PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT

First Delegated Legislation Committee

DRAFT PHARMACY (PREPARATION AND DISPENSING ERRORS - REGISTERED PHARMACIES) ORDER 2018

Monday 4 December 2017

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Friday 8 December 2017

The Committee consisted of the following Members:

Chair: Mr Graham Brady

† Brine, Steve *(Parliamentary Under-Secretary of State for Health)*
† Cartlidge, James *(South Suffolk)* (Con)
† Chishti, Rehman *(Gillingham and Rainham)* (Con)
† Cooper, Julie *(Burnley)* (Lab)
† Coyle, Neil *(Bermondsey and Old Southwark)* (Lab)
† Cummins, Judith *(Bradford South)* (Lab)
† Cunningham, Mr Jim *(Coventry South)* (Lab)
† Davies, Chris *(Brecon and Radnorshire)* (Con)
† Flynn, Paul *(Newport West)* (Lab)
† Grant, Mrs Helen *(Maidstone and The Weald)* (Con)
† Lord, Mr Jonathan *(Woking)* (Con)
† Norris, Alex *(Nottingham North)* (Lab/Co-op)
† Rutley, David *(Lord Commissioner of Her Majesty's Treasury)*
† Syms, Sir Robert *(Poole)* (Con)
† Tomlinson, Justin *(North Swindon)* (Con)
† Whitford, Dr Philippa *(Central Ayrshire)* (SNP)
Woodcock, John *(Barrow and Furness)* (Lab/Co-op)

Leoni Kurt, *Committee Clerk*

† attended the Committee

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Monday 4 December 2017

[Mr Graham Brady *in the Chair*]

Draft Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018

4.30 pm

The Parliamentary Under-Secretary of State for Health (Steve Brine): I beg to move,

That the Committee has considered the draft Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018.

I do not believe we have danced before, Mr Brady, so it is very much a pleasure to serve under your chairmanship. The order was laid before Parliament on 13 November and extends to the whole of the United Kingdom. Its purpose is to create, for registered pharmacy professionals working in a registered pharmacy, new defences to the criminal offences set out in sections 63 and 64 of the Medicines Act 1968. The order makes those defences available in defined circumstances to pharmacy professionals making genuine dispensing errors. This marks an important step forward in addressing barriers to providing a safer, higher-quality service. Let me make it clear that the order does not cover pharmacy professionals working in non-registered hospital pharmacies. That will be addressed in a separate order that we intend to consult on early next year.

The Mid Staffordshire inquiry highlighted the importance of putting patient safety at the heart of everything we do and achieving a careful balance between assuring accountability to the patient and developing a culture of openness and transparency, so that we learn from errors and improve practice and safety. Indeed, Professor Don Berwick stated:

"The most important single change in the NHS in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care."

The order very much follows that philosophy.

Pharmacy professionals are highly regulated individuals —in relation to dispensing errors, more so than any other healthcare professionals. Indeed, they are subject to triple jeopardy in the event that they commit a dispensing error. They face prosecution for strict liability offences under sections 63 and 64 of the Medicines Act 1968, prosecution for offences under general criminal law and sanctions under professional regulation requirements. That can lead, we believe, to defensive practices. It has been demonstrated in other industries where safety is critical that working under such threat of sanction is a hindrance to the reporting of errors and accidents and therefore to wider learning.

Evidence suggests that patient safety and service quality can be improved through increasing the rate of reporting and learning from dispensing errors. That will have benefits to patients locally and throughout the NHS. By removing the fear factor of a strict liability offence for inadvertent dispensing errors, our aim is to create a much more open and transparent culture, which in turn should help to improve learning and prevent mistakes from happening in the first place. We will be working closely with pharmacy regulatory and professional bodies across the UK to make that a reality.

Let me be clear that registered pharmacies already have a range of systems and procedures in place to prevent dispensing errors from occurring. More than 1 billion prescription items are dispensed every year, and it is a testament to the professionalism of pharmacy staff that errors occur in only a very small proportion of cases. Dispensing errors can, however, occur within a registered pharmacy for a variety of reasons. For example, there are many thousands of medicines, and some have very similar names and brandings. Medications may also have complicated dosing schedules.

The order is not about accepting the inevitability of error in the system. It seeks to ensure that we collect information on errors that do occur and think hard about how they can be prevented in the future, including through spotting trends at a national level. That may involve improving systems and procedures and designing out errors as far as is practicable, but without knowledge of what has gone wrong that is just not possible.

We are not removing all safeguards for patients. There will remain offences under general criminal law—for example, in cases of gross negligence and manslaughter—and sanctions under professional regulation, as I have said. In such circumstances, the professional regulators, the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland, can still subject individuals to regulatory fitness-to-practise procedures. Sanctions would depend on the circumstances of the error but could ultimately include the individual being removed from the professional register and no longer being permitted to practise.

The order is well supported: it was overwhelmingly endorsed during the public consultation, including by patients, the public and groups such as Action against Medical Accidents, who will now want to see pharmacy professionals play their part and demonstrate increased learning from, and reporting of, errors. The order has also been some five years in gestation, so I am pleased to attempt to land it today through the Committee. I am fully committed to ensuring that that happens, and we have already taken action in that regard.

In each of the four home nations, a number of initiatives to support reporting and learning have been introduced, such as medication safety officers or champions, and national reporting systems. Regulatory and professional bodies in pharmacy have also put in place standards and guidance to support the desired culture change, with community pharmacy trade bodies encouraging their members to follow those standards and encouraging pharmacy teams to report, learn, act, share and review.

Action is also being taken in each of the home nations on medication error more generally throughout their healthcare systems. It is a sobering fact that 5% to 8% of all hospital admissions are medication-related. In September, the Secretary of State for Health and the chief pharmaceutical officer for England launched an initiative that focuses on reducing prescribing and medication errors throughout the national health service in England. The programme will look at a number of

areas, including how we use technology, understanding how best to engage patients in their medicines and advancing the transfer of information between care settings.

As I mentioned at the start, while the order provides a defence for pharmacy professionals working in registered pharmacies, it is important to recognise that pharmacy services can occur outside of those settings, and therefore that not all pharmacy professionals will be able to avail themselves of the defences set out in the order. That is deliberate. Work is progressing to develop similar measures for pharmacy professionals working in hospitals and other care settings. That will ensure that, regardless of their position in the healthcare system, pharmacy professionals will be encouraged to report and learn from errors.

In summary, the order supports improved patient safety by encouraging a culture of candid and full contributions from those involved when things go wrong. Within that culture, pharmacy professionals—I have to say, they are some of the most motivated and professional people I have met in our national health service during my time as an MP and a Minister—can increase their learning from dispensing errors and identify mitigating actions to make reoccurrence much less likely. I commend the order to the Committee.

4.37 pm

Julie Cooper (Burnley) (Lab): It is a pleasure to serve under your chairmanship, Mr Brady, and to respond on behalf of the Opposition to the important order in front of us.

As the wife of a retired community pharmacist—I have no interest that I am obliged to declare—I have to say that 24 years' experience of owning and running a community pharmacy has given me an in-depth understanding of the sector and the challenges that community pharmacists and their staff face every day. As the Minister mentioned, more than 1 billion prescription items are dispensed every year—the vast majority from community pharmacies—and the trend is that prescription numbers will increase each year, reflecting the general increase in demand in the national health service and the ageing population. An average community pharmacy dispenses between 300 and 500 prescriptions a day.

It is important to consider that that volume of work is only one part of the role performed by community pharmacists. They are an integral part of the primary care team and make a huge contribution, including giving advice on a range of health and wellbeing issues; providing support for public health initiatives, such as those employed to reduce smoking, drug abuse and obesity; medication use reviews; diagnostic testing; diabetic and asthmatic care; and minor ailment schemes. The list is endless.

In that context, genuine errors will happen occasionally. As the Minister mentioned, it is a credit to the profession that those are very few and far between, but it remains a fact that pharmacy professionals are one of the few health professional groups to face criminal conviction and potential imprisonment, for an inadvertent dispensing error—that is, where there is a discrepancy between the prescription and the medication supplied to the patient. The prosecution of pharmacists and dispensing technicians is very rare, but it does occur, so pharmacy professionals always have that fear hanging over them.

The principal beneficiaries of the order will be professional community pharmacists and registered dispensing technicians practising in registered premises—and, of course, patients. The draft order, which will amend the Medicines Act 1968, will be welcomed by community pharmacists, technicians and their professional bodies. I am aware that the National Pharmacy Association, the Pharmaceutical Services Negotiating Committee, the Royal Pharmaceutical Society and patient groups support the proposed changes; I am sure they agree that they are long overdue.

Most products are prepared outside registered premises and arrive ready to be dispensed. Errors in such cases may take the form of selecting the wrong product or providing incorrect dosage instructions. However, there are still many instances in which pharmacy staff members are required to prepare medications on site, in which case errors may take the form of miscalculation of required quantities, addition or subtraction of necessary ingredients or incorrect instructions for use. The order will introduce a new defence against criminal liability that will apply to both preparation and dispensary errors and will be open to pharmacy professionals who can prove that the error occurred when they were acting in the course of their profession.

Such a defence really is overdue. In 2009, the chairman of the Pharmacists' Defence Association warned:

> "Inappropriate use of the criminal sanction will lead to defensive practice…less innovation".

During the passage of the Health and Social Care Bill in 2011, Earl Howe said that the legislation needed to be reviewed so that criminal liability did not arise as a result of genuine dispensing errors.

Ensuring the right to legal defence against prosecution in cases relating to an inadvertent error will undoubtedly remove some of the fear burden and lead to a greater willingness to admit errors. It will also assist in promoting a culture of transparency that will help to inform future learning and improve protocols for the dispensing and preparation of medicines. The better practice learned will result in fewer errors and improved patient safety and is therefore eminently desirable.

The order will offer protection to pharmacists and dispensing technicians, but its main purpose is quite rightly to improve patient safety. Proposed new section 67B(5) will require the accused to prove in their defence that on discovery of the error, every step was taken to report it at the earliest opportunity to the person in receipt of the medication. That provision will give pharmacy professionals the chance to minimise the effect of errors and will positively incentivise them to admit them, as the act of so doing will aid their defence. This new duty of candour has the potential to lead to a major cultural change.

Pharmacy professionals who show deliberate disregard for patient safety will not benefit from any of the defences in the order. Where they are found to be wilfully negligent or intent on causing deliberate harm, they will continue to face criminal prosecution. The order will protect only those practising in registered premises who are already subject to professional regulation. For the sake of the protection of patients, it will not provide a defence for other groups or individuals external to registered premises involved in the medicine supply chain.

[Julie Cooper]

The Opposition welcome the order and believe firmly that it is a step in the right direction, but it does not go far enough. Even after it is implemented, pharmacists will still not be on a level playing field with other healthcare professionals; they may benefit from access to improved defences, but as the Pharmacists' Defence Association maintains, they will still face the prospect of a police investigation and a lengthy trial. They will have to hold on to the hope that they can successfully use the defences, but they may still face prosecution under other provisions of the 1968 Act. I hope that the Minister will consider further legislation to ensure that inadvertent errors are totally decriminalised. I welcome his comment that the situation for pharmacy professionals not covered by the order will be consulted on early next year; I ask that it be looked at as early as possible, because pharmacists in hospitals need these defences.

There is an omission in the order. We know that learning from reported errors is anticipated, but there is no formal requirement in the order to deliver on that. It is reliant upon good will. I am sure that many pharmacists and pharmacy dispensary technicians will want to take it upon themselves to improve their existing protocols so that errors cannot reoccur, but there is no formal requirement in the order for them to so do.

As we all want to prioritise patient safety and wellbeing, I hope the Minister will undertake further work to positively promote patient safety within the pharmacy setting. One really useful suggestion I would like to make is to allow pharmacies full read and write access to patient records. All health professionals involved in the care of a patient surely need access to the fullest information, without the danger of knowledge gaps or incorrect information regarding past medications. That would aid continuity of care and contribute to safer patient outcomes.

There is so much more to do, but we welcome the order as a starting point and look forward to the Minister bringing forward further improvements.

4.46 pm

Dr Philippa Whitford (Central Ayrshire) (SNP): I, too, and the Scottish Government welcome the order, as does our Scottish chief pharmaceutical officer. This is an anomaly that is being corrected, and the key thing is that it leads to more reporting. We understand that there were almost 21,000 reported errors in 2016, but it has been suggested that a considerably higher number were not reported. I echo the argument that risk to patients is increased if pharmacists are not flagging up simple things such as poor labelling, things that are difficult to read or mistakes that someone else has made. That is where everyone wants to get to.

I am keen to support the shadow Minister's point that the obligation to report should be formalised, rather than pharmacists just having to contact the patient. That is how they will be able to utilise the defence, as they must show that they have taken every possible action to contact the patient and correct the mistake. That changes a defensive reason to hide errors into a reason to report errors, but it really needs to happen through a reporting system. I am interested in what the national reporting system will be and whether it will be across the UK, so that lessons can be shared as widely as possible.

The order will amend sections 63 and 64 of the Medicines Act, which contain a power that has hung over pharmacists, even though it has rarely been used. The Secretary of State for Health talks a lot in the Chamber about getting away from a blame culture and moving to a learning culture. I do not think there is any argument about that, but I want to know how mistakes will be reported.

I also echo the point about information sharing. In Scotland, we have had community pharmacies providing minor ailments treatments and other treatments, including a chronic medicine service, for about 10 years. We are moving to a point where patients are registering with their community pharmacy, in the same way they do with their GP and dentist, so that records are shared. We also use e-prescribing widely in general practice and hospitals. That technology helps to reduce errors right from the prescriber, which is what I used to be, to the patient. The system simply flags up the danger of prescribing penicillin to someone who is allergic, using the wrong dose or bad interactions. Using technology in that way, to prevent system errors right through from the prescriber to the patient, needs to proceed as quickly as possible. A lot of that comes back to data sharing and getting the confidence of the public back.

I agree with the shadow Minister's call for the Minister look at other areas of pharmacy. If we start to have a single system through e-prescribing, that will become easier. Although it is suggested that that will be brought forward early next year, the legislative burden in this place is a tad heavy at the moment, and I certainly would not like to see it delayed for another five years. In essence, we welcome the order but want to know exactly what the reporting system will be and when the move to things such as e-prescribing will be made.

4.49 pm

Paul Flynn (Newport West) (Lab): This is a fascinating piece of legislation in that by far the greatest pressure on us in most areas of law is to make punishments more severe, but here we have an order that calls for an intelligent approach of drawing back from what appear to be excessively severe punishments for errors, mistakes, crimes or whatever they may be, in the knowledge that, human nature being what it is, there will be an atmosphere of more openness. That seems an entirely beneficial and persuasive argument and a good reason for putting the order forward.

We have clearly had a legacy of excessive and unreasonable punishments hanging over pharmacies, but that is not to say that all is well in the prescription of drugs in this country. In 2003, a COX-2 inhibitor drug called Vioxx was identified as a problem in America because the Food and Drug Administration there published a report saying it believed that the drug, which was not a life-saving one at all, had caused 120,000 heart attacks and strokes, many of which had led to death. I wrote to the regulatory body here asking why we did not spot that and how many prescriptions had been issued in 2003. I was told that there were 4,500 prescriptions, but there had been only half a dozen reports of bad reactions. We have errors and weaknesses in our system for spotting issues of that kind, and I believe that if we are doing something wise, generous and sensible as far as pharmacists are concerned, we might look to them to play a fuller part in future as the frontline in identifying bad reactions

to drugs such as the COX-2 inhibitors. They can also help us to avoid the great scourge in America at the moment, which is now coming here: the misuse and overuse of opioid drugs. That has become a greater killer in America than traffic accidents or gun crime, and we are seeing an increase in deaths from opioid drugs and addiction to them here.

I believe we would all say that we welcome the order, but there is a great deal more to be done to protect the public from the dangers of prescribed drugs, and pharmacists could play a major role in that.

4.52 pm

Steve Brine: I thank my shadow, the hon. Member for Burnley, and the hon. Members for Central Ayrshire and for Newport West for their contributions and their support for this measure.

I am well aware that the hon. Member for Burnley has in-depth understanding and knowledge of this issue from her previous life supporting her partner, a community pharmacist. She is absolutely right to highlight the wide portfolio that community pharmacists hold. I sometimes think it is even wider than mine, and I have said in the House, and will say again now, that community pharmacists are absolutely central to me and to the primary care objectives that I hold in this job for primary care and for the public health and prevention agenda. Primary care and public health are pulled together under my portfolio for a reason, and community pharmacists sit together as a hub in the middle of those two bits of my work.

The hon. Lady is absolutely right to say that the order will be welcomed—I think alongside the hashtag #abouttime. For many people in the community pharmacy sector, the changes are long overdue. I spoke to the Royal Pharmaceutical Society's conference in the summer—I suspect she was there—and I said that this was long overdue and that I would sort it. I have tried to remain true to my word, and I have.

I think the defences in the order strike the right balance, which the hon. Lady outlined coherently, while not leaving the door wide open. We still have to make sure that patient safety is protected—the current Secretary of State above all would say that—but I do believe that it strikes the right balance. I note her request for early work in respect of hospital pharmacists, and I am very amenable to that. I do not want that to drag on for many years; I want it sorted quickly, and officials know that.

On read and write access to patient records, many pharmacists already have read access and some already have write access. I am interested in making the change, and I am exploring more with officials how to make it happen; it is of some frustration to me that it seems to be an IT issue as much as anything else. If pharmacists are to be integrated within our primary care system as much as I want them to be, I suggest that that is very important.

Julie Cooper: This all centres on acknowledging that pharmacists are the experts when it comes to medication. I think that most GPs who work alongside pharmacists day in, day out will hold their hands up and say that. GPs used to be regularly on the phones to us saying, "Can I just ask you about this? I am thinking of prescribing this, but I am not sure. Is this best, or would it be better with something else?" That is good teamwork between people who are specialists in their areas.

In the light of that, it is quite ridiculous that pharmacies cannot record their advice and intervention on a patient record for other health professionals to see. It would be entirely in the patient interest, and in the interests of making sure that patients do not fall through the gaps between the different health professionals.

I will make one further point about recognising that expertise, if you will allow me to, Mr Brady. Pharmacists could be used to do more, as I have said many times in the House. When he talked about protections, my hon. Friend the Member for Newport West reminded me of the work that is happening on antibiotics and a recent Westminster Hall debate on their overuse and the development of antimicrobial resistance. Pharmacists could lead on that in the interests of wider patient wellbeing and safety.

Steve Brine: The hon. Lady is absolutely right. Pharmacists have been absolutely brilliant, focused and motivated supporters of the "Keep Antibiotics Working" campaign. I responded to that Westminster Hall debate on antibiotics, as she knows.

On the hon. Lady's wider point, I believe, and I believe the evidence backs me up, that in the best health economies, the three planks—secondary care, primary care and pre-primary care, which is where we could see a community pharmacy as being—work hand in hand. The sustainability and transformation partnerships are supposed to be a one-NHS solution for different areas and different health economies to help the population achieve good health when they become unwell, but also to practise good preventive health. I absolutely agree with her that pharmacists know their patients and customers, and that they spot things because they see those patients much more regularly than GPs do. That is why they are absolutely central.

On the point about the obligation to report, which was mentioned by the hon. Members for Central Ayrshire and for Burnley, I said in my opening speech that the Government are already working with the regulators and professional bodies to ensure that pharmacy professionals are supported in the implementation of the order. An absolutely critical part of that is making sure that they report errors, because if they do not, this will all be somewhat wasted. There are a huge number of examples that I could give; maybe I can write to the hon. Member for Burnley with the details. The national reporting and learning systems were established in England to collect data and report on safety incidents. The health service safety investigations Bill, which is in draft and undergoing pre-legislative scrutiny at the moment, also adds power to this argument.

I think that, with this order, we have something of a rare gem in Committee Room 9: it is something that we all agree is needed. We are delivering it as a Government, as I promised we would. It will add further impetus to the work already under way to reduce medical errors across the health service and will provide much-needed assurance to pharmacy professionals that they can do their job with confidence. I know they have that confidence, but there has been this little niggling thing undermining them. I hope the order addresses that.

[Steve Brine]

As the Whip next to me coughs—I am sure that was purely accidental, as opposed to a hint—I will finish by saying that, should both Houses approve the order, commencement orders will be drafted to enact the changes in England, Scotland, Wales and Northern Ireland. I thank hon. Members for their attentiveness, their interest and their contributions, and I commend the draft order to the Committee.

Question put and agreed to.

4.59 pm

Committee rose.