



# PDA response to the Red Tape Challenge

Medicines, Pharmacy;

1. The Responsible Pharmacist Regulations
2. The Controlled Drugs (Supervision of Management and Use) Regulations 2006

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# About the PDA

The Pharmacists' Defence Association (PDA) is a not for profit organisation which is a defence association and a union for pharmacists. The aim of the PDA is to act upon and support the needs of individual pharmacists and, when necessary, to defend their reputation.

## The primary aims of the PDA are to;

- i) Support pharmacists in their legal, practice and employment needs.
- ii) Provide insurance cover to safeguard and defend the reputation of the individual pharmacist.
- iii) Provide representation for its members.
- iv) Pro-actively seek to influence the professional, practice and employment agenda to support members.
- v) Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care.
- vi) Work with like-minded organisations to further improve the membership benefits to individual pharmacists.

The PDA currently has more than 19,000 members and is one of the largest bodies representing pharmacists. More than any other body we work hard to promote and maintain the interests of pharmacists and provide a counterpoint to the voice of commerce as represented by pharmacy owners.

As a risk management organisation, we seek policies that reduce the chances of harm being caused to members of the public especially in situations where government policy and employer led operational frameworks detrimentally affect the public interest.

# 1. The Responsible Pharmacist Regulations

## Key Recommendation;

### Scrap the Responsible Pharmacist Regulations and reinstate the concept of Personal Control

Though many of the conceptual objectives contained within the RP regulations are attractive in theory, two and a half years of operational experience has shown that they have failed to achieve these in practice and that they are unlikely to in the longer term. Furthermore, independent assessment and real time operational experience has shown that they cause defensive practice and behaviours which are generally damaging to the public interest.

The regulations themselves are built upon a significant rampart of bureaucracy involving the generation and storage of records and the production, maintenance and regular review of a wide range of written operational procedures. Despite the fact that these requirements are significantly impractical, a failure to observe them may result in criminal prosecution and/or professional regulatory sanction. As a consequence of these and many other issues associated with these regulations, as far as pharmacists are concerned the RP regulations represent a highly unpopular icon and are an obvious case for scrapping under the Red Tape challenge.

We recommend that once the RP regulations are scrapped we return to the concept of “personal control” which the RP regulations replaced. A fundamental tenet of the RP regulations – being able to identify the pharmacist in control at any point in time – can be achieved in any number of ways; any other more workable and beneficial elements can be enshrined in professional regulatory guidelines. This would result in a very significant reduction in unnecessary red tape whilst at the same time providing an opportunity for some of the more problematic founding principles of the original RP regulations to be revisited and repaired.

### Why the RP regulations don't work

The concept of the RP regulations was first considered by the profession in 2006. At the very outset, widespread concerns were expressed at many of the early consultations. These concerns were broadly in three areas;

- 1. Their operational impracticability**
- 2. Their detrimental impact upon the patient and professional interest**
- 3. Their capacity to be abused by employers.**

## 1. The operational impracticability of the RP regulations

The RP regulations sought to replace the requirement of the physical presence of the pharmacist in the pharmacy with a new legal framework. This was intended to guarantee that a new written quality framework system would replace the previous convention that a pharmacy could only operate whilst a pharmacist was physically present (in personal control). This was meant to be an enabling mechanism allowing pharmacists to leave the pharmacy when they so chose to do, so as to develop their professional roles out-with the pharmacy whilst simultaneously maintaining professional responsibility and accountability for all pharmacy operations that continued in their absence.

The new framework enshrined in statute that a pharmacy could only operate lawfully if a RP was signed on. Such a record would have to be made by the RP and kept by an owner for several years; failure to do so would result in criminal prosecution. Before a RP could sign at the commencement of duties, he would have to establish written standard operating procedures (SOPs), or accept the existing ones by reading them and being happy with their content. Once the RP was satisfied with the SOPs (either by establishing them or by accepting those already in existence), the RP would then be able to sign on and the pharmacy would be able to commence its operations on that particular day. The RP is required to review the SOP's at least once every two years, or sooner in the event that a critical incident occurs requiring an SOP review/rewrite.

### **The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008;**

1. Pharmacy procedures
  - 1.1 The matters which must be covered by pharmacy procedures are –
    - a) The arrangements to secure that medicinal products are;
      - i) Ordered
      - ii) Stored
      - iii) Prepared
      - iv) Sold by retail
      - v) Supplied in circumstances corresponding to retail sale
      - vi) Delivered outside the pharmacy ; and
      - vii) Disposed of in a safe and effective manner
    - b) The circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products;
    - c) The identification of members of pharmacy staff who are, in the view of the Responsible Pharmacist, competent to perform certain tasks relating to the pharmacy business;
    - d) The keeping of records about the arrangements mentioned in paragraph a)
    - e) The arrangements which are to apply during the absence of the Responsible Pharmacist from the premises;
    - f) The steps to be taken when there is a change of the Responsible Pharmacist at the premises;
    - g) The procedure which is to be followed if a complaint is made about the pharmacy business;
    - h) The procedure which is to be followed if an incident occurs which may indicate that the pharmacy business is not running in a safe and effective manner
    - i) The manner in which changes to the pharmacy procedures are to be notified to pharmacy staff.
  1. Pharmacy Procedures must be recorded –
    - a) In writing
    - b) In electronic form
    - c) In both forms
  2. Pharmacy procedures must be available at the premises for inspection by –
    - a) The person carrying on the pharmacy business;
    - b) The superintendent, if any (a)
    - c) The Responsible Pharmacist; and
    - d) Pharmacy staff
  3. Pharmacy procedures must be reviewed regularly.
  4. In this regulation, "pharmacy procedures" means the procedures referred to in section 72A(3) of the Act.

The requisite written procedures are enshrined in statute as a cornerstone of the RP regulations. They are detailed and lengthy and to demonstrate the extent of their impracticability and the level of frustration encountered by working pharmacists we set out the extent of their statutory requirement as found in – Statutory Instrument 2008 No. 2789

Typically, such procedures are often already available in the pharmacy as they have been drafted by the owner of the pharmacy. In some instances, the areas that are statutorily required to be covered by these procedures are broken down into around thirty separate documents, in some pharmacies this may well be as many as one hundred and thirty separate standard operating procedures. It is simply not possible for a RP to be able to read through, digest and then formally adopt such a significant operational handbook prior to signing on.

Furthermore, with 37% of community pharmacists currently working as self employed locums, moving from one pharmacy to another and sometimes for duty periods as short as half a day in a single pharmacy, it is possible to see why the red tape associated with this exercise represents an substantially unworkable process.

It is demonstrably very difficult to properly comply with the SOP requirements; consequently a significant proportion of an RP's work can be technically in breach of procedures which devalues their importance and impedes wider adherence to such documents.

## 2. Their detrimental impact upon the patient and professional interest

### a. Their impact upon professional judgement

In pharmacy, the greatest public benefit is seen where the unique skills and knowledge of the pharmacist are deployed to allow that pharmacist to exercise their professional judgement in the interests of the patient. However, the RP regulations have reduced the scope for the pharmacist to act independently in the patient interest and have instead created a slavish SOP led culture in pharmacy.

PDA members have described many instances where they have to operate defensive practice by rigorously adhering to SOPs to minimise the likelihood of professional, criminal and employer disciplinary proceedings. There is good reason for this as certain employers routinely discipline and will even dismiss pharmacists for not following SOPs to the letter.

In community pharmacy many PDA members have faced disciplinary action at the hands of their employers either because they were trying to use the regulations to improve the pharmacy environment or because employers were using the RP regulations to hold pharmacists responsible for matters that they could never have a chance of being able to control. An example is where a RP was disciplined because unbeknown to the RP, shop staff had been stealing and the employer decided to discipline the pharmacist citing that the RP was responsible for securing the safe and effective running of the pharmacy and that they had failed in that duty.

Furthermore, in the first instance of its kind an Employment Tribunal has ruled that the SOP must be obeyed and upheld the decision of the employer to dismiss a pharmacist for non- adherence.

The SOP will always be an important tool in the pharmacy, it will set out the general operational framework and act as a template to guide technicians to ensure that dispensary operations comply with agreed standards. However, such standards should NEVER restrict the professional decisions of pharmacists as this can easily lead to the public interest being harmed.

If the RP regulations were intended to empower pharmacists through SOPs, then they have singularly failed and these documents must not be the underpinning foundation of the regulations.

### b. Professionalism vs commercialism

In the event that a RP wishes to change a written procedure as is required by statute, they face significant hurdles. Since many of the SOPs are written in the Head Offices of the largest pharmacy multiples, they are understandably resistant to local changes and alterations. Since certain SOP's are considered by RP's to be driven by a cost cutting agenda, it is possible to see how this can lead to friction in the work place. Consequently, RP's face difficult choices when in situations where they have to balance their employment prospects with their professional judgement.

### c. Their impact upon Hospital practice

In hospitals the problems caused by the RP regulations are of significant concern with many PDA members have been reporting difficulties. These included; satellite dispensaries being closed down altogether because of the inability to adhere to the letter of the RP law; ward based clinical pharmacists suspending their wider clinical services so that RP cover could be provided in the dispensary. In some hospitals a list of random pharmacists names were entered into the RP register by a junior member of staff simply to keep the register system going. Of greater concern to PDA members are situations where senior pharmacists were making clinical decisions about medicines out on the wards, which dispensary based RP's were having to take the statutory responsibility for by dint of the RP regulations.

Added to these matters are situations that require hospital pharmacies to adhere to the RP regulations for certain periods of time, but not for others depending on what they are doing at the time. This leads to confusion and an inconsistent standard of operations in the hospital pharmacy setting which impacts directly on both the professional and the public interest.

## 3. Their capacity to be abused by employers

The RP regulations were supposed to produce professional empowerment of the pharmacist; in retrospect they have had the opposite effect.

With the focus upon SOPs (as described above -a largely employer generated system) the RP has been significantly dis-empowered. What has become apparent is that some of the largest employers, employing many thousands of pharmacists, have been using the RP regulations to pursue commercially orientated goals and not the professionally orientated ones that were intended by the authors of the regulations.

It is now apparent that the rationale behind the regulations has not been supported by the application of them. Instead, pharmacists cannot operate pharmacies in a way that they see fit and due to the master / servant relationship that exists with their employer, they work in an environment controlled by their employer but yet they take the legal and statutory responsibility. This means that the public protection measures that were available under the previous regulations have been weakened. Under previous regulations, it was the owner/superintendent who was held to account in the event that something was to go wrong in the pharmacy. This resulted in a more cautious approach being taken by the superintendent/owner, for fear of direct reprisals and/or professional and legal sanction. However, it is no longer the owner/superintendent that is described in the statute as the person that has to ensure that the pharmacy is operating safely and effectively, it is the RP.

This means that owners can afford to become less risk averse with the operational manifestation of their commercial agenda since it is the RP who would face sanctions. PDA members have complained about a number of approaches that have been actively taken by owners that they believe they would have not been able to prior to the appearance of the RP regulations.

One example is the two hour absence provided in the regulations which was supposed to be used by the RP to enable him to leave the pharmacy and develop professional roles.

In some large multiples, this two hour absence has not been used for this purpose at all. Instead, the RP was being asked to arrive for work at 9.00am and take legal responsibility from 7.00am for work that had already commenced prior to their arrival. In short some employers were using absence to extend their business hours whilst reducing the cost of pharmacy cover.

In other situations, the staff quality and quantity was being reduced by certain employers for cost cutting purposes and these new levels were being written into written procedures in the pharmacies by the employer. When the RPs raised concerns about these cuts, these were met with significant resistance from the employers. In situations where the employers forced through the changes, the RP's inevitably ended up in situations where they were taking strict legal responsibility for staffing situations which they had not instigated and which they were very unhappy about.

Another example of how the regulations are being abused by some employers is the rest break scenario. The current RP regulations allow a two hour absence from the pharmacy for the pharmacist as long as the pharmacist is signed on during that period of absence. Many employers are requiring the pharmacist to take their unpaid rest break (the period during which they are meant to enjoy a full physical and mental respite from the pharmacy), whilst remaining signed on as a RP. This means that during their rest break, the RP needs to be contactable and also still continues to take full statutory responsibility for ongoing pharmacy operations.

## Results of an independent evaluation of the impact of Responsible pharmacist Regulations

The Royal Pharmaceutical Society commissioned some independent research entitled "Evaluation of the impact of Responsible pharmacist Regulations" which was published in September 2011. This work secured the views of nearly 2,000 pharmacists from all sectors of the profession – to include pharmacy owners. It delivered some very powerful conclusions some of which we enclose;

1. Only one in three RPs believe that they have the authority to make changes to SOPs and staff roles and responsibilities and fewer have done so.
2. One in five locums read the SOPs at very few of the premises that they work in as RP, a quarter never read them at all.
3. Seven in ten pharmacists believe that the Regulations put the RP in a difficult position by making them legally responsible for people and processes outside of their control; qualitatively this was driving behaviours which were felt to undermine patient safety, as well as adding professional stress and workplace tension.
4. Just over half of all pharmacists felt that RP regulations had no impact upon their roles.
5. There was evidence that the Regulations were driving RPs towards more defensive practice. Half of pharmacists felt that they should be more empowered to exercise professional judgement (by the regulations) but in reality they needed to follow SOPs more closely.

## Conclusions

There are many other areas of concern with these RP regulations such as the absence provisions. In particular, there is a worrying lack of a strategic fit of these regulations with the future practice of pharmacy which seeks to make the pharmacist more available to the public in the pharmacy and not less so. There has not been an example in recent memory of pharmacy regulation which has delivered so many unwelcome and damaging operational consequences and which has attracted so much derision from practising pharmacists. Even prior to the launch of the regulations in July 2009, more than 6,000 pharmacists signed a petition requesting that their launch in October 2009 be delayed.

We argue that these regulations deliver many disadvantages to those that they seek to govern and also to the public that they seek to protect. They deliver unacceptable levels of red tape which generally impede the operators of pharmacy business increasing their operational complexity. They are prone to be used in ways in which they were not intended and have resulted in many unintended and unwelcome consequences. They introduce both criminal and professional sanctions in ways which are entirely disproportionate. Most importantly of all in our view, they restrict the professional freedom of practising pharmacists and damage the public interest by reducing public safety and driving defensive practice.

We believe that only a fundamental revisiting of the foundations upon which the RP regulations were constructed can produce regulations that would be fit for purpose. We argue that the poor experience gained with the current regulations should be used to good effect when crafting any new arrangements in the future.

For all of these reasons, we ask that the current RP regulations are scrapped. In the short term they should be replaced by re-instating "personal control". In the medium term they should be replaced with more appropriate light touch workable professional guidance agreed between the professional body, the regulator and employer and employee representatives.

## 2. The Controlled Drugs (Supervision of Management and Use) Regulations 2006

### Key Recommendation;

#### Streamline the the Controlled Drugs (Supervision of Management and Use) Regulations

We understand that the Controlled Drugs (Supervision of Management and Use) regulations were introduced in response to the Shipman review to bring accountability for supervision of controlled drug use closer to the point of prescribing and use, giving more control to local NHS management through Primary Care and NHS Trusts. The intention was to make another Shipman disaster less likely by giving accountability for monitoring controlled drug use to a named individual in each Trust.

However we believe that this was the wrong answer to the wrong problem and that the result has been an increase in bureaucracy that has added nothing to patient safety and has taken away the pharmacist and pharmacy time from patient care.

#### Why the regulations don't work

The Controlled Drugs (Supervision of Management and Use) Regulations 2006 sit on top of the original Misuse of Drugs Act 1971 and the Misuse of Drugs (Safe Custody) Regulations 1973.

In adding to these regulations rather than causing them to be reviewed they perpetuate out of date regulations and cement rigid process and procedure rather than applying a flexible and responsive approach in the patient interest.

In essence the regulations don't work for two reasons.

- 1. The legislation which they overlay – the Misuse of Drugs Act and the Safe Custody regulations – is out of date**
- 2. The duties ascribed to Accountable Officers are overbearing and unnecessary**
- 3. Accountable officers add to the burden of bureaucracy placed on pharmacies.**

## 1. Out of date regulation

Legislation was introduced in the early 1970s to deal with the rising incidence of the misuse of drugs that began in the previous decade. At that time healthcare facilities may have been a significant source of drugs of misuse either through prescribing or theft.

Since then the number of people regularly misusing drugs has continued to increase but the drugs they choose to use have changed (see panel – from DRUG STRATEGY 2010 Reducing Demand, Restricting Supply, Building Recovery : Supporting People to Live a Drug Free Life )

Estimates of number of illicit drug users, 16-59 year olds

	Ever taken	Last year	Last month
<b>Class A</b>			
Cocaine (Powder cocaine, Crack cocaine)	2,838,000	813,000	365,000
Ecstasy	2,692,000	517,000	203,000
Hallucinogens (LSD, Magic mushrooms)	2,969,000	161,000	42,000
Opiates (Heroin, Methadone)	283,000	50,000	38,000
<b>Class A/B</b>			
Amphetamines (Amphetamines, Methamphetamine)	3,777,000	319,000	110,000
<b>Class B</b>			
Cannabis	9,912,000	2,152,000	1,250,000
<b>Class B/C</b>			
Tranquillisers	948,000	145,000	73,000
<b>Class C</b>			
Anabolic steroids	226,000	50,000	19,000
Ketamine	656,000	159,000	79,000
<b>Not classified</b>			
Amyl Nitrate	3,091,000	351,000	115,000
Glues	739,000	57,000	17,000

Source: Drug Misuse Declared: British Crime Survey 2009/10

The drugs with greatest frequency of misuse are not used in significant amounts in healthcare delivery and certainly not within community pharmacy. The fastest growing drugs of misuse are novel “designer” compounds which were not envisaged when the Misuse of Drugs act was written and for which it was not designed.

Safe custody regulations and attendant documentation were designed in a different age of medicines production and supply. Few drugs are now supplied in their pure form – the vast majority are formulated within unit dose presentations which do not facilitate easy extraction of the pure drug. Healthcare facilities no longer provide a significant source of drugs in to the illegal market.

Furthermore the introduction of computerised GP patient record systems and pharmacy Patient Medication Records; electronic prescriptions; and electronic ordering and invoicing has resulted in the Controlled Drugs Register becoming a duplicate of information held in at least three other places.

## 2. Overbearing and unnecessary duties

Accountable officers have been made responsible for overseeing every aspect of CD prescribing, usage and administration within their trust. Amongst other things this gives them the right and duty to inspect pharmacy processes and procedures for the safe storage of CDs. However the GPhC as the regulator already has this power and duty and conducts regular inspection of pharmacy premises; similarly PCTs have the right and duty to monitor pharmacy contract performance and include CD procedures in their audit. A further layer of bureaucracy was never required.

In order to monitor CD usage in their trust Accountable Officers already have data on individual doctor’s prescribing habits provided by the NHS Business Services Authority. They did not and do not need access to Pharmacy Controlled Drug registers.

### 3. Adding to the burden of bureaucracy

As accountable officers have assumed supervision of management and use of controlled drugs they have responded by attempting to standardise processes and procedures, attempting to identify and eliminate all risks. As a result they have added to the number of Standard Operating Procedures (SOPs) that they expect pharmacies to have. These now include (depending on the accountable officer)

- Ordering of CDs
- Dispensing CDs
- Delivery of CDs
- Recording delivery invoice numbers
- Keeping a running balance
- Daily custody of keys
- Transfer of keys between pharmacists
- Procedures for dealing with lost or stolen keys

None of these are legal requirements but become essential because the accountable officer deems them to be “best practice” and not having them would disadvantage any pharmacist who was acting as a ‘Responsible Pharmacist’ when an incident occurred.

It is very difficult for any pharmacists to keep abreast of the number and complexity of SOPs and adding to that burden increases pressure on pharmacists and takes time away from patient care. (see the PDA response to Responsible Pharmacists Red Tape Challenge)

### Conclusion

The Controlled Drugs (Supervision of Management and Use) Regulations do not add to patient safety, will not prevent another Shipman disaster and add significantly to the burden of administration for community pharmacies. In doing so they add to the pressure placed on pharmacists and take away time that should be used in patient care.

In the short term the regulations need to be streamlined and in the medium term a full review of the Misuse of Drugs act and subsequent additions and modifications to it needs to be undertaken. This should involve professional bodies, the pharmacy regulator, pharmacy owners and employee representatives. It should also bring regulation of Controlled Drugs within the purview of the Department of Health rather than the Home Office.

## Further information is available from:

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