

Monitored Dosage Systems

Draft Standards

A consultation document

18 June 2014 to 10 September 2014

Contents

| | |
|--|----|
| About the Pharmaceutical Society of Northern Ireland..... | 2 |
| Why are we consulting? | 3 |
| How to respond to this consultation | 4 |
| Accessibility of information | 4 |
| Consultation period | 4 |
| Consultation questions | 5 |
| | |
| 1. What is a Monitored Dosage System (MDS)? | 6 |
| | |
| 2. Processes | 7 |
| 2.1 Standard Operating Procedures | 7 |
| 2.2 Standards for Pharmacy Premises | 8 |
| | |
| 3. Accountability and liability | 9 |
| | |
| 4. Suitability of medication | 9 |
| 4.1 Stability issues | 9 |
| 4.2 Re- dispensing medicines..... | 9 |
| | |
| 5. Information..... | 10 |
| 5.1 Labelling of MDS devices | 10 |
| 5.2 Monitored dosage system and Patient Information Leaflets (PILs)..... | 10 |
| 5.3 Record keeping..... | 11 |
| | |
| 6. Communication..... | 12 |
| 6.1 Counselling and advice..... | 12 |
| | |
| Appendix 1: Standards for registered pharmacy premises..... | 13 |
| Appendix 2: Limitations to the use of MDS..... | 16 |
| Appendix 3: Guidance on the supply of Controlled drugs (Schedule 2 and 3)..... | 17 |

About the Pharmaceutical Society of Northern Ireland

The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists in Northern Ireland.

Our primary purpose is to ensure that practising pharmacists are fit to practise, keep their skills and knowledge up to date and deliver high quality safe care to patients.

It is the organisation's responsibility to protect and maintain public safety in pharmacy by:

- Setting and promoting standards for pharmacists' admission to the Register and for remaining on the Register;
- Maintaining a publicly accessible Register of pharmacists, and pharmacy premises;
- Handling concerns about the fitness to practise of registrants, acting as a complaints portal and taking action to protect the public; and
- Ensuring high standards of education and training for pharmacists in Northern Ireland.

Why are we consulting?

This consultation seeks the views of stakeholders on draft standards for the provision of Monitored Dosage System (MDS).

These standards have been produced by the regulator with the primary focus of improving quality and safety in MDS provision by identifying the processes and systems required by community pharmacies in order that the supply of MDS is safe and appropriate to patients.

Safe administration of medicines is not guaranteed by use of MDS. MDS is just one of many options available to help patients take their medicines safely or support carers to administer medicines correctly.

For those pharmacies providing MDS it is essential that the right systems and processes are in place to ensure that the process of assembling and supplying medicines in an MDS is as robust and safe as possible and optimal patient care is maintained.

This consultation document explains the standards expected of a pharmacist providing a MDS service.

This consultation will be of particular interest to registrants affected by these proposals; pharmacy owners, employers and their staff; pharmacy professional and representative bodies; Department of Health, Social Services and Public Safety and other health and social care bodies.

How to respond to this consultation

We welcome your response to this consultation and have listed some questions to assist you. In order to help us analyse responses, we would strongly encourage you to complete the response template provided.

Responses should be sent by post, fax or email to:

Consultation on Draft Standards for the provision of MDS
Pharmaceutical Society of Northern Ireland
73 University Street
Belfast, BT7 1HL

Tel: 028 9026 7933
Fax: 028 9043 9919

Email: Michelle McCorry, consultation coordinator michelle.mccorry@psni.org.uk

Accessibility of information

If you are having difficulties accessing the documentation or you need us to make adjustments in order to be able to respond to this consultation, please contact us and we will do our best to address the issue.

If you wish your response to remain confidential, the Pharmaceutical Society NI will generally respect this request. However, the information you provide may be subject to disclosure under the Freedom of Information Act 2000.

Consultation period

The consultation will run for 12 weeks from 18 June 2014 to 10 September 2014.

When the consultation closes, we will analyse the responses we receive which will be taken into account by Council of the Pharmaceutical Society NI when making its decisions on the final document.

About this document

This document expands on the principles of the Code of Ethics¹ for the purpose of explaining the pharmacist's responsibilities if they are involved in the provision of monitored dosage systems (MDS) to patients.

The Code of Ethics of the Pharmaceutical Society NI sets out eight mandatory principles of ethical practice which a pharmacist must follow.

The eight principles are:

1. Make the safety and welfare of patients your prime concern.
2. Respect and protect confidential information.
3. Show respect for others.
4. Exercise professional judgement in the interests of patients and public.
5. Encourage patients (and/or their carers as appropriate) to participate in decisions about their care.
6. Maintain and develop professional knowledge and competence.
7. Act with honesty and integrity.
8. Provide a high standard of practice and care at all times.

This document does not detail legislative requirements, but when providing MDS, the pharmacist must comply with relevant legislative and contractual requirements, including Health Service terms of service where appropriate.

This document contains:

- Mandatory professional standards (indicated by the word 'must' and 'have to') for all registered pharmacists;

and

- guidance on good practice (indicated by the word 'should', 'might', 'may', 'would', 'will' and 'could') which the pharmacist should follow in all normal circumstances.

All pharmacists should be familiar with these standards and understand that they have a professional responsibility to raise concerns, if they believe the standards are not being met. Serious or persistent failure to follow this guidance will put a pharmacist's registration at risk. The pharmacist must, therefore, be prepared to explain and justify his² actions.

If a complaint is made against a pharmacist, the Pharmaceutical Society of Northern Ireland's Fitness to Practise process will take account of the requirements of the Code of Ethics and underpinning documents, including this one.

The pharmacist will be expected to justify any decision to act outside the terms set down in these documents.

¹Pharmaceutical Society NI Code of Ethics (2009)

<http://www.psni.org.uk/documents/312/Code+of+Ethics+for+Pharmacists+in+Northern+Ireland.pdf>

²'Pharmacist' appears with masculine pronoun and is understood to refer to male/female gender

1. What is a Monitored Dosage System (MDS)?

A Monitored Dosage System (MDS) is a medication storage device that aids medicines adherence to individual patients.

The preparation of a MDS device involves authorised pharmacy staff repackaging and dispensing prescribed medication into a storage device in order to assist patients in the day-to-day management of their medicines and in the adherence to their prescribed medicines.

MDS provision aims to support patients to live independently in their own homes.

For pharmacies providing MDS it is essential that their systems are robust and that quality assured processes are in place to ensure that the assembly and supply of medicines in a MDS device is as accurate and safe as possible.

2. Processes

Standard 1

The Responsible Pharmacist must ensure that standard operating procedures (SOPs) are written for each stage in the assembly and supply of medicines in the MDS device.³

Standard 2

The pharmacist must either have received a valid request from a prescriber or be in possession of a legally valid prescription before making a supply of medicine in the MDS device.

2.1 Standard Operating Procedures

Notwithstanding the SOPs which need to be written in every pharmacy under the Responsible Pharmacist regulations⁴, appropriate SOPs must also be written for each stage of the assembly and supply of medicines to a patient in a monitored dosage system.

³ The Health Act 2006 requires each registered pharmacy premises to have a Responsible Pharmacist in charge in order to operate lawfully (the one pharmacy/one pharmacist rule). The Act requires the Responsible Pharmacist to secure the safe and effective running of the pharmacy at all times.

⁴ The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 came into force on 1 October 2009. These regulations can be accessed at: http://www.opsi.gov.uk/si/si2008/uksi_20082789_en_1

The SOPs should address the following elements:

1. Prescription management and record-keeping
2. Protocol to address medication changes – with a clear audit trail
3. Assembly and supply
4. Advice and information
5. Patient consent

Standard 3

The pharmacist must adhere to a written protocol when addressing changes to medication thus providing a clear audit trail.

2.2 Standards for Pharmacy Premises

Standard 4

The pharmacist must ensure the dispensing area in the pharmacy is maintained in a good state of repair and is clean, tidy and uncluttered for the safe assembly of the MDS device⁵.

In accordance with the Pharmaceutical Society NI 'Standards for pharmacy premises'⁶ all pharmacists are obliged to provide pharmaceutical services in a safe and secure environment so that the professional activities are carried out to an acceptable standard thereby ensuring quality in patient care. These standards include the assembly and supply of medicines in a MDS device.

⁵ Standards for registered pharmacy premises (2010) http://www.psn.org.uk/wp-content/uploads/documents/521/community_pharmacy_premlises_standards.pdf

⁶ Ibid

3. Accountability and liability

Standard 5

The pharmacist must ensure that only suitably trained and competent staff must be involved in the assembly, preparation and supply of a medicine in the MDS device.⁷

4. Suitability of medication

Standard 6

The pharmacist must use their professional judgement on all medicines to be included in the MDS device to determine their suitability

4.1 Stability issues

Many manufacturers indicate that their medicine(s) is (are) not suitable for inclusion in a MDS device based on the absence of evidence from stability studies, and that repackaging into a MDS device may affect the safety or efficacy of the medicines.

The decision on whether to include or exclude a medicine from a MDS device is solely reliant on the professional judgement of the pharmacist.

4.2 Re- dispensing medicines

Pharmacists should not re-dispense medicines originally dispensed elsewhere, as the pharmacist would be unable to vouch for the proper sourcing or storage of said medicines and automatically becomes liable for re-dispensing them.

⁷ To comply with the Responsible Pharmacist Regulations, the Responsible Pharmacist has a statutory duty to establish, maintain and review pharmacy procedures; identifying the members of pharmacy staff who are, in the view of the responsible pharmacist competent to perform specified tasks relating to the pharmacy business.

5. Information

Standard 7

Pharmacists must ensure that they label medicine supplied to a patient in a MDS device in accordance with the relevant legislation

5.1 Labelling of MDS devices

In legislation, MDS devices are subject to the same labelling and leaflet requirements as other 'dispensed medicinal products' and are therefore required to be labelled in accordance with the legislation pertaining to the type of product⁸.

Not labelling a dispensed medicine, in accordance with relevant legislation, may constitute an offence.

5.2 Monitored dosage system and Patient Information Leaflets (PILs)

Standard 8

Pharmacists must ensure that a PIL is provided on each occasion a medicine is supplied to a patient in the MDS device or at appropriate dispensing intervals.

It is a requirement of the Human Medicines (Part 13: Packaging and Leaflets) Regulations 2012⁹, as amended (in accordance with the related European Directive), that a patient information leaflet (PIL) is provided on each occasion a medicinal product is supplied or at appropriate intervals which have been agreed with the patient/carer.

In addition, each time there is a change to a patient's medicine(s) a new PIL should be issued detailing the relevant product information.

If you require additional copies of a PIL you can obtain these direct from the manufacturers or from www.medicines.org.uk

⁸ For dispensed relevant medicinal products the legislation is the Human Medicines Regulations (Marketing Authorisations etc.) Regulations 2012, as amended and for dispensed non-relevant medicinal products the legislation is the Labelling Regulations 1976, as amended.

⁹ http://www.legislation.gov.uk/ukxi/2012/1916/pdfs/ukxi_20121916_en.pdf

5.3 Record keeping

Standard 9

The pharmacist must ensure that the patient's computer-held records and labels correspond with the details written on the patient's prescription and that a record is made on the Patient Medication Record (PMR) and any supporting documentation record of any changes to the patient's medicines recording who authorised the change.

The provision of a MDS service requires that the appropriate supporting documentation is recorded and retained where available, for example:

- Decisions and reasons for medicines inclusion/exclusion in an MDS particularly if there are issues regarding stability of medicines
- A clear process for dealing with any changes to medicines and who requested the change
- A note of when medicines are picked up and the patient or carer should be asked to sign for the MDS device
- Carer/GP details
- Appropriate clinical information

6. Communication

Standard 10

The pharmacist must ensure that the patient and/or their carer are given appropriate advice on the medicines supplied and on the safe use of the MDS device¹⁰.

6.1 Counselling and advice

A patient and/or their carer who has been issued with a MDS device should be instructed on the following:

- The safe and appropriate use of the device - including the potential risks to children as the MDS device is unlikely to be child resistant and may not be tamper evident. Where possible demonstrate to new patients or their carers how to use the monitored dosage system to ensure that they understand exactly how to use it
- The protocol for ordering and collecting a MDS device
- The safe storage and administration of medicines from a MDS device
- What happens if the contents of the MDS device are spilled.

¹⁰ Standards and Guidance for the Sale and Supply of Medicines (2009) http://www.psni.org.uk/wp-content/uploads/documents/313/standards_on_sale_and_supply_of_medicines.pdf

Appendix 1: Standards for registered pharmacy premises

MDS provision criterion

Below is a checklist which can be used by pharmacists to assess compliance with the standards. The pharmacy must provide adequate facilities to safely assemble and supply a MDS device to patients. The pharmacist must ensure the following:

| Indicators | Status | Audit result | Required action | Date completed |
|--|------------------|--------------|-----------------|----------------|
| Standard 1 The Responsible Pharmacist must ensure that standard operating procedures (SOPs) are written for each stage in the assembly and supply of medicines in the MDS device | Essential | | | |
| Standard 2 The pharmacist must either have received a valid request from a prescriber or be in possession of a legally valid prescription before making a supply of medicine in the MDS device | Essential | | | |
| Standard 3 The pharmacist must adhere to a written protocol when addressing changes to medication thus providing a clear audit trail | Essential | | | |

| Indicators | Status | Audit result | Required action | Date completed |
|---|------------------|--------------|-----------------|----------------|
| <p>Standard 4</p> <p>The pharmacist must ensure the dispensing area in the pharmacy is maintained in a good state of repair and is clean, tidy and uncluttered for the safe assembly of the MDS device</p> | Essential | | | |
| <p>Standard 5</p> <p>The pharmacist must ensure that only suitably trained and competent staff must be involved in the assembly, preparation and supply of a medicine in the MDS device</p> | Essential | | | |
| <p>Standard 6</p> <p>The pharmacist must use their professional judgement on all medicines to be included in the MDS device to determine their suitability</p> | Essential | | | |
| <p>Standard 7</p> <p>Pharmacists must ensure that they label medicine supplied to a patient in a MDS device in accordance with the relevant legislation</p> | Essential | | | |

| Indicators | Status | Audit result | Required action | Date completed |
|---|-------------------------|--------------|-----------------|----------------|
| <p>Standard 8</p> <p>Pharmacists must ensure that a PIL is provided on each occasion a medicine is supplied to a patient in the MDS device or at appropriate dispensing intervals</p> | <p>Essential</p> | | | |
| <p>Standard 9</p> <p>The pharmacist must ensure that the patient's computer-held records and labels correspond with the details written on the patient's prescription and that a record is made on the PMR and any supporting documentation record of any changes to the patient's medicines recording who authorised the change</p> | <p>Essential</p> | | | |
| <p>Standard 10</p> <p>The pharmacist must ensure that the patient and/or their carer are given appropriate advice on the medicines supplied and on the safe use of the MDS device</p> | | | | |
| | | | | |

Appendix 2: Limitations to the use of MDS

Not every medicine is suitable for inclusion in a MDS device.

Monitored dosage systems are mainly used for repackaging tablets and capsules; examples of medicines which are unsuitable include:

- Medicines that should only be taken 'when required' e.g. painkillers
- Medicines not suitable for MDS e.g. Pradexa®
- Medicines blister-packed with integral drying agents e.g. Ikorel®
- Dispersible formulations
- Non-tablet/ capsule formulations e.g. suppositories, wafer formulations, inhalers, eye drops and creams etc.
- Drugs which may cause skin reactions / hypersensitivity reactions on prolonged contact e.g. chlorpromazine
- Cytotoxic drugs
- Drugs requiring special temperature storage e.g. fridge lines
- Medicines with specific administration requirements e.g. alendronate
- Medicines that are too large to fit into an MDS e.g. Sandocal®

Appendix 3: Guidance on the supply of Controlled drugs (Schedule 2 and 3) in a MDS device

Controlled drugs can be supplied in a MDS device provided that:

- Appropriate checks have been made by a pharmacist to ensure the stability of the product in such a container
- If there is a statutory requirement for safe custody, the MDS device must be stored in the CD cabinet prior to collection
- If an entry in the CD register is required this should be made at the time of supply and meet the legal requirements.
- When the MDS device is not locked in the CD cabinet it must be kept under the personal supervision of a pharmacist at all times.

In situations where the dose and strength of the preparation may need to change rapidly to accommodate the patient's condition e.g. in palliative care, the addition of a controlled drug to a monitored dosage system is not appropriate.