PSI
CUMANN CÓGAISEOIRÍ NA hÉIREANN
The Pharmaceutical Society of Ireland

AN RIALTÓIR CÓGAISÍOCHTA
THE PHARMACY REGULATOR

Draft Guidance for Pharmacists on the use of Monitored Dosage Systems (MDS)

Draft Version Sept 2015

1. Introduction

The purpose of this guidance is to assist pharmacists in making appropriate decisions about whether a Monitored Dosage System (MDS) is suitable for a particular patient. The guidance will also support pharmacists when assessing which medicinal products are suitable for inclusion in the MDS and will outline the requirements needed of the retail pharmacy business, to ensure safe MDS dispensing occurs. MDS dispensing can be described as any process where medicinal products are dispensed from their original packaging into a box, blister or pouch system which indicates the days of the week and/or the times of the day medicinal products should be taken. There are many forms of MDS such as multi-compartment compliance aids (MCA), dose administration aids (DAA) and pouch dispensing systems. This guidance will refer to all these forms of dispensing systems as MDS. This guidance specifically relates to small scale systems requiring the manual packaging of medicinal products. Guidance may become available in the future regarding larger automated and computerised systems, e.g. Automated Dose Dispensing (ADD). Until this occurs, the broader principles explored here could be applied to these processes.

The primary principle of the statutory Code of Conduct states that the practice by a pharmacist of his/her profession must be "directed at maintaining and improving the health, wellbeing, care and safety of the patient". As such, MDS dispensing must only be employed in situations where it will support the safe and appropriate medication use by the patient concerned and facilitate adherence to the patient's medication regime. These systems may offer many benefits to patients; however pharmacists should be mindful that the use of MDS containers introduces additional and inherent risks for the pharmacist supplying medicinal products and for the patient receiving them.

2. Regulatory Environment

When supplying medicinal products to patients using an MDS, the pharmacist must be satisfied that he or she complies fully with all relevant legislation and guidance including;

- The Pharmacy Act 2007
- The Statutory Code of Conduct for Pharmacists
- The Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)
- The Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended)
- The Misuse of Drugs Acts 1977 to 2015 and the Orders and Regulations made thereunder
- The Health (Pricing and Supply of Medicinal Goods) Act 2013
- Any guidance issued by the PSI to facilitate compliance with any of these Acts and regulations or with any other legislation that may be relevant.

3. Guidance

3.1 Establishing an MDS service

An assessment should be carried out by the superintendent/supervising pharmacist as to the viability of providing such a service given the resources, equipment and staff present in the retail pharmacy business. The superintendent pharmacist, supervising pharmacist and pharmacy owner should ensure that adequate

time, staff and resources can be allocated for the provision of the MDS service by the pharmacist and staff members in order that the process is completed safely and appropriately. Pharmacists must ensure that patients availing of MDS dispensing services receive the same level of professional care as all other patients, and that MDS dispensing is implemented in a manner that maintains and improves the health, wellbeing, care and safety of the patient.

3.2 Patient Suitability

Prior to the provision of an MDS to a patient, alternative adherence supports should be considered by the pharmacist, including (but not limited to):

- Simplification or tailoring of the medication regimen in conjunction with the prescriber
- Reminder charts
- Large font information sheets, large font label, magnifying glasses, pictograms
- Memory aids, e.g. Software applications, timed alarms, calls from a relative
- Involvement of a carer or relative to administer medication

A risk-benefit analysis should be conducted by the pharmacist during the assessment process, which clearly outlines the advantages and disadvantages of supplying medicinal products in an MDS.

Pharmacists may find that conducting a medicine review[1] identifies further barriers to compliance which may be overcome by interventions such as a change in formulation or the use of non-child resistant closures on containers.

The use of an MDS should be assessed on an individual patient basis and include an assessment of the patient's existing compliance with their medication regimen, their health status and the safety and appropriateness of the MDS chosen. The assessment should establish the potential of the MDS to improve patient adherence and concordance. The needs of patients should be considered in light of their particular care setting. Pharmacists should be aware that MDS dispensing may be unsuitable for certain patients whose medication regimen is subject to frequent changes. Therefore pharmacists, in collaboration with the patient's prescriber and extended healthcare team, should assess the appropriateness of using MDS as a means of dispensing on an individual patient basis.

Supply of an MDS should only be made when the pharmacist and healthcare team have assessed each patient and concluded that the supply of an MDS best meets the patient's pharmaceutical care needs. Having decided that MDS may be an appropriate service for the patient, the pharmacist should complete a documented assessment of the patient's suitability. This assessment should address any issues the pharmacist, in the exercise of his or her professional judgement, deems significant and of pertinence to that individual patient. A standard operating procedure should be drawn up for this assessment process. Pharmacists should consider documenting any decisions made to dispense medicinal products into an MDS, as well as any decisions which result from issues related to dispensing medicinal products in an MDS for an individual patient.

Patient engagement in the assessment process is advised where at all possible. Prior to supplying medicinal products in an MDS, pharmacists should ascertain if patients (or their carer) would prefer to receive their

[1] In accordance with Regulation 9 of the Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

medicinal products in a conventional manner or in an MDS. Where medications can be taken at any time, pharmacists should ascertain from the patient when they prefer to take their medications so that the MDS can be used most effectively. Also pharmacists should obtain informed consent for each patient receiving their medicinal products in a dosage system and this should be documented.

Regular, periodic re-assessment of the suitability of dose dispensing for a patient is an important part of the process. Ad hoc re-assessment should also occur when the patient's circumstances, medication or health status changes. Pharmacists should record that such assessments have taken place.

3.3 Considerations for Patients in Residential Care Settings

The provision of pharmacy services to patients in residential care settings or nursing homes must ensure that patients receive the same level of professional care as those patients who attend personally at the pharmacy. The decision to supply medicinal products in an MDS should always be based on patient need and appropriateness, accounting for the needs of the patient in light of their care setting and supports available. Therefore pharmacists should not enter into contracts with residential care settings or nursing homes that require the routine dispensing of medicinal products using MDS, without an appropriate assessment of patient need and medicinal product suitability. Additionally, MDS dispensing may not be suitable or of value to all patients, such as to those who are administered their medication directly by a healthcare professional. Pharmacists should be mindful that MDS containers are not a suitable intervention for patients where intentional non-compliance is an issue or in situations where an MDS may be more convenient for the pharmacist or other healthcare professional e.g. nurse. The decision to supply medicinal products in an MDS should be based on patient need and appropriateness rather than the requirements of any establishment or institution.

More detailed guidance on this area, and the policies and procedures to follow when supplying to patients in residential care settings is available in *PSI Guidance on the Supply by Pharmacists in Retail Pharmacy Businesses of Medicines to Patients in Residential Care Settings/Nursing Homes*.

3.4 Medicinal Product Assessment

The manufacturer's original packaging of medicinal products has been designed specifically to protect and preserve the stability of the products concerned.[2] Therefore pharmacists should carefully assess each medicinal product for its suitability for inclusion in an MDS, consider the consequent stability of the product and the associated impact MDS dispensing may have on medicinal product efficacy and patient safety.

Reference sources that may be consulted when assessing a medicinal product's suitability include, (but are not limited to):

- pharmacopoeias
- SmPCs
- internationally available stability data
- the marketing authorisation holder's medical information department
- medicines information (MI) centres

[2] Other functions of the manufacturer's original packaging include product traceability and provision of patient information, stability and protection from heat, light and moisture.

While pharmacists must be aware of general principles regarding the stability of medicines, there are no conclusive guidelines in Ireland that can be applied for each medicinal product to evaluate its suitability for inclusion in the specific MDS used. Pharmacists should use the information available to them and use their professional judgement when deciding whether a product is appropriate for MDS dispensing.

Important considerations when assessing stability include:

- The duration of time which the product is intended to be stored out of its original packaging
- The type of MDS chosen and the processes used in the preparation of the MDS
- Medicinal products which require protection from heat (e.g. soft gel capsules) may be adversely affected by MDS that use heat sealing
- The hazards associated with physical and chemical interactions between one or more products dispensed together into a single MDS pouch and between the product(s) and the packing materials

The pharmaceutical form of a medicinal product must be considered when determining its suitability for inclusion in an MDS. Depending on the MDS employed, some products may be inappropriate for inclusion including those unsuitable due to their formulation. These include:

- Effervescent, dispersible or uncoated medicinal products
- Products which are unsuitable due to their storage requirements (e.g. products sensitive to light moisture or requiring refrigeration)
- Products which are potentially harmful to handle (e.g. cytotoxics)
- Medicines that should only be taken “when required”
- Those products whose dose is subject to frequent changes and dependent on test results (e.g. warfarin)

Careful consideration should be given to medicinal products such as:

- Controlled drugs
- High tech medicines
- Exempt (i.e. unlicensed) medicinal products
- Medicines which carry a greater risk of allergic reactions occurring (e.g. penicillins)

Pharmacists should consider potential risks when medicinal products are supplied together in an MDS, for example (note this list is not exhaustive):

- Medicinal products unsuitable for co-administration (e.g. antacids and tetracycline)
- Medicinal products with different methods of administration (e.g. chewable, buccal or sublingual)
- Medicinal products with specific administration instructions (e.g. those that should be taken 30 minutes before the first food/beverage/medicinal product of the day)

All supplies of medicinal products in an MDS should reflect the instructions of the prescriber.

3.5 Dispensing Using MDS

MDS Choice

When choosing an MDS, its suitability for both the patient and the medicinal products required should be considered. The MDS used should be capable of delivering the correct medicinal product at the correct dose and correct time for the individual patient. The pharmacist should assess each patient on a case by case basis and select an MDS appropriate to their needs and medication regime. For example some patients may take all their medications at the same time each day, whilst others may need to take medications at different times throughout the day.

Best practice would advocate the use of tamper proof, disposable systems. Where non-tamper proof systems are used the pharmacist should consider the risk of medication errors if drugs are moved from one compartment to another or if drugs are added to or removed from the system, either deliberately or inadvertently. Where non-disposable systems are used, steps should be taken to ensure that the MDS is clean and dry before each use.

The system chosen should:

- Be capable of supporting the dosage frequency of the patient's medication regimen
- Be easy to use for the patient, in terms of knowing when and how to remove the correct medicines at the correct time
- Provide a means of identifying each medicinal product dispensed in the MDS pack (e.g. an accompanying written description or photo)
- Provide clear visibility to the pharmacist checking the filled MDS before it is sealed and the patient/carer using the MDS
- Be of appropriate size to safely and securely pack the medicinal products
- Protect the medicinal products from moisture and potential contaminants.

Designated Area

Specific work areas should be identified and appropriately maintained for each stage of the process of the preparation of MDS. The work areas and equipment should be located in the dispensary under the supervision of the pharmacist, and designed and maintained to suit the nature and scale of the operations carried out. The layout and design of the designated MDS work area should minimise the risk of errors and interruptions occurring and should allow for a logical sequence of operations to be carried out. Where more than one staff member is dispensing a number of MDS packs for different patients concurrently, the work area should be appropriately segregated to minimise the potential for error. Protocols should be in place governing the cleaning of dispensary areas where medicines are removed from their primary packaging for inclusion in an MDS container.

Equipment and References

If equipment is needed when dispensing an MDS (e.g. for sealing the MDS packs) it should be only used in accordance with the manufacturer's instructions. Suitable equipment and facilities should be available (for example sterile gloves and tablet counters) and other equipment required to safely provide this service. Records of equipment maintenance and repair should be kept in the pharmacy. Reference materials to help

with the preparation of the MDS should be accessible to staff e.g. electronic software used for tablet identification.

Further information can be found in the *PSI's Guidelines on the Equipment Requirements of a Retail Pharmacy Business.*

Preparation, Assembly and Labelling

MDS preparation and assembly should be carried out under the supervision of a pharmacist at all times. MDS should not be overfilled as overfull packs are difficult to check and may be prone to improper sealing as a result of overfilling. MDS should be sealed as soon as possible after preparation and checking by the pharmacist and care should be taken that they are not left exposed to the environment for extended periods of time. If an error is detected after sealing, the pack should be opened, the corrections made and the medicines repackaged in a new MDS.

The MDS should protect the medicinal products from heat, light and moisture. Medicinal products should be stored in an MDS pack (and therefore out of the manufacturer's original pack) for as short a time as possible.

A label must be generated for each item dispensed into the MDS and this label attached directly to the MDS. MDS packs that have inadequate space for the affixing of all labels generated during the dispensing process should not be used. Pharmacists should ensure that the font and labelling is clear, legible and of an appropriate size for an individual patient's circumstances. Pharmacists should also ensure that when the MDS is supplied that the current package leaflet (PL) is given to patients and/or their carers including any relevant information on the authorised packaging of the medicinal products.

Pharmacists should ensure that the MDS employed assists the patient/carer in identifying each medicinal product in the MDS, enabling them to follow appropriate directions. If a patient's medication changes mid-month or mid-cycle, pharmacists must dispose of previously dispensed medicines and prepare a new MDS.

Storage

Packed MDS awaiting collection should be stored in an appropriate area of the dispensary until collected by the patient/carer. Medicinal products should be protected from light and heat. Where the MDS pack contains a schedule 2 or 3 controlled drug, the MDS must be stored in a controlled drug safe until supplied to the patient in line with Safe Custody Regulations.[3] The pharmacist should endeavour to ensure that there are suitable arrangements in place to mitigate the risk of excess packs being available for collection at the same time by the patient or the patient having excess packs at home which may cause further confusion.

Medicinal products returned to the pharmacy unused and still sealed in the MDS pack must not be reused or returned to stock. These medicinal products must be disposed of in the correct manner[4].

Supervision and Checking

Each stage of the preparation and supply of an MDS should be subject to robust quality control measures and be carried out under the personal supervision of a pharmacist. A thorough and robust checking mechanism should be utilised by the pharmacist, including but not limited to establishing the identity of the

[3] Misuse of Drugs (Safe Custody) Regulations 1982, as amended

[4] Please refer to PSI *Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business*

tablet which has been removed from its original packaging[5], and ensuring that the correct tablet, of the correct strength and quantity are in each compartment. A double check system should be employed where possible. When checking a prescription (particularly in situations where the pharmacist did not personally enter the prescription into the PMR), pharmacists should refer back to the patient history at the point of checking in order to complete the therapeutic review. The final check should involve reviewing the prescription, against the label and against the products contained in the MDS[6]. This requires the pharmacist to check the original packs of the medicinal products which have been included in the MDS.

Pharmacists must be mindful that they have overall responsibility for the safe supply of medicinal products in an MDS pack, notwithstanding that many steps in the MDS dispensing process can be completed by an appropriately trained member of staff. The final check of all MDS prepared medicinal products must be conducted by the pharmacist, in addition to the therapeutic review and assessment of all products included in the MDS. As there is a responsibility for the pharmacist to personally oversee the entire MDS preparation process, MDS should only be prepared in the dispensary under the personal supervision of a pharmacist.

Communication

The frequency of supply of the MDS to the patient should be decided on a case by case basis in discussions between the pharmacist and the patient. This should involve consideration of the patient's individual needs, support and medicines. Open dialogue between all members of the patient's healthcare team should be encouraged so that every individual involved in the supply of the MDS is clear and understands any specific supply requirements or restrictions applicable to individual patients.

Patients should receive comprehensive instructions and counselling, particularly when initiated on MDS dispensing for the first time. The pharmacist should ensure at each supply that the patient has sufficient information and advice for the proper use and storage of the MDS pack. Counselling patients on the use and identification of medicinal products (physical appearance) supplied via MDS and on medicinal products supplied in an alternative manner, e.g. products for "as required" use and inhalers, is important. All necessary storage instructions should be provided to the patient, e.g. protecting the MDS medicinal product(s) from light. As many MDS containers are not child resistant it is particularly important that pharmacists counsel patients to keep the MDS containers, 'out of the reach of children.'

As with all medicinal products supplied, the pharmacist must comply with Regulation 9 of the *Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended)* particularly regarding the counselling and medicine therapy review that must be undertaken in the supply of prescribed medicinal products form a retail pharmacy business. Further information on this can be found in PSI *Guidelines on the Counselling and Medicine Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business*.

Issues of Liability

Pharmacists should be mindful of the potential liability issues that may arise when a medicinal product is removed from the manufacturer's original packaging and dispensed into an MDS pack. Pharmacists should be aware that the manufacturers' original packaging has been approved as part of the product's marketing

[5] References to ascertain the identity of tablets removed from their original packaging include tablet identification software and the individual product's SmPC.

[6] For further information on checking dispensed prescribed medicinal products, please refer to PSI Guidelines on the Counselling and Medicine Therapy Review in the Supply of Prescribed Medicinal Products from a Retail Pharmacy Business.

authorisation for use due to its ability to provide the correct environment and adequate protection for the medicinal product concerned. When a medicinal product is repacked into an MDS by a pharmacist, the pharmacist is using the medicinal product outside of the product's marketing authorisation. As such, pharmacists should give consideration to any potential legal liability that may arise where they operate outside of the product's marketing authorisation. Pharmacists should consider documenting any decisions made to dispense medicinal products into an MDS, as well as any decisions which result from issues related to dispensing medicinal products in an MDS for an individual patient.

3.6 Record Keeping

The pharmacist should document all parts of the assessment process when supplying an MDS to a patient. For each patient availing of the MDS service:

- Informed consent should be documented.
- A record should be made on the patient's PMR.
- Appropriate records should be maintained to support the consistent and appropriate filling of the patient's MDS e.g. medication charts/records of the medicinal products regularly included in the patient's MDS, records of the times of day that each medicinal product is taken.

Pharmacists utilising an MDS medication chart for each patient should consider which details need to be recorded (e.g. dose to be taken and what time to be taken) and also specific notes relating to each patient's care. Such a chart should also include notes detailing particular advice from the patient's prescriber, allergies the patient may have, any impairments the patient has or any other such information that the pharmacist in the exercise of his/her professional judgement deems significant. Medicinal products not supplied via MDS but still used by the patient should be listed in a separate section of the chart. The pharmacist must ensure that if such charts are used to assist in the preparation of MDS packs of prescribed medicinal products, they are routinely checked for accuracy against the most recent valid prescription.

The batch number and expiry date of each drug packed in an MDS should be recorded. Records should also be made of the packing date, of the person who filled the MDS, if this was not carried out by the pharmacist, and the pharmacist who checked the MDS.

Errors and near misses should always be reported and recorded and the staff members involved informed of the error. All errors and near misses should be regularly reviewed and used to amend practice, policies and procedures to minimise the risk of a similar incident happening again.

3.7 Policies and Procedures

A system for the professional management and clinical governance of the MDS service must be established. Superintendent and supervising pharmacists should ensure that appropriate and robust documented policies and procedures are put in place for all aspects of the MDS service and that these are reviewed and updated regularly in accordance with best professional practice. These procedures should include procedures for situations where errors are discovered at final check or after the MDS is sealed before supply to the patient. All staff participating in the provision of MDS services should be appropriately trained in the relevant policies and procedures, and re-trained where necessary following any update of a relevant policy or procedure.

The superintendent pharmacist and supervising pharmacist must be satisfied that all pharmacists practising in the pharmacy, and relevant staff members, are trained on, and are following, the relevant and up-to-date policies and procedures pertaining to the safe dispensing of medicinal products in MDS packs. Staff should receive appropriate training relevant to the type of monitored dosage system(s) used and appropriate to all levels of involvement in the process. Training should be on-going and documented.

It is essential that the pharmacy owner and/or the superintendent pharmacist ensures that there are adequate numbers of pharmacists on duty in a pharmacy to ensure the safe supply of prescription only medicines.

4. References

- The Pharmacy Act 2007
- PSI Code of Conduct for Pharmacists
- Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2011
- The Council of Europe Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care
- Misuse of Drugs (Safe Custody) Regulations 1982, as amended
- PSI Guidelines on the Disposal of Medicinal Products within a Retail Pharmacy Business
- PSI Guidelines on the Sale and Supply of Prescribed Medicinal Products from a Retail Pharmacy Business
- Church, C., Smith, J. How stable are medicines moved from original packs into compliance aids? Pharm J 2006; 276:75-81.

5. Self-Assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with these guidelines and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidelines; it is not exhaustive and should only be used to assess pharmacy practice in combination with these guidelines and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
When establishing an MDS service, are the superintendent and supervising pharmacists and management staff aware of the assessment of staff, time, equipment and resources which is necessary to ensure that an MDS service can be provided safely and appropriately?				
Have all staff received training relevant to the type of MDS used and appropriate to their level of involvement in the process?				
Does a written MDS dispensing procedure				
Is there a sufficient number of trained and competent staff allocated to the provision of this service?				
Is each medicinal product carefully assessed to establish its suitability for inclusion in the MDS?				
Are all pharmacists aware of the criteria which should be used to appraise the selection of a suitable MDS for each patient?				
Is there a designated area in the pharmacy for the safe preparation and assembly of the MDS?				
Is there suitable equipment available for the safe preparation and assembly of the MDS?				
Is the equipment used in the preparation and assembly of the MDS appropriately				
Are there reference sources available to assist pharmacists with the dispensing of MDS				
Is there comprehensive patient and MDS assembly records maintained in the retail pharmacy business?				

Are there robust documented policies and procedures in place to ensure the safety and accuracy of all aspects of the MDS service?				
Upon the supply of the MDS, do all pharmacists offer to discuss with the patient or their carer, all such matters that the pharmacist in the exercise of his/her professional judgement deems significant?				
Are returned medicinal products packed in the MDS disposed of in the correct manner?				
Are all medicinal products labelled correctly when supplied either in the MDS and/or out of				
Are Package Leaflets (PLs) for the MDS dispensed medicinal products given to				
Is informed patient consent obtained (where possible) and documented when MDS dispensing is initiated for the patient?				
Is there an appropriate storage area in the dispensary for MDS awaiting collection by patients/carers?				
Are all MDS packs containing Schedule 2 or 3 controlled drugs kept in the CD cabinet until collected by the patient?				
Is there a policy in place for pharmacists to review and reassess each patient's suitability for MDS supply at least on an annual basis?				
Is protective clothing worn by all staff members involved in the preparation of the MDS pack?				
Are the batch numbers of the medicinal products packed in the MDS recorded?				
Are all patients counselled to ensure that the dispensed MDS packs are kept out of the reach of children?				
Are all pharmacists aware of their responsibilities regarding supervision and checking of the entire MDS preparation				
Where possible, are tamper-proof MDS packs supplied to patients?				

Is appropriate supporting documentation kept at the retail pharmacy business to maintain an audit trail?				
Do all patients availing of MDS dispensing services receive the same level of professional care as all other patients?				
Is MDS only supplied to patients deemed suitable following a documented assessment by the pharmacist?				
Are all pharmacists aware of the potential liability issues that may arise as a result of the provision of MDS?				
Is the patient's prescriber aware that the patient is using the MDS?				
Are all staff aware of their duties under the Data Protection Acts 1988 and 2003 when managing confidential patient data?				