Pharmaceutical Society ni

Protecting Registering Regulating

To: All registrants

Pharmaceutical Society of Northern Ireland
73 University Street
Belfast
BT7 1HL
May 2015

Dear Registrant,

The Pharmaceutical Society of Northern Ireland consulted on a set of proposed standards regarding the use of monitored dosage systems in pharmacy practice. On concluding the consultation exercise we determined that a regulatory statement was the most proportionate mechanism to identify the issues in the operation of this service.

The framework for the supply of medicines to patients is well defined and legally established in the statutory legislation regarding medicines. The establishment of mechanisms of medicines supply to patients via monitored dosage systems has helped in the convenience and concordance of medicines administration for patients. However, we have also evidenced through our fitness to practise proceedings an increased risk in the profiling of systems & people management and ultimately the governance of the services from pharmacies.

The risk issues identified include amongst others:

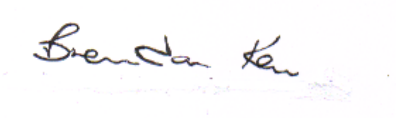
- The wider use of pharmacy staff and the diverse skill mix in the pharmacy.
- The quality of procedures in the pharmacy.
- The final check process.
- The ordering of unnecessary medications for patients by pharmacists.
- Repeating medication profile from pharmacy patient records rather than the authority of prescriptions.
- Poor/no recording of any changes made to the dosage after the initial supply of medicines.
- The use of drivers and couriers to supply to patients.

This list is neither exhaustive nor exclusive but does highlight the increased risk profile in regard to MDS services. The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008[1] detail the minimum procedures required from a Responsible Pharmacist in the supply of medicines from a registered pharmacy premises. This has enhanced application to supply by MDS services where the original packaging and labelling of the medications are removed. It is essential that pharmacies have robust and exact procedures for the accountability, risk management and professional activities involved in the provision of this bespoke service.

Detailed below are extracts from the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008[1] and the Professional Standards and Guidance for the Sale and Supply of Medicines issued by the Pharmaceutical Society of Northern Ireland in 2009[1]. These define the legal and professional frameworks for risk management and professional accountability. It is the responsibility of the responsible pharmacist and the superintendent pharmacist/pharmacy owner to ensure that the pharmacy procedures including the oversight of staff and systems are safe and effective.

Guidance has been issued by many pharmaceutical professional bodies in regard to how to develop and implement procedures relating to MDS supply. This is available to superintendent pharmacists, pharmacy owners and Responsible Pharmacists and is published in the public domain. In a review of the evidence presented in a number of recent fitness to practise investigations, it is clear that the procedures in some pharmacies are inadequate or not fit for purpose, and/or not adhered to.

In conclusion, a MDS service is considered to be a valuable one, providing benefits to patients in both health and social care. However, it demands that all pharmacists put in place adequate and appropriate risk management and governance arrangements to ensure the safe and effective supply of medicines by MDS to patients.



Brendan Kerr
Registrar and Head of Regulatory Services

[1] See Appendix, page 3

Appendix

Relevant legislation and professional standards

The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008
1. Arrangements to ensure that medicinal products are:-
• Ordered;
• Stored;
• Prepared;
• Sold by retail;
• Supplied in circumstances corresponding to retail sale;
• Delivered outside the pharmacy; and,
• Disposed of, in a safe and effective manner.
2. Circumstances in which a member of the pharmacy staff, who is not a pharmacist, may give advice about medicinal products;
3. Identification of members of pharmacy staff who are, in the view of the responsible pharmacist, competent to perform specified tasks relating to the pharmacy business;
4. Maintenance of records about the matters mentioned above;
http://www.opsi.gov.uk/si/si2008/uksi_20082789_en_1

Mandatory professional standards and guidance on the responsible pharmacist regulations
In addition to the legal requirements above, the Responsible Pharmacist must ensure that:
Pharmacy Procedures and members of staff
- All necessary steps are taken to ensure Pharmacy Procedures are operated accordingly by members of staff.
- Members of staff are competent to perform the tasks required of them in the Pharmacy Procedures

http://www.psni.org.uk/documents/352/Standards+on+the+Responsible+Pharm_.pdf

Professional standards and guidance for the sale and supply of medicines
3. Supply of prescribed medicines standards
3.12 appropriate systems and procedures are in place if he prepares monitored dosage systems;
http://www.psni.org.uk/wp-content/uploads/documents/313/standards_on_sale_and_supply_of_medicines.pdf