Hospital Pharmacist Edition Summer 2013

insight

pda the pharmacists' defence association

The magazine of the **Pharmacists' Defence Association**

A PERFECT STORM?

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A Perfect Storm!

Recently, I attended a workforce summit where a senior pharmacist who works for the Department of Health (DH) stated that in her opinion as many as 20,000 pharmacists could soon no longer be practicing. This gives us a very worrying glimpse into her view of the future; we must ensure that it never occurs!

There are storm clouds on the horizon any one of which could be damaging, but laid over one another, could result in what can only be described as a **'perfect storm'**.

The profession can and must come to grips with these potentially destructive forces and ensure that they are driven away.

Following on from its now discredited RP regulations and its previously failed efforts to deliver decriminalisation of dispensing errors, the government is now developing a plan that it calls the Rebalancing Medicines Legislation and Pharmacy Regulation initiative – potentially the biggest storm cloud of them all, if it's not handled correctly.

This exercise is to look at creating a legislative and regulatory framework for the supervision and supply of medicines, the issue of decriminalising dispensing errors and ways in which the skills of pharmacists and pharmacy technicians can be used to best effect.

These aims could be welcome – BUT BEWARE!

The government's track record in these areas is poor; previous efforts have demonstrated that it is often unprepared to listen to anyone that has an informed view that is contrary to its own.

It appears that if the Department of Health can't win the arguments, then it will simply try to avoid them.

The storm is gathering on many fronts;

Rebalancing Medicines Legislation and Pharmacy Regulation Initiative

The government's track record suggests that in the worst case scenario the re-balancing initiative could lead to;

1. Remote supervision - pharmacies without pharmacists.
2. The wholesale movement of roles from pharmacists to pharmacy technicians.

Things however, may not be so cut and dried. Members of the board will inevitably want to emerge from this exercise with their credibility intact and it is hoped that at least they will consider any evidence seriously. Despite the fact that the board members were hand-picked and given a specific programme brief *(page 5)*, already there are signs that the programme may not all go the DH's way.

This has already been evidenced, when, at its first meeting, the board decided to move the issue of decriminalisation of dispensing errors up the pecking order to become a top priority; something that previously, DH officials told us would only be done at some point in the future.

The profession must now present its evidence and arguments to the board in a way which is persuasive and patient safety orientated. To this end, the PDA has instigated an extensive fact finding exercise to prepare its submission. Already we are concerned with the view that has been put forward by the Guild of Healthcare Pharmacists; that pharmacy technicians should be added to the list of healthcare professions that should be allowed to operate PGD's. We discover that this view is one that secures minimal support amongst hospital pharmacists generally. The majority of hospital pharmacists that do support such an idea appear to be those in the senior posts.

Other storm fronts include;

P Medicines on self-selection

This issue could do much to cause problems for patients and pharmacists alike, hospital pharmacy will not be immune from the impact – please sign the PDA's petition!
www.the-pda.org/pmedspetition

The excess of pharmacists

The supply and demand forces bearing down upon pharmacists could harm the professional and standards agenda.

A lack of professional autonomy

Hospital pharmacists are increasingly working under pressure to deliver targets from non- pharmacists such as bed managers demanding that patients be discharged. Pharmacists must be able to operate with professional autonomy to best serve patients –this is a leadership issue.

Throughout this edition of Insight (especially pages 6,8,14, 21 and 26), we describe how we are setting our compass towards patient safety and improved patient care as we plot a course for safer ground. When the time comes, we will be appealing for your support.

Mark Koziol, M.R.Pharm.S.

News...

BPA issues apology to PDA

The PDA became aware earlier this year of false and misleading statements being made by the Boots Pharmacists' Association (BPA) to pharmacists and pre-registration graduates working in Boots. The PDA wrote to the Chief Executive of BPA seeking an apology and a retraction of these misleading statements. We sought an undertaking for the BPA not to repeat them again and for the BPA to make a donation to the charity, Pharmacist Support, in recognition of its wrongdoing. The BPA has agreed to these requests and the matter has now been concluded.
The BPA will be disseminating its apology to all Boots pharmacists over the coming months. The apology is as follows:

"In or around October 2012, the BPA made certain statements about the PDA. It has been brought to our attention that they were inaccurate. The statements were published on our website, in a letter issued by our CEO to all pharmacists dated October 2012, in a media statement issued by our CEO, and in the magazine entitled 'Counsellor' distributed in all Boots stores nationwide. The statement suggested that the PDA was primarily an insurance company and may have been interpreted to infer that the PDA's objectives were less credible than the BPA's. The BPA apologises to the PDA and PDA Union for making these statements and to all Boots pharmacists for any confusion that may have [been] caused. In fact, the PDA is a not for profit organisation, and is not and never has been an insurance company. The PDAU is an independent trade union in accordance with the Trade Union and Labour Relations (Consolidation) Act 1992 and is not funded by an insurance company. Both organisations are funded by membership subscriptions."

GPhC makes incorrect allegations against a pharmacist

The GPhC recently failed in its attempt to place the total blame on a pharmacist for the incorrect supply of a CD on the grounds that he was the Responsible Pharmacist (RP), even though he did not dispense or pass out the drug to the patient. Early on in the investigation, the PDA had expressed concerns to the Fitness to Practise Inspector about proceeding with such allegations.

The situation involved a patient's carer who presented herself for methylphenidate. The medication was previously dispensed and checked by another pharmacist and stored in the controlled drug cabinet waiting for the regular supply to be collected. The technician approached the pharmacist for the CD key, which he gave her without question and on the basis of a long-standing working relationship in which her subsequent acts were always shown to him for checking. She mistakenly took another patient's medication from the cupboard, and gave it out without referring to the pharmacist. The supply contained the same medication, but the dose, format and patient's name was incorrect.

The initial allegations made by the GPhC stated that, whilst the pharmacist was the RP, he had supplied a patient with the incorrect medication, which he had incorrectly labelled. And in doing so, his conduct was inappropriate and/or contrary to sections 85, 68 and 58 of the Medicines Act 1968, as well as contravening principle 1.1 of the GPhC standards for conduct, ethics and performance.

Back in 2010 and with PDA support, pharmacist Elizabeth Lee had a conviction quashed in the Court of Appeal for breaches of Section 85 of the Medicines Act. The judges decided then that this section could not be applied to individual pharmacists, but only to the owners or 'persons conducting' the pharmacy business. This more recent case also involved an allegation of mis-labelling of a product and it is disconcerting therefore that the pharmacy regulator continues to pursue pharmacists under this section of the Act.

The PDA defence effort

At the beginning of the hearing, the PDA legal representative had argued successfully that the allegations were incorrect in that they originally stated that the RP had "supplied" and "incorrectly labelled" the medication. The PDA argued that the allegations should read that the patient received the incorrect medication whilst our member was the RP, not that the pharmacist "supplied" it. This amendment enabled the defence to take on a more powerful dimension and to be successful in its case, while the GPhC had to establish that the RP was professionally liable.

The evidence established that the technician who gave out the medication did so without applying any further diligence other than that which had already occurred through the original dispensing and checking processes. She did not involve the pharmacist at the point of supply to the patient, nor even follow the SOPs in so much as checking the name and address of the patient. She made an entry in the CD register and showed this and the annotated prescription to the pharmacist.

The chairman of the tribunal remarked that: *"On the basis of what he [the pharmacist] had seen, he had no way of suspecting that the wrong medication had been given to the patient"*. He further commented that the pharmacist had every right to trust the technician as they had worked together for some time.

The committee could find no evidence that the pharmacist was not a careful practitioner nor that his practices were in any way detrimental to the patients interests. It was determined by the panel that the pharmacist's fitness to practise was not impaired. In this particular situation the chairman seemed to agree with the PDA's legal representative that the pharmacist was "simply let down" by his trained technician of many years standing, and he had a right to trust her competence.

News...

Representing pharmacists' interests in Europe

In recent years the affairs of the EU have become much more relevant to pharmacists working as employees or locums in the UK.

Much of medicines regulation, employment legislation and working time directives are fashioned by EU initiatives.

It has become increasingly important to ensure that the EU Commission can understand the issues that concern UK pharmacists. If the interests of employee and locum pharmacists are to be supported by the EU and any threats or opportunities created by the European Commission are to be influenced before they land on UK shores, then the PDA must be well positioned in the European theatre.

The European Association of Employed Pharmacists (EPHEU) is an umbrella organisation of pharmacist representative bodies based in EU countries. EPHEU is recognised by the EU Commission as representing the interests of employee and locum pharmacists across the whole of Europe, and earlier this year the PDA was admitted to full membership.

There are several influential EU commissioners maintaining close links with EPHEU, so this is a key organisation.

The first assembly attended by the PDA took place in Paris in April, where delegates were keen to learn about the conditions under which pharmacists in the UK work. A presentation was delivered setting out the statistics of PDA member defence activity. The assembly was shocked to learn of the large scale and nature of incidents where pharmacists needed support from the PDA.

In contrast, whilst other EU countries also handled disputes between employers and employees, this was both quantitatively and qualitatively a far less hostile situation. The pharmacy president from one of the largest EU countries commented that:

"The UK was the best 'worst' example of what happens when multiple pharmacy ownership is allowed to dominate community pharmacy."

Now that such a productive line of communication has been established with the EU Commission, the PDA will seek to discuss its concerns about the UK government's plans for remote supervision – the plan to operate a pharmacy in the absence of a pharmacist.

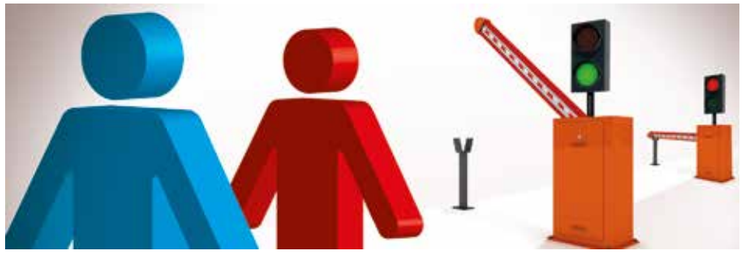
Boots union recognition: ground-breaking decision favours PDAU

Following a ground-breaking decision by the Central Arbitration Committee (CAC), the PDA Union's (PDAU) long-running application process for voluntary union recognition by Boots has been allowed to proceed to the next stage.

A full hearing of the CAC judged that the right to bargain collectively with an employer was, in essence, a human right. Consequently, an agreement between Boots and the Boots Pharmacists' Association (BPA) agreement could no longer block the PDAU's application.

The next stage of the process is to demonstrate that the majority of Boots' pharmacists are likely to support the PDAU's application. This ruling has the effect of also preventing other employers from using such blocking tactics in the future. Boots has applied for a judicial review of this decision.

"We believe that Boots and the BPA will go to great lengths to prevent us from gaining formal recognition for negotiating rights. But we are not deterred,"



said John Murphy, PDAU General Secretary.

"Despite strong resistance, the CAC allowed our application to proceed to the next stage, which was a truly ground-breaking decision."

The PDAU had applied to Boots for voluntary union recognition back in 2011, but was promptly refused. In 2012, PDAU used a statutory process to gain formal recognition through the CAC. Boots then asked the PDAU to withdraw its application to the CAC so that talks could be held. Unbeknown to the PDAU, while its application was temporarily withdrawn Boots signed an agreement with the BPA.

When talks with PDAU failed, the application to CAC was re-submitted, but Boots claimed that it was null and void because it already had an existing union agreement with BPA. However, that agreement excluded any rights of negotiation on terms and conditions.

More recently, the BPA had its application to become an independent trades union refused by the certification officer, who concluded that he had a

"clear image of a union that has over the years been drawn into a situation in which it is indeed liable to interference by Boots".

This is the first time in twelve years that such an application has been refused.

News...

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Road Map – exciting developments

Scotland

The PDA's Road Map strategy focuses on pharmacists being enabled to work as autonomous healthcare practitioners on individual contracts with the NHS. Through such a vehicle, they should be able to deliver pharmaceutical care, develop clinical relationships with patients, and work in a much more integrated way with GPs. Pharmacists working in this way could deliver these services from various locations, such as community pharmacies, care homes etc, and make a big difference through providing high quality pharmaceutical care by reducing unnecessary hospital admissions and improving care for patients with long term conditions (LTCs). Added to this are the benefits of reducing medicines waste and ADRs, as well as improving capacity for GPs, enabling them to tackle more acute presentations because they have referred their LTC patients to such pharmacists.

Last year these PDA Road Map proposals where received with enthusiasm by the Scottish Government, which is in the process of reviewing pharmaceutical care in the community in Scotland. The final outcome of their work is expected in winter of 2013 (see **www.the-pda.org/ScottishRoadMap**).

England

More recently, a series of opportunities have aligned themselves to provide an excellent pretext for the launch of PDA Road Map proposals in England. These include the current A&E and hospital admissions crisis, the Francis Report, and the recent call from government for ideas on how to improve services to patients with LTCs. Additionally, there is the creation of the Royal Pharmaceutical Society's Faculty, which will enable the creation of a structured career and skills

framework in community pharmacy *(page 8)*. Many of these developments underpin the very foundations of the PDA's strategic initiative for creating new roles for pharmacists. As a result of these opportunities, the PDA is currently submitting its English Road Map proposals to both the Health Minister and the Minister for Care (see **www.the-pda.org/EnglishRoadMap**)

"We have waited some time for the ideal conditions under which to share our thinking with government in England,"

said Mark Koziol, PDA Chairman.

"We believe that our radical proposals on how pharmacists can help will go some considerable way towards helping to solve some of the serious problems currently faced by the NHS."

Wales

The PDA has been invited to partner RPS Wales and the Welsh Pharmaceutical Committee in an important strategic development initiative seeking to develop the roles of pharmacists in Wales. The work of this group is aimed at developing and then outlining the professional aspirations for pharmacy, and to submit these ideas to the Minister for Health in Wales. It will seek to propose how patient care can be provided closer to home. The PDA's contributions will focus on the delivery of pharmaceutical care by individual pharmacists, as described above. Reports will follow in a future edition of Insight.

The Commission on Future Models of Care

Director of Policy at the Nuffield Trust Research Foundation, Dr Judith Smith, who is currently chairing the Commission on Future Models of Care through pharmacy, recently visited PDA HQ to discuss the thinking behind the PDA's Road Map. The final report of the Commission (Autumn 2013) will suggest how policy makers, commissioners and the profession can put into practice such new models of care.

Commenting on the work of the commission, PDA Chairman Mark Koziol said:

"The current models of care do not reflect the difference in the aspirations of pharmacists compared to those organisations that own pharmacies, and this is why we have ended up with models of care such as MURs, which coalface pharmacists have found very difficult to deliver to a high standard and to defend professionally. We were delighted that Dr Smith came to see us and explained that the litmus test of the success of this commission will be that it recognises these two sets of interests and provides both with an exciting way of achieving their hopes and ambitions".

Employers provide professional indemnity insurance – *oh really?*

Some pharmacy employers have recently explained to their employees that they do not need to take out their own professional indemnity (PI) insurance because they will insure them in the event that something goes wrong. However, pharmacists are urged to think through the implications of such a proposition very carefully as employer-provided professional indemnity is a very different proposition to the independent indemnity carried by an individual.

The employer-provided indemnity allows the employer to control the defence. This can lead to situations where the brand and reputation of the employer can become the primary concern for the lawyers handling the defence, and not the protection of the employee. This can (and has in the past) led to poor outcomes for the individual pharmacist.

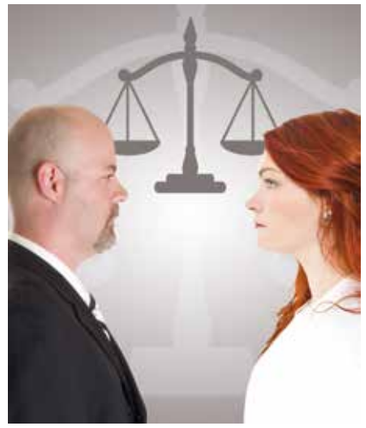
PI insurance carried by the individual pharmacist will focus upon protecting the pharmacist; it will not seek to protect the reputation of the employer. Defence efforts will look carefully at whether the error was down to the pharmacist or another member of staff, defective employer systems, inappropriate skill mix, poor working environments or staff shortages that were tantamount to a disaster waiting to happen. If such problems exist, then lawyers acting on behalf of the pharmacist will make sure that the employer takes some, or even all, of the responsibility. This may entirely extract the pharmacist from the firing line and could even result in the employer being investigated by the regulator.

Challenging the employer's view

It is perhaps unsurprising that some employers would find such an approach challenging, and could be a reason why they may prefer their employees to rely on the company-provided PI insurance. A recent statement from one major pharmacy employer, entitled **'Indemnity provisions for pharmacists'**, says that the company does not require its employee pharmacists to arrange their own cover. In describing the detail of the company-provided PI insurance it describes certain conditions, which include;

- In some cases the company may, as a condition of the indemnity, require pharmacists to give their full cooperation. The company reserves the right to take over the conduct of such a claim, and pharmacists would be expected to provide reasonable assistance in its defence or settlement.
- The company may, at its discretion, withdraw or discontinue an indemnity previously offered if an employee does not follow advice from the company's legal or other advisors.

This makes it very clear that the company would have ultimate control over the defence, and could even deny protection if the employee did want the defence strategy to be organised in a particular way. This cannot be in the best interests of pharmacists.



In the Elizabeth Lee case, efforts made by the PDA in the Royal Court of Appeal resulted in charges against her being dropped because of a landmark point of law ruling by the Law Lords clarifying that an offence under section 85.5 of the Medicines Act could only be committed by an owner of a pharmacy and not by an employee. We believe it highly unlikely that an employer (or their insurer) would ever want their lawyers to take such an approach, as it would be highly damaging to their interests.

Individual pharmacists are realising that it is in their interests to be protected by a professional indemnity insurance policy that is independent of their employer. We recommend that it should also be independent of any trade association, such as the NPA, whose role is to represent the interests of employers. It is important for a pharmacist's defence efforts to avoid any possibility of a conflict of interest.

The independent professional indemnity insurance provided as part of the wider PDA membership benefit puts pharmacists at the very centre of the defence strategy, and it will never allow that strategy to be subsumed by the interests of an employer.

Skill Mix in Pharmacy

it's time for an intelligent debate!

Some senior pharmacist government officials believe that the involvement of pharmacists in what they call 'dispensing' is a waste of valuable resources. Fuelled probably by a greater knowledge of pharmacy practice within the hospital service they view 'skill mix' as a means by which community pharmacists (by placing a greater reliance upon pharmacy technicians) are supposed to move away from dispensing and progress onto other as yet undefined activities.

But to what extent will it be appropriate to expect pharmacists to move away from 'dispensing' and for pharmacy technicians to act? Where exactly can patients expect safety to fit into the current plans for Skill Mix being drawn up by the Department of Health?

There has been no detailed debate within the profession and currently no definition of the role of the pharmacy technician, nor has there been a discussion about how the respective roles of pharmacists and pharmacy technicians fit together to ensure patient safety. Despite that, the government changed the law and since 2011 pharmacy technicians have been required to register with the GPhC.

There is no doubt that pharmacy technicians have important roles to play. However, the lack of wider thinking and debate about the real opportunities offered by Skill Mix in pharmacy has left only the government's philosophy that technicians should take over roles previously undertaken by pharmacists on the table. This has created a position where the term Skill Mix is viewed with uncertainty by pharmacists. Pharmacy technicians too are cautious since there is no clarity of role and relationship and consequently no attractive or clear way forward.

Where do pharmacy technicians fit in?

If this is not addressed, then it will result in a situation which is not attractive from either a patient safety nor an efficient use of NHS resources perspective.

With the commencement of the rebalancing medicines legislation and professional regulation initiative now underway *(page 5)*, the time has come for this subject to be analysed carefully, particularly in relation to community pharmacy.

This article is the first in a series which examines the issues...

The origins of Skill Mix

Both hospital and primary care pharmacy sectors have developed a range of patient facing services where pharmaceutical care is delivered directly to patients by pharmacists in clinics, or on the wards. Hospital pharmacy has also developed advanced clinical services enabling pharmacists to specialise in a niche area of practice. Some of these advanced roles are closely associated with challenging drug therapy such as cytotoxics, whereas

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How best to make patient safety paramount?

others are more to do with a clinical specialisation such as oncology, where the pharmacist is pivotal to the design of the medication regime, it's prescribing and on-going maintenance.

Increasingly, hospital pharmacy practice has also developed a range of roles that integrate pharmacists with other members of the secondary healthcare team.

At the same time, pharmacists are still involved in the more traditional dispensary based safe supply roles.

Much of this was achieved due to a national strategy planned and executed by enlightened hospital pharmacy leadership in the 90's which created a grading structure linked to incremental responsibility and reward in the hospital setting.

During the 1980's the nursing profession too used a very similar graded structure approach as a basis upon which to stake a claim for nurse prescribing.

The system is not perfect and is under strain due to NHS financial pressures, but it demonstrates that the professional re-engineering that led to the benefit of patients and pharmacists became possible because it could be supported by a structured career and skills framework and through the creation of a 'Skill Mix' amongst pharmacists. The optimisation of the use of pharmacist's skills as medicines experts in the widest sense of the word led to clinically significant roles for pharmacists. Skill Mix amongst hospital pharmacists allowed them to start off at the basic grades and then move up through these when taking on more advanced roles and developing clinical relationships with both patients and other members of the healthcare team. This was driven by powerful forces - the human desire for advancement and financial reward.

The positive tension created by this structured career framework pulled pharmacists out of the dispensary.

However, severe shortages of pharmacists at the time (caused by acute shortages in community pharmacy and a large pay differential) potentially threatened the development of pharmacist ward based activities - some creative solutions needed to be found. This resulted in pharmacy technicians being involved in expanded roles and some were roles previously undertaken by pharmacists. Consequently, 'Skill Mix', in so far as it related to pharmacy technicians was used so as to enable pharmacist involvement in more clinical roles, roles that were already flourishing.

From a risk management perspective the safe supply of medicines occurs when there is the correct blend of clinical and technical input into the prescribing and dispensing activity and an interface with the patient. In the hospital setting, the in - patient rarely presents to the pharmacy with a prescription. The pharmacist interface with the patient and the prescriber occurs mainly out on the wards.

Confused about the government programme!

The fact that the main clinical input and the counselling of the patient is delivered away from the pharmacy meant that it was much easier to clarify the role of the pharmacy technician and it also meant that fewer pharmacists were required in the dispensary. Despite that however, even today pharmacists are supervising the dispensing activities in hospital pharmacies in more than 85% of cases.

Why the poor take up of MURs in community pharmacy?

As the largest sector of practice employing more than 70% of all pharmacists in settings that are the most accessible for patients, community pharmacy if harnessed correctly, could make a big difference to millions of patients and reduce the pressures upon the NHS. However, community pharmacy leadership is dominated by the increasingly large multiples. Their agenda is much more about keeping the costs of the service to bare minimum and maximising profits. A structured career framework benefitting patients and pharmacists is not an attractive one at board room level and has not emerged on any significant scale. In the hospital setting, the greater involvement of pharmacy technicians occurred as a consequence of a successful Skill Mix amongst pharmacists leading to the much more appropriate use of their unique skills and making them much more accessible to their patients.

Worryingly, the government, in almost a complete reversal of what happened successfully in the hospital setting, has expended much energy in seeking to develop the role of the pharmacy technicians, without first developing a structured career and skills framework for community pharmacists. Furthermore, through the concept of remote supervision they intend to make the pharmacist less accessible to the public in the community pharmacy and not more so.

Worse still, the absence of a career and skills framework for pharmacists in community pharmacy has given the government no alternative other than to develop 'supply plus' services such as MURs and NMS which base themselves largely on the notion that they can be delivered routinely by any and every pharmacist in any community pharmacy irrespective of their career, experience and training history alongside the supply activity. Through targeting, they are being commoditised and this undermines the professional autonomy of pharmacists. Consequently, these services are a long way short of genuine pharmaceutical care which would require professional autonomy and the development of a one to one clinical relationship with patients. ➔

Where do pharmacists fit in best?

It would be based on prescribing skills, an appointment led service and the authority to change medication regimes in light of a clinical assessment in a clinical setting. Arguably, the current MUR programme has ended up actually harming the development of a large scale genuine pharmaceutical care programme within community pharmacy.

Added to these strategic problems, are the more operational ones. The inherent design of the current MUR and NMS services means that community pharmacists are expected to deliver them on top of their current excessive workload whilst they are simultaneously trying to ensure the safe and effective operation of the pharmacy.

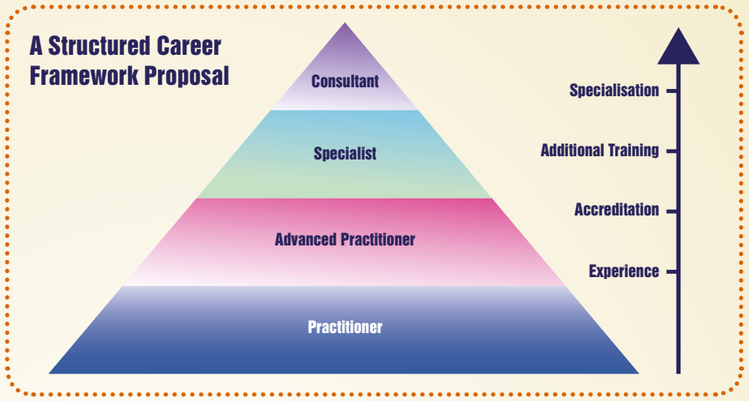
Their design fails to properly and safely harness the skills, let alone the support of community pharmacists. They have become iconic examples of the painful relationship between professionalism and commercialism in pharmacy *(page 12)* and they are not the great transformational hope that they were intended to be. This is evidenced by the current levels of dissatisfaction amongst pharmacists, patients, other healthcare professionals and ultimately frustration within government circles as they fail to understand why their 'new opportunities' are not enthusiastically taken up by this large pharmacy sector.

Creating Skill Mix amongst pharmacists

Skill Mix amongst pharmacists in the community setting must become an important tactical objective. This must rely upon a structured career framework so as to produce a skills pyramid which has pharmacists operating at a variety of skill levels, differing levels of experience and a range of expertise which is driven by additional training such as pharmacist prescribing.

Creating a framework that involves Practitioners at its base, Advanced Practitioners, Specialists and Consultant pharmacists is an approach which could manage much more sensibly the increasing pressures placed upon community pharmacy.

This would allow the service to be much more versatile and quality driven, more accessible and patient facing.



It would be much more able to handle reactive and proactive interventions with the public both on a 'walk in' and appointment led basis. Providing generalist services such as public health and safe supply of medicines, whilst at the same time using second pharmacists with additional training to develop clinical relationships with patients and to deliver detailed pharmaceutical care and continuity of care. A more structured and integrated approach involving community pharmacists within a skills framework could also significantly reduce the workload of GPs as they could refer more of their routine patients with Long Term Conditions to specialist pharmacists based in the community pharmacy. Such an approach could also allow individual pharmacist practitioners to deliver pharmaceutical care to elderly patients based in residential homes. In such a way, pharmacists could reduce unnecessary A&E presentations and make a beneficial impact upon the medicines waste and ADR agenda.

Such a framework would give context, structure and clarity to the role of pharmacy technicians and their relationship with pharmacists and patients. As the experiences in hospital pharmacy showed, within such a framework, pharmacy technicians would have important roles to play ensuring that pharmacists became more accessible to the public.

A clear structure would remove confusion, provide an attractive way forward for both pharmacists and pharmacy technicians to develop much more comprehensive roles and services and reduce the risks to patient safety that are inherent with the current approach.

The combined effect of this could be a vastly improved patient journey, making much better use of pharmacists, pharmacy technicians and community pharmacies and utilising the valuable resources of the NHS to much better effect.

Conclusions

Currently, the government is planning to use Skill Mix to develop the roles of pharmacy technicians but it is proceeding without first articulating a workable and viable vision nor any model of care for pharmacists that genuinely relies upon their unique skills in the delivery of pharmaceutical care.

It appears not to have learned the lessons from the successful development of Skill Mix in hospital pharmacy which has allowed pharmacists to spend much more time in patient facing situations and technicians to develop increasingly important roles. Nor has it commenced a debate about the impact of its proposals upon patient safety.

More worryingly, in seeking to rely upon pharmacy technicians so as to develop its proposal for remote supervision (the plan to operate a pharmacy in the absence of a pharmacist), it will make pharmacists less accessible to the public in a community pharmacy and not more so.

If it truly wants to optimise the use of the valuable resource that pharmacists represent, then it must lift its game when considering Skill Mix in pharmacy.

Co-operative pharmacy criticised by Discipline Committee Chairman after collapse of MUR fraud case

A PDA member recently appeared before a GPhC Fitness to Practise (FtP) Committee accused of Medicines Use Review (MUR) fraud. After three days of evidence from the Co-operative pharmacy, an application was made by the PDA for the case to be thrown out due to a lack of any credible evidence. The FtP Committee agreed and the case against the pharmacist was dismissed. Whilst that was good news for the member, the background to this case which became apparent as the hearing progressed is shocking. The conclusion was that the Co-operative pharmacy was wrong to view this matter as fraud, managers had badly mishandled the investigation and had it done so properly, the company would never have referred the pharmacist to the GPhC for fraud.

The allegations were that the pharmacist had caused false MUR figures to be submitted to head office and to the NHS; these allegations were vigorously denied by our member from the very outset. Our member felt that this was a very busy understaffed pharmacy with enormous pressure to reach MUR targets and she had not committed any fraud whatsoever. During the hearing the conduct and behaviour of senior managers in the Co-operative pharmacy came under close scrutiny through cross examination by PDA legal representatives. The result was a worrying expose of the approach taken by at least one senior Co-operative manager towards MUR targets and serious flaws in the handling the investigation and preparation of evidence by the company.

RDM concentrates on profit to the exclusion of patient benefit

A key witness for the Co-operative pharmacy was Brian Handley, a Regional Development Manager (RDM) who was a non-pharmacist and had previously worked as a business manager for Punch Taverns. The committee learned from a corporate email that one of Mr Handley's tactics to pressurise pharmacists to reach their MUR targets was to arrive at a pharmacy and not to leave until two MURs had been completed. He also made it clear via his memo that there would be no acceptable reasons for pharmacists not delivering two MURs each day. This email from Mr Handley containing threats about not achieving MUR targets was heavily criticised by the Committee members, who also felt his attitude on the witness stand showed a concentration on profit to the exclusion of patient benefit, and demonstrated a lack of understanding of the clinical importance of MURs.

RDM's approach could compromise patient safety

Shortly before our member became aware of the allegations from the Co-operative pharmacy, she complained to Mr Handley about inadequate staffing levels and heavy workload at the branch; concerns which were shared by staff members. Mr Handley dismissed these concerns out of hand and explained that according to his calculations the pharmacy was actually overstaffed. The Committee criticised his approach to the concerns expressed by the pharmacist manager, stating that it was inappropriate. The Committee explained that his approach was likely to result in an increase in the likelihood of errors and compromise patient safety.

Investigation and evidence gathering processes were significantly flawed

The Committee considered that there was some force in the PDA's suggestion that the investigation carried out by Mr Handley was not even-handed. It also found that when the Co-operative Pharmacy's NHS standards pharmacist was asked to become involved, she did not review the matter independently, but simply accepted Mr Handley's investigation and adopted the material she already found in the file.

The Chairman was particularly unhappy with the preparation of witness statements by the pharmacy superintendent's office. Under PDA cross examination witnesses were asked why three independent staff statements were very similar in parts and contained terminology that the staff members did not even understand. One staff member told the hearing that the statements were

written by the company and she was told to sign them even though she did not have the time to read them properly. It further transpired that the witnesses did not agree with some of the contents of their own statements.

The Chairman was forthright in his criticism and commented:

"We are struck by what appeared to be a mismatch between the recollection of some of the witnesses and their witness statements. The preparation of witness statements and evidence for a complaint such as this, where an allegation of dishonesty is made against a professional, is an onerous task and has to be completed with conspicuous fairness and attention to detail, and care has to be taken to ensure that statements reflect the accurate recollection of witnesses. We do not believe that sufficient care was taken with the preparation of the witness statements of Mrs [A], Mrs [B] or Mrs [C], or that a clear and fair analysis of the issues was undertaken.

Senior Co-operative Pharmacist criticises the RDM

The Co-operative Pharmacy's NHS standards pharmacist, Gillian Stone whilst on the witness stand was placed in the uncomfortable position of agreeing with the Committee that the actions and behaviour of Mr Handley as a senior manager in the business were inappropriate and not endorsed by the company. She tried to distance herself and the company from what the RDM had said and done in the pursuit of MUR targets for profit. Ms Stone also agreed that Mr Handley's attitude towards the pharmacist when she raised concerns about workload and staffing was inappropriate and could have put patient safety at risk as well as make errors more likely.

Conclusion

The PDA has a portfolio of threatening, offensive and intimidating communications received by members which shine a spotlight on the culture prevailing at a senior level within some organisations.

As a consequence, the PDA has frequently raised concerns within government and the profession about the commoditised approach to the provision of MURs. This has led to unethical behaviour by business managers and a relentless pursuit of MUR numbers solely to maximise profits. The PDA has also raised concerns about the unacceptable situation whereby individuals in a position of authority over pharmacists are not required to be registered with the GPhC and therefore there are no meaningful regulatory sanctions to protect the public from the impact of their behaviour.

Other Co-operative Pharmacy RDMs have sent threatening emails to pharmacists highlighting the consequences of not reaching their target of 400 MUR each year and Co-operative pharmacists continue to face disciplinary allegations for not completing enough MURs. The Co-operative has previously been criticised by the GPhC for its approach to targeting MURs.

The PDA has written on two occasions previously to the pharmacy superintendent of Co-operative Pharmacy to highlight these matters. Unfortunately the company has not taken up our offer to meet to discuss the problem and we continue to be involved in other cases.

John Nuttall, the Managing Director of Co-operative Pharmacy recently blogged on the Chemist & Druggist website

"Targets per se are not the root cause of the problem, it is the way some managers and healthcare professionals only see tasks to be performed and patients as no more than a number."

In the interests of fairness, we asked the company if it wanted to comment on this case:

A spokesperson for The Co-operative Pharmacy said:

"We acknowledge that mistakes were made rather than fraudulent action taken, but The Co-operative Pharmacy has a duty to make the GPhC aware of any concerns regarding the conduct of a registered pharmacist or technician. It is for the GPhC to determine whether there is a case to answer and whether there should be a referral to the fitness to practice committee. In this case the GPhC hearing concluded that no further action should be taken against the pharmacist in question and we have learnt lessons from this case."

"Since the case came to light three years ago, the NHS has reviewed its guidance on MURs and we have updated our procedures accordingly. We have clear guidelines for all staff to follow and we ensure that the message regarding completing MURs is to improve the quality of patient care.

Despite this, the PDA continues to handle incidents involving MUR pressure within The Co-operative Pharmacy.

Due to increasing concerns about the general conduct that prevails in the area of MURs, the PDA has brought this particular case to the attention of the Department of Health.

The Perfect Storm

There are now a number of storm clouds on the pharmacy horizon. These need to be identified, analysed and tackled – there is much to do. This feature provides some insights into the opportunities that can be exploited and the work that must be done to ensure that pharmacy can set a course for safer ground.

The opportunities

While the storm clouds on the horizon are worrying, they will all have to be tempered with the prevailing healthcare environment and wider developments in society. Much can be found in these areas that could be very supportive of a progressive and healthy future for pharmacists, but it will be important for pharmacy to align its arguments accordingly.

Shortages of NHS resources

The required £21 billion operational savings that need to be delivered in the NHS provide the opportunity to ensure that the unique skills of pharmacists are used to best effect. This significant factor, is likely to become much more critical in the future as the increasingly elderly population places even greater strain on the limited resources of the NHS. This represents a solid potential prospect which could ensure the future for pharmacists, as long as pharmacy can rise to the occasion.

A very large slice of the entire NHS budget is spent on medicines, and the evidence that there is a lot of waste and harm caused by ADR's and non-compliance is widely available. Recently, the national media has focused on the A&E admissions crisis, GP capacity, and the NHS direct crisis, prompting governments throughout the UK to ask healthcare professions to suggest radical ways to help resolve the crisis. The PDA is responding to this challenge and its Road Map proposal is being seriously considered by many in decision making positions *(page 6)*.

The Francis Inquiry

In the wake of the Howard Shipman crisis, a huge wave of regulatory changes swept through all of the healthcare professions, making healthcare regulation virtually unrecognisable and pharmacy was no exception. Inevitably, the Francis Inquiry will have an impact of similar magnitude. The PDA is now preparing and crafting its arguments to ensure that this impact does not encourage employers to create unacceptable working environments and enforce improper practice conditions upon pharmacists to the detriment of patients.

In the community setting, MURs are being relentlessly targeted and staffing shortages are affecting the safety of the supply process. In hospital, pressure by bed managers to discharge patients has reached critical proportions, and in primary care pharmacy a focus on cost cutting is increasingly a primary consideration. These are all factors that impact on patient safety and demonstrate what happens when employer diktat undermines the professional autonomy of pharmacists. The PDA will be using the Francis Inquiry recommendations to critically focus on these matters and to demonstrate the

! STORM WARNING ! STORM WARNING ! STORM WARNING ! STORM WARNING ! STORM WARNING ! STORM WARNING ! STORM WARNING ! STORM WARNING ! STORM WARNING ! STORM WARNING !

importance of allowing pharmacists to operate in such a way that puts the patient at the centre of the process *(page 21)*.

The *Which?* report

Yet again, community pharmacy is forced to react to another Which? report challenge. What the report does show is that when pharmacists are involved in the patient interface the overall patient experience is improved.

The conclusion that one draws is surely an obvious one; remote supervision – the plan to operate a pharmacy in the absence of the pharmacist – can never provide an improved outcome for patients. Additionally, this report can (and will) also be used to support the arguments against the proposal to allow P Medicines on self-selection.

The Royal Pharmaceutical Society (RPS) Faculty

The launch of the RPS Faculty provides a very powerful tool for the profession across all sectors of practice to be able to achieve its ambitions of developing new roles, but this is especially so in the case of community pharmacy. For decades, community pharmacists have been hampered with a flat career structure and no meaningful way of training up to more advanced status and commensurate rewards. This can now change, for if the strategic discussions about more advanced roles for pharmacists (as found in Road Map and elsewhere) are going to materialise, they will need to link into an accreditation process. The fact that one has now been created by the RPS is very encouraging.

The storm clouds

There are a significant number of storm clouds on the horizon – usually they are interlinked in some way and often they are complex. Here we examine some of the more serious ones and describe how they can be mitigated.

Rebalancing medicines legislation and pharmacy regulation

Decriminalisation

Described on pages 2 and 5 is the background to this new development. Every cloud has a silver lining – and in this case, the fact that delivering decriminalisation of dispensing errors is an aim of this board and one which has been moved to top priority is to be welcomed. However, the Department of Health's (DH's) track record on delivering decriminalisation is not good. The first effort of the DH during the period of the Elizabeth Lee case where it worked with the Crown Prosecution Service did not achieve decriminalisation. The second (and major) attempt was the DH proposal to change legislation and introduce 'due diligence defence'. However, when it learned about this, the PDA provided the DH with senior counsel opinion to show how that proposal actually worsened the prospects for the legal defence of pharmacists. This effort got all the way to committee stages in Parliament and then had to be withdrawn by the Minister. The 'rebalancing programme board' has now been charged with the task of resolving this complex matter once and for all. However, its efforts are already being hampered because the DH has chosen not to appoint anyone to the board with experience of defending pharmacy prosecution.

The PDA genuinely wishes them well in this important task and eagerly awaits their proposals.

Responsible Pharmacist regulations

There are very many concerns with the RP regulations – too numerous to list in this feature. The rebalancing programme board has been charged with the task of resolving some of these, in particular balancing the interplay between the responsibility of the RP and the superintendent. It is hoped, however, that the board can tackle the much wider problems with these regulations, many of which were identified by an independent report – for example, that they be dis-applied altogether in the hospital sector

Remote supervision

It will also be important for the board to conclude that, just because you have a sign up on the wall naming the RP and making them responsible, this does not mean that the pharmacy will be operating safely in the absence of the pharmacist. It is still very difficult to understand the thinking behind the government's plan to operate a pharmacy in the absence of a pharmacist through remote supervision. Not since this proposal was conceived in 2006, has it ever explained its rationale in a patient-centred fashion. In that regard, the findings of the Francis Inquiry and the Which? report will become highly helpful in focussing the board on what

It is still very difficult to understand the thinking behind the government's plan to operate a pharmacy in the absence of a pharmacist through remote supervision.

is important. The recommendations of Francis are so powerful, that they easily outrank speculative proposals from government that could dilute down the safety of the public. There is absolutely no doubt that a pharmacy is a safer place with the pharmacist present than with the pharmacist absent, and the PDA will be forcefully making this point to the board.

Roles for pharmacists and pharmacy technicians

A major policy platform for the DH was the creation of a register of pharmacy technicians, and this was completed in 2010. This is a positive development, ➔

but it will be important to establish how it affects the interplay between pharmacists and pharmacy technicians, in terms of their respective roles, how they fit together, and how they maximise safety for patients. Additionally, in terms of pharmacy, it is important to define a professional and a technical role and therefore provide clarity for both pharmacists and pharmacy technicians.

The danger is that the board makes its decisions based on considerations that are political, subjective and that do not look at patient safety considerations. Additionally, that they base their thinking upon the experiences of pharmacy technicians in the hospital sector (since this is where a significant number of board members are experienced in), for in reality community pharmacy arrangements are very different.

The PDA is undertaking an extensive piece of work in this respect, and will report its findings to the board. Already more than 1,300 pharmacists have participated in initial surveys and more will shortly follow. Extensive reference searches are being undertaken and examples of the interplay between pharmacists and pharmacy technicians from all over the world are being studied. Interesting findings are already emerging, such as the fact that of the 21,831 current registered pharmacy technicians, 16,358 (75 per cent) of them qualified under grandfather clause arrangements.

The findings of the PDA will be submitted to the board.

The danger is that the board makes its decisions based on considerations that are political, subjective and that do not look at patient safety considerations.

P Medicines on self-selection

In May, PDA roadshows were held throughout England, Scotland and Wales to solicit views of pharmacists on the changes proposed by the GPhC that enable P medicines to be sold on self-selection. Central to the concerns of pharmacists was patient safety and this came as no surprise. However, there was also a very considerable strength of feeling about the way that the GPhC has handled this issue from the outset. The new regulator has publicly stated that its expertise does not lie in pharmacy, yet it makes such sweeping changes to pharmacy practice, despite the strongest protestations from both the professional leadership body (the RPS) and the PDA (the largest union for pharmacists). It also denies pharmacists the opportunity to have a say via a consultation and these behaviours cause considerable disquiet and indignation. It asks serious questions about the conduct of the regulator in this matter, which will need to be answered. These meetings have additionally generated a considerable amount of campaign material, which will now be used so as to persuade the GPhC to think again.

The GPhC has confirmed that it plans to allow P Medicines on self-selection from some time in 2014. In turn, the PDA expects to be sharing its concerns with Parliament in the autumn of 2013. In the meantime, all pharmacists are urged to support the PDA's petition, which will be used in support of this campaign (see front cover) **www.the-pda.org/pmedspetition**.

Over-production of pharmacists and development of pharmacy roles

The PDA's seven point plan for dealing with the vagaries of too many pharmacists is described on **www.the-pda.org/7pointplan**. The good news is that, since this issue was brought to the forefront through a series of national PDA meetings in 2012, the government has agreed to take control of the student numbers from 2015.

This still leaves the problems of the interim over-supply to contend with, and to this end, it is crucial that new models of practice are developed creating an increase in pharmacist demand. A very considerable amount of work is being done in this respect *(page 6)*.

Setting the compass for safer ground

This feature has explored a small sample of tactical activities that will be needed to drive the overall strategy required to ensure that the vagaries of the 'perfect storm' are driven away. Additionally, there are areas where a debate in pharmacy will need to be commenced and where initiatives will need to be developed:

1. Ensure that the benefits of pharmacist involvement in the safety of the supply function are identified and embellished.
2. Accelerate the development and roll out of new roles – curtail commoditisation of services in the community pharmacy setting. Develop new contractual models *(page 6)*.
3. Create a structured career framework in the community setting. Consider Skill Mix among pharmacists before roles between pharmacists and technicians are clarified *(page 8)*.
4. Explore the definition of professional and technical, so as to clarify the roles and interdependency of pharmacists and pharmacy technicians *(page 15)*.
5. Harness the opinion and support of patient groups in relation to remote supervision.

Pharmacists will be hearing about many more campaign developments in the coming months.

Patient safety: dispensing errors affecting children

The PDA has noted an increase in the numbers of dispensing errors involving children. This article addresses the significance of such errors, discusses the most common errors, and offers practical ways to minimise risk.

The UN Convention on the Rights of the Child defines a child as a person below the age of 18, although there is no single law that defines the age of a child across the UK, and the BNF definitions of age refer to children as those being 12 years or younger. For the purposes of this article, errors affecting those under 18 years have been considered.

The development of drug management plans in children are fraught with difficulties. Differences in the pharmacokinetics between adults and children can make it very much more difficult to predict drug effects. There is often a lack of paediatric trial data assessing safety and efficacy, which can necessitate the use of unlicensed and off-label medicines. There are often higher costs to the NHS associated with the use of 'specials' as above. There is an increased risk of ADRs in children. Palatability issues may affect drug compliance and concordance, which may complicate regimes. Dose calculations can be complicated. All these factors can contribute to the increased overall risk of errors.

Dispensing incidents involving children often understandably elicit emotive responses from parents/guardians, who may then wish to progress matters. There are many ways in which this could affect pharmacists. For example, the risk of a complaint being made to the GPhC, which is obliged to investigate any such complaint, but won't become involved in the issue of compensation. There is the possibility of a claim for compensation and the consequent soaring costs involved. More recently, dispensing errors more often come under scrutiny by employers and can lead to disciplinary action. Typically, this arises where the SOPs have been breached, which is invariably always the case at some point if an error occurs.

The law on claiming compensation

Claimants usually have three years from the date of the error in which they can lodge a claim for compensation if they have suffered harm. The rules are different in children, however; a child has from the date of the negligent act through until three years from the date of their 18th birthday in which to lodge a claim. Therefore either the claim must have been settled, or court proceedings must have commenced, before they reach their 21st birthday. This rule gives the guardians of the injured child the choice of either to pursue a claim immediately, or to wait.

The former will involve the agreement of compensation to be awarded and placed in a court fund until the child reaches the age of 18. Alternatively, they can wait until the child reaches the age of maturity and let them make their own decision as to whether they wish to pursue a claim for the injuries they sustained as a child. Where the claimants' guardians have settled on behalf of a child before making any payment, an approval of the court to the agreement is still formally required. During these proceedings, known as a Child Settlement Order, certain information may need to be provided to the court. For example, details of the circumstances of the error, details of whether and to what extent the defendant admits liability, a schedule of past and future losses, and an opinion on the merits of settlement given by a solicitor acting for the child. It is the judge that determines whether the proposed settlement is acceptable and in the best interests of the child. Such an order inevitably adds to the costs of a claim – usually in the order of £3,000 – £4,000.

The total numbers of dispensing incidents logged with the PDA involving patients under the age of 18 shows an upward trend, trebling from 4 per cent in 2008 to 12 per cent in 2010, and the increase seems to be continuing. Analysis of the types of incident has revealed that the single largest type of error is that of the mis-labelling of dosage instructions for oral antibiotics. It comes as no surprise, given the frequency of prescribed items such as amoxicillin, penicillin and trimethoprim suspensions for this patient group. Fortunately, such cases are not as high up the scale of clinical significance, and the effects are not permanently damaging. This is not to detract from the level of distress that is often caused to both the patient and the parents.

Case studies

A prescription was presented for ranitidine suspension 5mg/5ml, at a dose of 5mls three times a day, for a three month-old infant. The labelling and dispensing was carried out by a pharmacy technician, and presented to the pharmacist for checking, who conducted an appropriate clinical check, but omitted to notice that the 75mg/5ml strength solution had been selected. The parents pursued compensation from the pharmacy owner, whose insurer (the NPA) passed it on to the pharmacist directly involved in the error.

The child's mother claimed that she administered the wrong strength for three days, and the infant was admitted into hospital for observations. In this case, the parents made the claim without resorting to a third party lawyer. Although we would advise the parents to seek legal advice on any settlement, they may choose to take the offer of settlement and to give the insurers a 'parental indemnity'. This allows them to settle quickly and indemnify the insurers against any further claims, but does leave them exposed (however unlikely) should the child or child's representatives decide to sue them for an inadequate settlement at a much later date.

Another medicine commonly involved in dispensing errors is fluoxetine liquid 20mg/5ml. A recent case involved a teenager being prescribed a dose of 10mg each day, but was labelled and given as 10ml to be taken each day, resulting in four times the prescribed dose.

The most costly error involving a child handled by the PDA was the dispensing of a hormone ethinylestradiol 4mcg daily, intended to bring on delayed puberty. The incorrect dosage of 1mg, 4od dispensed resulted in excessive acceleration of the child's puberty and a series of tests over two years were required to assess whether the harm done would have longer-lasting side effects. Although parties have agreed compensation, the court has yet to give it the seal of approval. The total compensation figure involved in this case was in the order of £75,000. The court may yet decide to rule that it would be in the child's best interests to wait until she reaches adulthood and reassess the long-term harm.

Some frequent mistakes that have occurred in the dispensing of children's prescriptions

Prescribed medicine	Given in error
Chloramphenicol 0.5% eye drops	Chloramphenicol 5% ear drops
Sodium chloride 0.9% nasal drops	Sodium bicarbonate 5% ear drops
Clobazam suspension	Clonazepam suspension

Risk management

- Flag up children's prescriptions at the first point of contact, so all members of the team have a heightened awareness about the patient.
- Make the age on a prescription the first thing that you look for, and when conducting a final check, try and build up a mental image of the patient piecing together all of the information.
- Have a system where all such flagged prescriptions are automatically referred to the pharmacist to counsel and hand out.
- If possible, allow some time at the end of the day to review all high-risk prescriptions, especially all children's prescriptions.
- Ensure care is taken when items are put away upon delivery, to minimise the risk of a selection error.

Members are reminded to report all errors that have caused, or have the potential to cause, harm to a patient to the PDA as soon as they are aware of them, even if there are no obvious signs of escalation.

Self-employed locum, employee or worker?

Pharmacists' employment status may not always be as it seems.
Ruth Williams, PDA Legal Advisor, explains

The PDA receives a high volume of enquiries from members unsure of their employment status. Many do not have a written contract defining the relationship between them and their 'employer' and query their status at the point of a dispute or if contacted by HM Revenue & Customs.

Employee

All employees are workers, but as employees they have a wider range of employment rights and responsibilities to and from the employer. Employees have a right not to be unfairly dismissed, provided they have one year's (or two years' if employment commenced after April 2012) continuous service. They have rights to paid holiday and are protected from being discriminated against. National Insurance and income tax deductions are made at source by the employer.

Self-employed

These individuals are usually operating their own business providing services to multiple clients. They have far greater control over how and when to deliver their service and the ability to substitute themselves. Employment legislation does not generally cover them because they are in effect not employees. They do, however, enjoy protection under health and safety and anti-discrimination legislation.

Worker

Different from the genuinely self-employed. The status of worker includes individuals working under a variety of contracts. The key requirements for establishing 'worker' status are that they:

- Perform work or services personally and cannot send a substitute or sub-contract the work
- Are not undertaking the work as part of their own business.

Case study

- A member was a long term locum of some 20 years working solely for one independent pharmacy. There was no contract in place at the start, but a contract of sorts was introduced five years ago.
- The member in effect ran the pharmacy and had responsibility for opening and closing, accepting deliveries, etc.
- She invoiced the pharmacy for her work and paid her own tax and National Insurance.
- If she was not able to work on a particular day then another locum worked instead. On occasion she arranged that locum cover herself.
- In 2012 her employment/ engagement was terminated and the company paid her four weeks' severance pay on termination.

Were there grounds to bring proceedings in the Employment Tribunal for unfair dismissal or holiday pay? To answer that question, the matter of her employment status needs to be determined.

The Multiple Factor test is used:

- Is there an ability to substitute?
- Does the worker receive a regular wage or a one-off payment or fee?
- Does the employer have the right of exclusive service?
- Can the employer dictate the place of work and the way it is carried out?
- Who owns the tools or other means of production?
- Who bears the main opportunity of profit or risk of loss?
- Who pays the tax and National Insurance?
- Discipline and termination – does the employer have the power to discipline and dismiss?
- Is the employer obliged to provide work? Is the worker obliged to accept it?

Only a detailed analysis of the answers to the questions posed above would provide an answer – each specific case would have to be taken on its merits. In this particular case, the fact that her contract provided her with a right to substitute for herself would strongly suggest that she was a self-employed individual enjoying no rights for unfair dismissal or holiday pay.

Other cases

Recently, there have been two PDA members who on the surface appeared to be working as self-employed locums, but who were successful in Employment Tribunal claims for worker status. As a result they were both awarded holiday pay. In these cases success hinged upon the absence of clarity in their contracts indicating that they were working on a self-employed locum basis.

In conclusion, a contract with clearly defined terms is a valuable tool in the determination of employment status. The PDA website has sample contracts that may be of help for pharmacists looking to provide locum services.

The Francis Inquiry – Driving improvements in patient care

Andrew Jukes, Chairman of the PDA's Hospital Membership Group and Project Lead on the Francis Inquiry, explains the implications of the inquiry for pharmacy

The inquiry by Robert Francis, QC, into the failings at Stafford Hospital has revealed severe failings in a healthcare system that fell below the radar of a complete range of individuals and organisations that patients and public should have been able to trust. This included front-line clinical staff, internal senior management, external commissioning, governmental and regulatory bodies.

a 'toxic mix' of responsibility failings, pursuing targets and financial parameters

The inquiry found that patients had become victim of a 'toxic mix' of responsibility failings, pursuing targets and financial parameters, and a culture where safety and quality of care was not central to any consideration. It demanded that lessons must be learnt and action taken; the patient must regain the central focus of the healthcare system.

Pharmacy seemed to escape the spotlight, but it has subsequently become clear that it only avoided a mention due to an oversight in methodology on the part of the inquiry. PDA members' experiences show that, whether it is in hospital, primary care or community pharmacy, pharmacists and therefore patients, are exposed to the problems alluded to by the inquiry.

Risks to patients and pharmacists

That there are potential risks to pharmacists and patients from the concepts embedded in Francis can be seen in the pattern of PDA defence activity. In 2012 alone there were more than 4,000 new incidents, and a significant proportion were episodes driven by conflicts between the patient orientated concerns of pharmacists and the commercial and organisational interests of employers.

There are many workplace situations creating tensions. In hospitals, the pressure to discharge patients, often speedily, means less quality time with other in-patients. There are reduced staffing levels and incorrect skill mix. In primary care the inappropriate use of skill mix can mean that unqualified staff are undertaking tasks that are beyond their capability, and an overt focus on cost savings ultimately reduces patient safety and damages the quality agenda. In community, MUR targets are often put above the safety concerns for patients *(page 12)* and now there is even a proposal to allow P medicines on self-selection.

What needs to be done?

The inquiry has demanded that it is for both individuals and organisations to challenge the current situation and strive for improvement. This provides a perfect pretext, allowing pharmacists and pharmacy representative bodies across all sectors of practice to consider ways of improving quality and safety for patients, and taking an unforgiving patient safety agenda to those who are creating the problems described above.

The professionally challenged environments in which many pharmacists currently work have an undoubted impact upon patient safety. A way forward must now be found to improve these environments so as to protect patients. Processes will need to be established that will enable pharmacists to say enough is enough to employers that place them in near impossible situations, enabling pharmacists to operate with more professional autonomy.

The PDA is working on a detailed project designed to deliver these objectives and to support pharmacists in all sectors of practice. Focus groups have been conducted, questionnaires issued, and conferences organised. The PDA is currently engaged in crafting policy that, prior to completion, will be scrutinised by public and patient representatives to ensure that it satisfies the patient safety focus test. It will then be used in discussions with regulators, the government and employers throughout the UK so as to improve the safety of patients.

The PDA is also developing practical risk management tools designed to be used by pharmacists in the workplace so as to help them identify, highlight and then take action against problem issues so as to safeguard patient interests. In so doing, these activities will also reduce a pharmacist's personal exposure to liability or regulatory activity. Details will be circulated to members in the near future.

Disability and your employee rights

By Caroline Gentleman, PDA Legal Advisor

Employers have a legal duty to make reasonable adjustments for employees with a disability. This article discusses what those adjustments are, and how you can obtain them.

Only employees who satisfy the definition of a disabled person are entitled to protection. How a disability is defined was originally set out in the Disability Discrimination Act 1995, now incorporated into the Equalities Act 2010. A person has a disability for the purposes of the Act if they have a physical or mental impairment which has a substantial long term adverse effect on their ability to carry out normal day-to-day activities.

Some impairments are easily identifiable and dealt with, particularly visible, physical ones. But a mental impairment, such as depression, where the effects are not so obvious, can be more problematic.

The Equality Act places a duty on employers to alleviate the disadvantage that employees experience in the workplace as a result of their disabilities, and is designed to get employees with disabilities back to work. Examples of adjustments that could be made for a pharmacist with a physical impairment include:

- Making adjustments to the premises by widening doors or moving furniture
- Arranging a full ergonomic assessment with specially designed chairs and stools
- Installing a higher workbench in the pharmacy to reduce bending
- Providing a work bench in a colour other than white so that it is easier for a pharmacist with a visual impairment to see medication
- Supplying visual aids, such as VisioBook CCTV or magnifiers
- Furnishing a work telephone modified with an amplifier or a text phone where there is a hearing impairment.

Examples of adjustments that could be made for a pharmacist with a mental impairment include:

- A phased return to work, reduced working hours, a later start time, or a reduction in responsibility
- A role as second pharmacist, if available
- Providing more time to check prescriptions - this is particularly important for individuals who find it difficult to concentrate.

How to obtain adjustments

- The first step is to establish if your impairment falls within the definition of a disability. The PDA can provide detailed advice for individual members on how to go about establishing whether you have a disability. For example, there is a distinction between depression and stress, as long term depression would come under the definition of a disability, whereas stress would be regarded as a condition and would not fall under the definition of a disability.
- The next step is to notify your employer in writing that you have a disability or have an impairment that may be regarded as a disability under the Equalities Act 2010. An employer must know you have a disability in order to take action.
- Ask your employer for an occupational health assessment, as one of the questions the occupational health provider will need to answer is whether your impairment falls within the definition of a disability under the Equalities Act.
- Allow occupational health to write to your GP or consultant for more information on your impairment, but you do not have to agree to provide your employer with access to your medical records.
- Explore whether you are eligible for a grant from Access to Work to cover the cost of aids, equipment and adaptations, by contacting your local Access to Work centre (for details on how to make an application go to www.gov.uk/access-to-work/how-to-claim).
- Meet with your employer to discuss what adjustments would help you in your job role.
- The cost of complying with the duty to make reasonable adjustments falls on the employer. An employer cannot refuse to make reasonable adjustments on the grounds of cost alone, and a balance needs to be achieved between the needs of the individual and those of the business.
- Employers should look at all factors, such as the extent to which the adjustment is practicable, the disruption to the business, the nature of the employer's business, its size and resources, and the availability of external finance and grants.
- Once adjustments have been agreed, ask your employer to confirm this in writing, and ensure that it is clearly stated whether the adjustment is permanent or for a fixed period of time.
- If your employer refuses to make adjustments then ask for the reasons for refusal to be set out in writing, and seek further advice from the PDA immediately.

Failing to make reasonable adjustments

A refusal to make reasonable adjustments may give you grounds for a claim in the Employment Tribunal, but strict deadlines apply and a claim needs to be submitted within three months of the date that your employer refused to make the adjustments. It is therefore imperative that you seek advice from the PDA at the earliest opportunity.

In bringing a claim against your employer you would be seeking:

a) A declaration that adjustments should be made, and

b) An element of compensation.

Fortunately, the PDA has not had to assist any members in bringing a claim against an employer for disability discrimination and a failure to make adjustments. We find that, once we become involved, common sense prevails and our members are given the adjustments they need.

If you have a disability and need advice on adjustments to your job role contact the PDA legal team for assistance.

Case study

The PDA dealt with one case for a pharmacist working at an NHS trust at band 8b who agreed adjustments with her employer to alleviate the impact of longstanding depression on her ability to do her job. The adjustments included mentoring on planning and organising her work, and more time to complete reports and prepare for meetings. After the adjustments had been in place for six months, the employer started a disciplinary process against our member on the grounds of capability, which could have resulted in her dismissal. The PDA represented its member at the capability hearing and was able to help the member negotiate further adjustments, such as reduced hours and flexible working arrangements, that would help her work at an 8b standard so that she could keep her position.

In another recent case a member with a visual impairment asked for a range of adjustments from a large pharmacy chain. This company has a salary allocation model in place that allows for pharmacists to spend 1.99 minutes per item dispensed, which he obviously struggled to meet.

Our member had applied to Access to Work and secured a grant that would cover a third of the cost of the adjustments so the employer would only have to pay £1,000. The employer refused all of the adjustments on the grounds of cost. We explained that, while the target for dispensing applied to everyone, it placed certain individuals at a particular disadvantage. Fortunately, due to PDA intervention, a senior HR manager is now involved and proper consideration is being given to the adjustments our member needs to carry out his role safely and effectively.

THE PDA union
strength in numbers

Iron fist inside a velvet glove – how employees are dismissed

With a few exceptions, employers generally dismiss an employee for one of two reasons:

1. Conduct – where an individual's conduct falls foul of a list of such offences set out in the employer's policies, or the misconduct is otherwise so bad that it could justify dismissal.
2. Capability – where an individual's ability to perform their role falls short of an employer's expectations.

Unfortunately, the number of PDAU members being put through a capability process is increasing rapidly.

Expectations

An employee is expected to do their job to an acceptable standard and meet reasonable demands made of them by their employer. For its part, the employer is expected to provide the necessary tools, training and resources for the employee to do their job to the standard expected. It is important to remember that it is a relationship where both parties have obligations towards each other.

Problems can arise when weak/unsubstantiated concerns about job performance are used to pressurise a pharmacist to do what their manager demands. For example, it is not uncommon for an area manager to want to move a pharmacist to a different branch in the belief that the pharmacy is not achieving its targets because of the pharmacist's performance. If the pharmacist is unwilling to move, or disagrees that they are to blame, they are often threatened with a capability process to "encourage" them to do the area manager's bidding.

Another example is when a pharmacist's inability to reach targets is due to a lack of trained staff, or where professional considerations mean that employer's targets (eg MURs), are unreasonable or even compromise patient safety. The PDAU is also aware of cases where the real motivation for starting a capability process is to cut salary, limit pay rises, or remove bonus entitlement.

A fair capability process that can withstand scrutiny by an Employment Tribunal considering a claim for unfair dismissal should focus on supporting the employee when there are genuine concerns, and not be used as a punitive exercise. However, it is important to remember that such processes are the precursor to a formal disciplinary process that may eventually result in dismissal. Should a pharmacist become aware that their employer is unhappy with their performance it is essential that they are proactive to avoid escalation, and to reduce the risk of being dismissed or being put at a financial disadvantage. Many companies withhold bonuses or restrict pay rises if someone is being managed in this way.

Advice

- Beware of innocuous sounding terms such as "counselling form", "performance improvement plan", or "record of conversation". These are all documents that can form part of a process that may ultimately lead to dismissal.
- If experiencing difficulty meeting targets, email HR or the pharmacy superintendent about specific issues about workload or environment. This can then be used as evidence to show that your concerns have been raised previously, and that you are not simply belatedly raising concerns in reaction to an employer-led process.
- It is essential to include detailed reasons why you are unable to meet targets or reach the required standards on any documents you are asked to sign. These could include lack of staff, unattainable targets, training requirements, or that you believe there are other reasons behind the decision to start a capability process. Never agree to targets that you are unlikely to achieve.
- Seek advice from the PDAU as soon as possible. The presence of a union representative is not needed at the early stages and normally not allowed by the employer. However it is important to get advice on how to handle the process based on individual circumstances.

The PDAU is of the view that the increasing use of capability processes by employers is primarily being driven by their unrealistic expectations, coupled with inadequate levels of trained staff, resulting in enormous pressures on pharmacists. It is not because there are suddenly more incapable pharmacists in the workplace.

Should pharmacy technicians take on the operation of PGDs?

The National Institute for Health and Care Excellence (NICE) has recently been consulting on the use and application of Patient Group Directions (PGDs). The Guild of Healthcare Pharmacists have suggested to NICE that pharmacy technicians should be added to the list of healthcare professionals allowed to operate PGDs.

If this suggestion were to be implemented, it would probably apply across all pharmacy sectors (hospital, primary care and community), with potentially far-reaching implications for patient care. So, in order to gauge the feelings of grassroots pharmacists (in all sectors) on this issue, the PDA conducted a member survey at the end of June. The survey received nearly 1,300 responses in just one week and it appears that this issue has generated some emotive debate whilst also drawing attention to some broader considerations.

The results were unequivocal, however there was a strong and passionate dichotomy of views with little disinterest in the middle. Whilst the vast majority of pharmacists (96 per cent) where very cautious about the proposal to allow pharmacy technicians to operate PGDs, a small minority (overall 4 per cent) were supportive.

What was also interesting about these results is that 74 per cent of all respondents supporting the involvement of pharmacy technicians in the operation of PGDs were senior hospital pharmacists. This was not a view that was shared by the vast majority of those hospital pharmacists in less senior roles.

Arguably, these results put a big question mark over the proposal itself, and challenge the thinking of the Guild on this matter.

The quality of the training experience

The major concern that emerged was over the genesis of the pharmacy technician registration, 75 per cent of pharmacy technicians (16,358) became registered pharmacy technicians by dint of a grandfather clause – this enabled them to join the register by demonstrating that they had been practising for a certain number of years – they were not required to sit any specific exams.

On this subject, Steve Acres, President of the Association of Pharmacy Technicians UK, recently stated that: ***"Pharmacy technicians who moved onto the statutory register through grand parenting have gone through a rigorous review of their competence as part of that process. Crucially, they will have been signed off by a pharmacist, usually their employer or line manager who certifies their competence."***

However, some of the respondents who had been involved in signing off pharmacy technicians urged caution in this regard, arguing that they signed off pharmacy technicians under the grandfather clause so as to enable them to simply carry on undertaking the tasks that they had previously undertaken for some time, but tasks which were now legally reserved for registered pharmacy technicians under new legislation. They were signed off on the basis that there would always be over-arching supervision by pharmacists and not on the basis of undertaking tasks requiring professional autonomy, clinical decision making and not working under the supervision of pharmacists – such as the operation of PGDs.

A number of pharmacists pointed out that length of service was no guarantee of standards, either. Another, who claimed to be lead pharmacist for PGDs at a foundation trust, said that technicians' ***"lack of underpinning clinical knowledge and skills would make this an unsafe practice".***

A small number of pharmacist respondents to the survey seemed very much in favour of the proposal as it stands. ***"In my view it is not about the competence of technicians, it is about the fitness to practise of pharmacists who oppose this. These are people who oppose technician development because these are the roles these Luddite pharmacists are currently doing themselves."*** said one.

Technicians or autonomous professionals?

The survey results and the accompanying comments received showed that pharmacists recognise that pharmacy technicians have important roles to play, but there are some concerns being expressed by pharmacists from all sectors. The fact that pharmacy technicians were now being registered by the GPhC was seen as a good thing, but somewhere along the line, this registration was being presented by the government and others as being the equivalent of being a highly qualified healthcare professional and this was worrying many respondents.

"The government's idea that registering pharmacy technicians will somehow turn them into a highly qualified healthcare profession in their own right is dangerous thinking and if we are not careful we will mislead the public into thinking that they are able to operate to the same standard as, say, doctors and pharmacists," said one.

Another suggested: ***"We should instead have them known as a registered technical group and not a profession in their own right."***

The whole essence of PGD's revolves around individual healthcare professionals being able to judge the point at which a patient presentation demands that a PGD be provided and then, upon delivering the PGD, being held personally accountable for its delivery. 58 per cent of pharmacists in community practice and half of those working in NHS hospitals cited a lack of professional relationships and accountability as the reason why they would be concerned about pharmacy technicians being able to operate PGD's. Many respondents asked whether pharmacy technicians themselves understood that they would be held personally liable for their actions in this area. Some expressed the view that pharmacy technicians could end up as scapegoats ***"I am wary of commercial organisations that try to provide services but take no responsibility for their provision,"*** said one.

Locums were particularly concerned about accountability, given that it would be difficult for them to be sure of individuals' competence levels and that under the RP regulations, the RP would be held legally accountable for ensuring the safe and effective running of the pharmacy.

What is a PGD?

PGDs are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. The MHRA states: ***"The supply and administration of medicines under PGDs should be reserved for those limited situations where this offers an advantage for patient care without compromising patient safety, and where it is consistent with appropriate professional relationships and accountability."***

In other words, PGD's are a professionally led service where the individual practitioner would need to be able to have the clinical and professional expertise to be able to identify on 'walk in' basis which patients would benefit from a particular PGD. The provider would need to have the appropriate professional relationship and be held individually accountable for the decision making.

PGDs should be drawn up by a multi-disciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to supply medicines under the PGD. The qualified healthcare professionals who are currently allowed to supply or administer medicines under a PGD are: pharmacists, nurses, midwives, health visitors, optometrists, chiropodists, radiographers, orthoptists, physiotherapists, ambulance paramedics, dieticians, occupational therapists, speech and language therapists, prosthetists, orthotists, dental hygienists and dental therapists. They can only do so as named individuals.

The survey results

The survey results are being used as part of a much more extensive PDA project to support its contribution to the Rebalancing Medicines Legislation and Pharmacy Regulation initiative *(page 5)*. Here are some of the top line results.

Should pharmacy technicians be added to the list of healthcare professionals that can supply or administer medicines?

Those unreservedly in favour
- **4 per cent**

And the reasons given (in ascending order);
- It would improve safety for patients
- It would help to clarify the role of a pharmacy technician
- The current level of qualification of a pharmacy technician is more than adequate to deliver PGDs safely and effectively
- Pharmacy technicians enjoy the appropriate professional relationships and accountability
- It would help pharmacists by reducing their workload
- Registration with the GPhC entitles pharmacy technicians to be treated the same as any other healthcare professionals

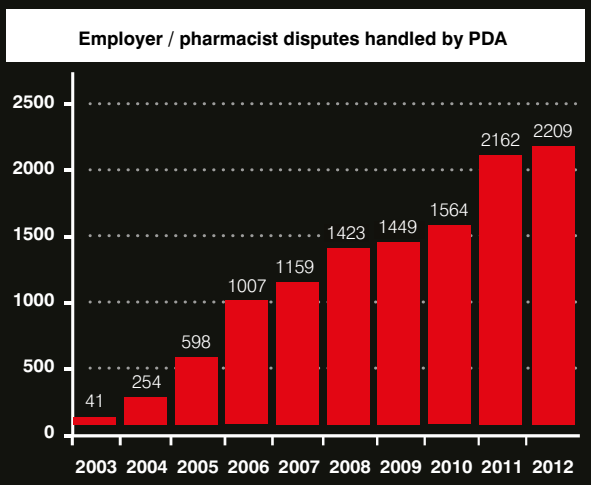
Those who were not
- **96 per cent**

And the reasons given (in ascending order);
- A lack of training rendering the service ineffective
- Reduced pharmacist presence leading to deskilling of the service and poorer patient outcomes
- Blurring of roles and causing confusion amongst patients
- Lack of appropriate professional relationships and accountability
- Lack of underpinning knowledge resulting in a detrimental impact upon patient safety

Think your chances of falling out with your employer are small?

THINK AGAIN!

The NHS is trying to save more than £20 billion in operational costs and this is a source of conflict.



The relationship between a pharmacist and hospital management must be based on understanding and respect as sometimes, there needs to be a robust discussion to ensure that financial interests do not overwhelm professional considerations and patient safety.

These days, with the financial pressures upon the NHS, such a discussion is becoming increasingly difficult to have.

Perhaps unsurprisingly, the number of disputes between pharmacists and their employers has dramatically increased and this problem continues to grow.

The PDA has supported many thousands of members with advice and support in various pharmacy employment disputes across all sectors. In many cases we resolve these through mediation, but in others we pursue employers who have treated our members harshly or unlawfully. Already we have secured more than £1million of compensation for our members in this way.

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

- ✓ More than £1,000,000 compensation already secured from employers who have treated pharmacists unfairly or illegally
- ✓ £500,000 worth of Legal Defence Costs Insurance
- ✓ £5,000,000 worth of Professional Indemnity Insurance
- ✓ Union membership option available

now more than 20,000 → have you?

~~17,000~~ **pharmacists have already joined the PDA.**

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