



Association of Pharmacy Technicians United Kingdom

Association of Pharmacy Technicians United Kingdom (APTUK) draft response to the Pharmacy legislation on dispensing errors and organisational governance consultation

Consultation introduction

The Department of Health and Social Care (DHSC) has issued a consultation on behalf of the four UK Health Departments shortly, seeking comments and views on two pharmacy-related draft Orders:

1. **The draft Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018** – This proposes to extend the defences for pharmacy professionals who make an accidental/ inadvertent preparation or dispensing error to cover pharmacy professionals working in hospitals and other specified services. This follows an earlier Order for pharmacy professionals working in [registered pharmacies](#) (largely community pharmacies), which entered into force on 16 April 2018.

The aim of the legislation

- Is to remove the threat of criminal sanctions for inadvertent dispensing errors, incentivising an increase in the reporting of dispensing errors, which will afford greater learning opportunities – translating to increased patient safety.
 - In order to benefit from the new defences a number of conditions will need to be met, including that the pharmacy service is overseen by a 'Chief Pharmacist'. It is proposed to introduce a statutory term of 'Chief Pharmacist', together with a statutory duty in respect of the safe and effective running of the pharmacy service, for which they are responsible. This reflects the requirements of Superintendent Pharmacists in retail pharmacy businesses owned by a body corporate, as amended – see below.
 - Pharmacy services without a Chief Pharmacist will not be able to rely on the defence. Organisations will not need a specific Chief Pharmacist role, but should ensure that the statutory functions of a Chief Pharmacist are included in the relevant individual's job responsibilities.
2. **The draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc. Order 2018** – This strengthens the organisational governance arrangements of registered pharmacies, specifically in regard to the role of Responsible Pharmacists and Superintendent Pharmacists.
 - The aim of the legislation is to ensure that pharmacy practice standards are set and enforced by pharmacy regulators and less by inflexible Government legislation.
 - It clarifies the relative roles of Responsible Pharmacists and Superintendent Pharmacists, and introduces a new statutory duty for Superintendent Pharmacists to ensure the safe and effective running of the retail pharmacy business.

An equality analysis for each of the draft orders has been published alongside the consultation. These set out how the Department of Health and Social Care has thought about the potential impact of the proposed policies on protected groups. As part of the consultation comments are also invited on the equality analysis.

The consultation guidance documents for both of the draft orders can be found here <https://www.gov.uk/government/consultations/pharmacy-legislation-on-dispensing-errors-and-organisational-governance>

The consultation closes on 11th September 2018

APTUK will be responding on behalf of our Board of Directors, Professional Committee, Associates, Branches, our members and the pharmacy technician profession.

The APTUK Rebalancing Task and Finish group have drafted the response below and seek views and comments for inclusion.

If you have any further comments please respond by email to Tess Fenn, APTUK President, by **Friday 7th September 2018** to president@aptuk.org



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Part 1 – The draft Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018

Part 1 – Question 1:

Do you agree with the approach to provide a defence for registered pharmacy professionals working in a hospital pharmacy, similar to that implemented for registered pharmacies (predominately community pharmacy)?

YES

However, it needs to be clear what constitutes a 'hospital' as the guidance document refers to definition of "hospital" from the Human Medicines Regulations 2012 – "hospital" as including clinics, nursing homes or similar institutions. To avoid confusion and to understand what is covered by the CQC in England it would be useful to publish a guidance document that can be used by professional leadership bodies to support professionals and to support employers in advising their staff.

Part 1 – Question 2:

Do you agree that in the case of hospital pharmacy services, this should be extended to include dispensing errors by registered pharmacy professionals which are made anywhere as part of a hospital pharmacy service, and so including elsewhere in the hospital, for example on a ward or in a hospital facility that does not have a recognisable pharmacy but supplies dispensed medicines in accordance with the directions of a prescriber?

YES

As above

Part 1 – Question 3:

Do you agree in principle with the proposal to extend the defences for registered pharmacy professionals making an inadvertent dispensing error to include other relevant pharmacy services?

YES

However it needs to be clear what constitutes other relevant pharmacy services, as the consultation guidance document (1.3) indicates that GP dispensing doctors are not covered. There are a number of Pharmacy Technicians (and dispenser/pharmacy assistants) and APTUK members who work in these dispensing environments and it needs to be absolutely clear to these staff that they are not covered by the exemptions for inadvertent errors.

Part 1 – Question 4:

Are there any other pharmacy services that you feel should be included within the scope of the new defences as specified in article 8 of the draft Order, i.e. that are not mentioned in the consultation document, and meet the criteria?

NO

The definitions used are broad and refer to any setting that may be regulated by the CQC (in England) and all settings appear to be covered.

Part 1 – Question 5:

Do you agree with the proposals that a pharmacy service that potentially benefits from the extended defences must have a Chief Pharmacist in order to rely on the extended defences?

YES

However there needs to be clear guidance on the role as stated in the guidance document and that there is a responsibility to build a culture of learning and safety locally and across the NHS.

It also needs to be clear to staffs working environments that may not have a Chief Pharmacist that they are not covered by the defence. This may apply to some private hospitals and smaller service providers.



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Part 1 – Question 6:

Do you agree that the pharmacy regulators should be enabled to set standards in respect of pharmacists who are Chief Pharmacists (or who are designated the responsibilities of a Chief Pharmacist), including a description of the professional responsibilities of a Chief Pharmacist?

YES

It is also important for it to be clearly understood and articulated that this mirrors the Superintendent role. It also needs to be clear that the regulator will need to consult on any standards that might be developed.

Part 1 – Question 7:

Do you agree that the conditions of the defences for pharmacy professionals working in hospitals and other pharmacy services should broadly align with those required to be met by pharmacy professionals working in registered pharmacies?

Absolutely YES

Conditions should be the same for all pharmacy professionals wherever they are selling or supplying medicines.

Part 1 – Question 8:

Do you agree that the defences should apply where an inadvertent preparation or dispensing error is made in a situation where a pharmacist was both the prescriber and dispenser?

YES agree however guidance should be given that this in exceptional circumstances and not normal or best practice. This should be included in any standards set by the regulator.

Part 1 – Question 9:

Do you agree that the defences should apply where an inadvertent error is made in a situation where a pharmacist sells or supplies a medicine against any patient group direction?

YES

However it needs to be clear what part of the legislation defence covers this.

Part 1 – Question 10:

Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.

NO

Part 1 – Question 11:

Do you have any additional evidence which we should consider in developing the assessment of the impact of this policy on equality?

NO, none at the moment although the guide of 20 minutes for a pharmacy professional to comprehend the order would be dependent on a high quality and succinct guidance document.

Part 2 – The draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

Part 2 – Question 1:

Do you agree that the Superintendent Pharmacist should be a senior manager of the retail pharmacy business (which may be just one part of the company for which they work) with the authority to make decisions that affect the running of the retail pharmacy business so far as concerns the retail sale of medicinal products and the supply of such products?

YES

It is absolutely crucial that the SP is a pharmacy professional with sufficient experience and authority to oversee policy and procedures for the sale and supply of medicines.



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Part 2 – Question 2:

Do you agree with the removal of the restriction for companies with “chemist” in their title such that the Superintendent Pharmacist no longer has to be a member of the board of the body corporate?

YES as the new order states that they have to be senior and have the ability to make decisions that impact on the day-to-day running of the pharmacy.

Part 2 – Question 3:

Do you agree with the proposed general duty for the role of the Superintendent Pharmacist?

YES

The duties outlined in the proposals are all rationale and align with organisational governance.

Part 2 – Question 4:

Do you agree that the Superintendent Pharmacist general duty should extend to all medicines – general sale list (GSL) medicines, as well as prescription only medicines (POM) and pharmacy (P) medicines?

YES

However it will need to be clear for professionals and the public where the GSL responsibilities lie where parts of a business are commercial rather than supply/sale being from a pharmacy.

Part 2 – Question 5:

Do you agree that the role of the Superintendent Pharmacist should extend to other services, such as clinical and public health services?

YES

Absolutely yes, as this supports the transformation of a pharmacy from a retail business to a healthcare provider and aligns with all the devolved countries policies on healthcare. By default, it also ensures that it is the responsibility of the SP to ensure that the right skill mix of staff is proportionate for the services provided by the pharmacy.

Part 2 – Question 6:

Do you agree that the restriction whereby a Superintendent Pharmacist can only be a Superintendent Pharmacist for one business at any given time should be removed from primary legislation and the issue be left to the pharmacy regulators?

YES, as there needs to be flexibility in the system that is responsive to timely change. It is also rationale to bring more consistency across an organisation.

Part 2 – Question 7:

Do you agree with the proposal to retain the requirement for Superintendent Pharmacists to notify the General Pharmaceutical Council when they stop being Superintendent Pharmacist for a particular pharmacy and to extend the requirement to Northern Ireland and the Pharmaceutical Society of Northern Ireland?

YES, absolutely as the requirements should be aligned across the UK and the regulator must know who the SP is to ensure that the general duties are being carried out to protect the public.

Part 2 – Question 8:

Do you agree with the proposal to provide the pharmacy regulators with power to set professional standards for Superintendent Pharmacists and describe their role?

YES, as the development of the professional standards will be consulted on by the regulator and will be utilised as part of the regulators premises inspection process



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Part 2 – Question 9:

Do you agree that the statutory duty of the Responsible Pharmacist should be engaged only for the time when the Responsible Pharmacist is actually designated the RP role for that pharmacy, and is therefore in charge?

YES, due to the change in the SP general duties and further future requirements set by the regulator. It is unreasonable to expect an RP to continue responsibilities outside of the time they engaged in this role.

Part 2 – Question 10:

Do you agree that the trigger for when there needs to be an RP in charge of the premises is when medicines are being sold or supplied, or handled, assembled prepared or dispensed at or from the premises with a view to sale or supply?

YES

Part 2 – Question 11:

Do you agree that Responsible Pharmacist's duties should be clarified so that it is clear these are related to the operation of the pharmacy business "at or from" the particular premises (e.g. including home deliveries of medicines)?

YES, it absolutely rationale that the RP duties should follow the complete journey of the medicines/products right up to hand over to the patient.

Part 2 – Question 12:

Do you agree that the pharmacy regulators rather than Ministers should set out the detail of the Responsible Pharmacist's statutory responsibilities?

YES, as there will still be the need for the regulator (now and future) to publish and consult on any draft rules and the rules will be subject to the negative resolution parliamentary process and will need approval by Privy Council.

Part 2 – Question 13:

Do you agree that the pharmacy regulators should have the power to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time?

YES, for the same reasons as 12 and there needs to be flexibility in the system to allow for emergencies, such as pandemic flu etc, as well as the example given in the consultation document.

Part 2 – Question 14:

Do you agree that the duty on the Responsible Pharmacist to establish, maintain and keep procedures under review is removed and instead is subsumed into the general duties of Superintendent Pharmacists?

YES, this is rationale and ensures consistent safe practice for a pharmacy every day on a daily basis irrespective of the RP who may frequently change and may be a locum. This gives assurances to the general public and pharmacy staff alike. In addition the GPhC Standards for registered Pharmacies 2018 states:

"Pharmacy owners are responsible for ensuring the safe and effective provision of pharmacy services at or from a registered pharmacy. They are accountable for making sure that the standards for registered pharmacies are met."

Part 2 – Question 15:

Do you agree that the duties relating to record keeping should be set out by the pharmacy regulators, rather than in Ministerial legislation, and be enforced where appropriate via fitness to practice procedures?

YES, as this would be addressed through premises inspection by the regulator. However these need to be clear and the public will need to be fully aware of this requirement so that any breaches can be notified to the regulator for timely investigation.



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Part 2 – Question 16:

Do you agree that the pharmacy regulators should be provided with a new general rule/regulation making power in respect to the Responsible Pharmacist and remove the specific Ministerial regulation making powers in respect of:

- (a) the qualification and experience of Responsible Pharmacists;**
- (b) the Responsible Pharmacist and supervision;**
- (c) procedures; and**
- (d) the record-keeping of the Responsible Pharmacist**

YES, in terms of a-d, particularly as point b will still be within the provision of Part 12 of the Human Medicines Regulations 2012 and Supervision, in general terms, is still an aspect of the Rebalancing Programme. APTUK seek assurances that this remains the case and will be taken forward as part of the Board's original scope to ensure this is also 'Rebalanced' to optimise a safe pharmacy service meeting the needs of patients now and for the future.

Part 2 – Question 17:

Do you agree that the pharmacy regulators should be given new powers to set professional standards for Responsible Pharmacists and describe their role?

YES, this is a rational approach and will provide assurances to the public that the PR is competent to undertake this role in all situations and on every day the pharmacy is open.

Part 2 – Question 18:

Do you agree that the Pharmacy (Northern Ireland) Order 1976 should be amended to provide for the appointment of a Deputy Registrar and to provide that the Deputy Registrar may be authorised by the Registrar to act on their behalf in any matter?

YES, as this is a rational approach

Part 2 – Question 19:

Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.

The impact assessment cites that 'pharmacy professionals '..... will also receive communications about the changes in the course of their normal engagement with their professional bodies', as a means of familiarising themselves with the changes.

APTUK accepts this responsibility as a professional leadership body for Pharmacy Technicians, as undertaken for the Pharmacy (Preparation and Dispensing Errors- Registered Pharmacies) Order 2018. However, APTUK raise that this has a significant impact on the workload of a voluntary organisation in terms of volunteer time to prepare and disseminate information, answer queries and the administrative costs in distributing publications.

Part 2 – Question 20:

Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?

APTUK inform that the changes may also affect Pharmacy Technicians as we are aware that there are a number of Pharmacy Technicians currently in post working within Superintendent Teams. It could be assumed that these Pharmacy Technicians would be responsible for developing, reviewing and maintaining Standard Operating Procedures. This is often the case for registered pharmacies in the secondary care sector and also transfers across to community pharmacy in some organisations. Therefore APTUK recommend that the impact assessment and impact on equality also applies to Pharmacy Technicians in this respect and also with familiarising themselves and teams of the changes, as Pharmacy Technicians are often also responsible for Professional Development and training.