concerns about staffing are being ignored?

A. Unresolved issues about staffing or other serious professional concerns should always be made in writing. Initially this may be better through a local senior pharmacist, which should allow a quicker resolution in the larger companies. It is important that a copy also goes to the pharmacy superintendent, so that they can build a picture of the issues. If this route is not available or is judged ineffective, then the matter should be directed straight to the pharmacy superintendent, who has a personal professional responsibility outlined in the Code of Ethics. These are articulated in the Code as such “that adequate support staff and information about the pharmacy are provided to enable all pharmacists, including temporary staff and locums, to perform their duties effectively”

Q 5 What if my employer says there is no money to pay for any extra pharmacy staff?

A. The majority of the larger organisations have a pharmacy staffing level model that should be used as the basis of any budgetary exercise. A transparent and open discussion of the staffing level with the manager should be initiated to discuss how shortfalls could be addressed. Issues around confidentiality should not be used as an excuse for failing to provide staffing level information. If the employee still has concerns about the staffing levels, these should again be documented and raised directly with the pharmacy superintendent.

Q 6 What if there is enough trained staff, but the non-pharmacist manager moves dispensary staff away from the pharmacy to cover staff shortages elsewhere in the shop?

A. The pharmacist in charge needs to judge if the conditions being imposed on them by the removal of trained staff will adversely affect their ability to comply with their professional and legal duties. If this is the case and the manager cannot be persuaded to staff the pharmacy to an adequate level, then it is appropriate to put the pharmacy superintendent on notice of this problem. Frequently non-pharmacist managers do not comprehend the risk to patient safety or the serious issues that can arise from inadequately staffed pharmacies. The manager by under-staffing the pharmacy is potentially putting the pharmacy superintendent at risk of RPSGB action. Pharmacists may need to be assertive in their interaction with managers, in order to resolve the matter.
Q7 If I send letter to the Superintendent Pharmacist, would the PDA be interested in receiving copies, and if so what would it do with them?

A. The PDA would most certainly welcome copies of any such letters. These would enable us to get an overview of where things are going wrong and why, thus supporting the profession’s risk management agenda. Furthermore, it will allow us to put together a convincing portfolio of evidence in the event we either need to challenge a particular pharmacy employer or provide the authorities with evidenced based statistics on issues that affect patient safety.
Superintendent Pharmacist letter template

Putting the Superintendent Pharmacist on notice

Dear

Inadequate Staffing / Failure to disclose safe staffing levels

I am writing to you to express my concern regarding the staffing levels in………………….. Pharmacy *on the ………/ *over a period of time between ……. and ……. when I was the pharmacist in charge .

*I requested to see a ‘statement (or policy) of staffing levels, skill mix and working times’ which could not made available to me.

*I requested to see a ‘statement (or policy) of staffing levels, skill mix and working times’, and this was refused by……………..

*I requested to see a ‘statement (or policy) of staffing levels, skill mix and working times’ and was informed that no such statement (or policy) was in existence.

It is my understanding that there are additional specific responsibilities placed upon superintendent pharmacists contained in the Code of Ethics, and it is with these in mind and the conditions I encountered in this pharmacy, that I write to you.

Part 2 of The Code of Ethics subsection A2 gives guidance and clarification to the personal professional responsibilities of the superintendent pharmacist and states he or she should:

(e) not seek to impose conditions on pharmacists which may adversely affect their ability to comply with their professional and legal responsibilities"

(f) ensure that adequate support staff and information about the pharmacy are provided to enable all pharmacists, including temporary staff and locums, to perform their duties effectively.

I believe that the levels of staff made available to me were inadequate and potentially in contravention of A2 [e] & [f] of the code. In addition, I was entitled to any relevant information I required in order to be satisfied that I was operating in a safe environment and able to perform my duties effectively. The ability to influence staff levels is outside my personal control.

I attach the evidence that I was able to acquire as to the most appropriate staffing levels (please see the attached audit sheet and a record of the conversations I have had with either yourself or senior management). I have therefore concluded that it is professionally incumbent upon me, and in accordance with sound clinical governance, to bring to your attention the fact that these inadequate levels gave me serious cause for concern regarding patient safety.

I would be grateful for your comments.

Yours sincerely

*delete as appropriate
About the Pharmacists’ Defence Association (PDA)

The Pharmacists’ Defence Association (PDA) is a not-for-profit organisation 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 11,000 members.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist
- 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

Further information is available from:

The Pharmacists’ Defence Association
69 Albion Street
Birmingham
B1 3EA

Tel: 0121 694 7000
Fax: 0121 694 7001
Email: enquiries@the-pda.org

www.the-pda.org

The lack of support and dispensary staff became a real problem forcing me to leave after 30 years service.