Policy on the Use of Monitored Dosage Systems (MDS) in NHS Highland

All Care Settings, NHS Highland

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Policy Reference: id1389	**Date of Issue:** April 2014
Prepared by: MDS Short Life Working Group	**Date of Review:** April 2016
Lead Reviewer: Clare Morrison and Thomas Ross, Lead Pharmacists, NHS Highland	**Version:** 2
Authorised by: Medicines Safety Subgroup of ADTC	**Date:** 2 April 2014

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Contents

	Page No.
1. Executive summary	3
2. Background	4
3. Appropriate use of MDS 3.1 When is an MDS inappropriate?	5
4. Alternative methods of improving adherence	6
5. Assessment for use of MDS 5.1 Patient assessment 5.1a Patients living in their own home 5.1b Housebound patients 5.1c Patients resident in care homes 5.1d Hospital in-patients 5.2 Medicines assessment 5.2a Specific considerations	7
6. Process for the prescribing and supply of MDS 6.1 Who should supply MDS 6.2 Practicalities of MDS supply 6.2a Patients living in their own home 6.2b Patients resident in care homes 6.2c Hospital in-patients 6.3 Practical advice on the supply of MDS 6.3a Advice for patients and/or carers 6.3b Guidance for pharmacies and dispensing practices	11
7. Review of MDS provision	14
8. Discontinuing MDS provision	15
9. Implementation plan for care homes	15
Appendix 1: Information for patients and carers	16
Appendix 2: Information for health and social care professionals and staff	18
Appendix 3: Compliance needs assessment referral form	21
Appendix 4: Compliance needs assessment tool	23
Appendix 5: Compliance needs assessment report	26
Appendix 6: Template patient medication reminder chart	27
Appendix 7: Original Pack Dispensing in Care Homes – Information Sheet	28

1 Executive summary

There are many reasons why patients are unable to manage and/or comply with their medicines. This has significant clinical, safety and financial implications.

There are also many measures that can be taken to support and help patients to manage their medicines. In many cases these will be patient specific to meet the needs of the individual and patients may have developed their own means to help them adhere to their medication regime. Patients should always be supported to manage their own medicines where at all possible.

The use of Monitored Dosage Systems (MDS) has frequently become regarded as an answer to supporting patients manage their medicines.

Whilst it is recognised that MDS may help some patients, the evidence to support this is limited. There are many situations where the use of MDS is inappropriate or unnecessary. Not all patients benefit from a MDS, indeed some may come to harm, and not all medicines are suitable for inclusion in a MDS. In addition, there are likely to be patients who could benefit from the provision of a MDS that currently are unable to access such a service.

This policy aims to address the use of MDS in all care settings in NHS Highland and details:

- When use of MDS is appropriate/inappropriate
- Alternative methods for supporting patients with their medicines
- Assessment for compliance needs in different care settings
- Processes for the prescribing and supply of MDS
- Review of MDS provision
- Discontinuing MDS provision
- Education and training requirements

This policy sets out the ideal and exemplary standards for the use of MDS. It is recognised that in many situations the current use of MDS does not meet these standards. It is therefore expected that changes to current MDS provision will take some time to implement in order to meet the standards in this policy.

In the meantime, all relevant professionals and services, should begin where at all possible to work towards the standards in this policy.

2 Background

For the purpose of this policy, monitored dosage systems (MDS) are defined as compliance aids into which solid dosage form medicines (eg, tablets or capsules), having been removed from their original packaging, are repackaged.

MDS are frequently recommended by health and social care professionals to try to improve patients' medication adherence in response to problems or concerns. They are commonly used both by patients who self-administer their own medicines and in care settings where staff administer medicines to patients. However, there are a considerable number of issues with MDS that are described below. Therefore, MDS should never be seen as the answer for addressing all adherence problems. The preference, where at all possible, should be that medicines are supplied in their original packaging.

In July 2013, the Royal Pharmaceutical Society published *Improving patient outcomes: The better use of multi-compartment compliance aids*[1]. This guidance is aimed at all healthcare professionals and highlights the need for a patient-centred approach, based on individual assessment to identify the best intervention, of which MDS is just one, that will support patients with use of medicines.

Nunney *et al* (2001)[2] identified that there is evidence of inappropriate use of MDS devices. In addition, it has been estimated that referral for use of MDS can be inappropriate in up to 80% of cases (Bhattacharaya 2005)[3].

There are a considerable number of issues related to MDS. These include:

1. Patients and/or carers should always be directly involved in decisions about their medicines and how best to manage their medicines. A discussion with a patient and pharmacist/dispensing GP should always take place before any decision is made to provide a MDS.

2. A number of other steps should be taken to improve a patient's adherence with medicines before considering a MDS. This should be informed by an individual patient assessment. At present there is an inconsistent approach to assessment and many patients are not assessed at all.

3. Not all patients have the manual dexterity or mental capacity to be able to manage a MDS.

4. When removed from original packaging, the effectiveness of some medicines can no longer be guaranteed to meet that approved under the product's licence, ie, use of an MDS is unlicensed storage. As a result, those involved in the prescribing, dispensing and administration of medicines take a greater responsibility for the patient's

[1] Royal Pharmaceutical Society. Improving patient outcomes: The better use of multi-compartment compliance aids, July 2013. http://www.rpharms.com/support-pdfs/rps-mca-july-2013.pdf [Accessed 20 January 2014].
[2] Nunney, J, Raynor, D.K. How are multi-compartment compliance aids used in primary care? The Pharmaceutical Journal 2001; 267: 784-9
[3] Bhattacharya, D. Indications for Multi compartment Compliance Aids (MCA) – also known as Monitored Dosage Systems (MDS) – provision. 2005; University of East Anglia.

response to medicines provided in MDS than if the medicines had been supplied in their original packaging.

5. Not all medicines are appropriate for MDS, eg, liquids. Not all solid oral dosage medicines are suitable for MDS, eg, medicines sensitive to moisture. This can lead to more than one system of medicines administration being in place.

6. MDS can de-skill both patients and carers in managing medicines.

7. There is no specific NHS funding for the dispensing of MDS. Pharmacists or dispensing GP practices cannot be compelled to provide medicines in MDS.

8. Use of MDS can lead to the wastage of medicines.

This policy applies to all care settings and service providers across the NHS Highland area.

3 Appropriate use of MDS

MDS may assist some patients to manage their medicines in situations where:

- The patient has difficulty accessing medication from original packaging
- The patient has difficulty following a medication regime due to factors such as:
    - Complexity of the regime as a result of the number of medicines to be taken and/or the frequency that medicines have to be taken
    - Sight impairment
    - Confusion
    - Some situations of forgetfulness
    - Learning difficulties

However, the evidence to support these benefits is limited. It is therefore essential that all patients are assessed (see appendix 4 for assessment tool) before a MDS is provided. On-going review is also required to assess on-going suitability of MDS.

3.1 When is an MDS inappropriate?

The routine use of MDS is inappropriate in the following situations:

1. Patients resident in care homes.
   The Royal Pharmaceutical Society (RPS) Scotland report *Improving Pharmaceutical Care in Care Homes Report* of March 2012[4], stated: "Due to concerns around safety, patient empowerment, effectiveness and efficiency, the RPS calls for the supply of medicines in original packs in care homes to be promoted as standard".

2. When MDS is being provided solely for the benefit of, or on the wish of, a formal/employed carer. In such circumstances reference should be made to the NHS

[4] Royal Pharmaceutical Society Scotland. Improving Pharmaceutical Care in Care Homes, March 2012 (http://www.rpharms.com/promoting-pharmacy-pdfs/rpscarehomereportfinalmarch2012.pdf - accessed April 2013)

Highland Home Carer Administration of Medicines Policy. Please note this policy is currently being updated and is not in place in Argyll & Bute.

3. Patients assessed under the NHS Highland Home Carer Administration of Medicines Policy as requiring level 3 input. Please note this policy is currently being updated and is not in place in Argyll & Bute.

4. Patients who have not been assessed for suitability for MDS.

5. Patients with intentional non-adherence to medication or poor motivation.

6. Patients who have difficulty accessing medication from a MDS due to manipulation problems or cognitive impairment* (including forgetting to take medicines in general).

7. When the medicines required by the patient cannot be placed in MDS, eg, for stability reasons (see Section 4.2 below).

8. Patients who have their medicines changed frequently. This is particularly the case for patients receiving Controlled Drugs that may require frequent dose alterations (eg, in palliative care).

The use of MDS can reduce patients' and carers' knowledge and understanding of their medicines and how to manage them.

* The Montreal Cognitive Assessment (MoCA) is a cognitive screening test designed to assist health professionals, particularly Occupational Therapists, for detection of mild cognitive impairment that can assist in identifying and targeting appropriate interventions. Further information can be found at http://www.mocatest.org/.

4 Alternative methods of improving adherence

There are no specific means of improving adherence that can be recommended for all patients as each patient has individual contributory factors. As part of the patient assessment process before provision of MDS, consideration should be given to other methods of supporting patients with their medicines, including:

1. Simplifying the medication regime through medication review, eg, reducing inappropriate polypharmacy, or reducing the frequency that medicines have to be administered such as switching to once or twice daily dosing (rather than three or four times a day).

2. Supplying medicines in packaging with appropriate closures, eg, non-click lock bottle tops or tops with winged caps.

3. Ensuring directions and warnings on labels can be read and medicines identified, eg, larger font, coloured or coded labels.

4. Providing memory aids, eg, reminder charts. A template reminder chart is provided in Appendix 6.

5. Linking medicines taking to patient's regular activities, eg, putting a reminder next to the tea bags.

6. Support from carers/relatives.

7. New technology such as reminder Apps on smartphones and use of telemedicine.

8. Finding out reasons for poor adherence (eg, side effects, misinformation about medicines or poor health literacy) and addressing them.

9. Weekly dispensing.

In addition, patients may have developed their own individual means to help them adhere to their medication regime. Patients should be supported to manage their own medicines where at all possible.

Provision of MDS should only be considered after other alternatives have been explored with the patient.

A patient information leaflet to explain methods of improving compliance and when MDS may be appropriate is available (see Appendix 1). In addition, a leaflet for health and social care professionals on the same topic is also available (see Appendix 2).

5 Assessment for compliance needs

Assessment of compliance needs comes in two parts, each of which is covered below:

1) Patient assessment
2) Medicines assessment

MDS should only be provided to patients who have been appropriately assessed and identified as having a potential benefit from an MDS device. Therefore, all patients must be assessed by a pharmacist/dispensing GP using the NHS Highland Compliance Needs Assessment Tool (see Appendix 4) before provision of an MDS is considered.

It is also important to carefully determine and consider if the medicines the patient is taking are suitable for inclusion in MDS, as described in section 4.2. In many cases, the pharmacist will have to use professional judgement to risk assess whether a medicine should be dispensed in MDS. This assessment will require consideration of any detrimental effects on the medicine in removing it from its original packaging against the potential benefits for the patient through improved adherence to their medication regime.

Specific considerations:

- Patients and carers should be advised that MDS are unlikely to be child resistant and can pose a particular risk to young children.
- Controlled Drugs should be assessed in the same way as other medicines.

5.1 Patient assessment

5.1a Patients living in their own home

Patients having difficulty adhering to or managing their medication should be referred to their community pharmacy/dispensing practice for assessment of their pharmaceutical needs. A referral form can be found in Appendix 3. A community pharmacy/dispensing GP will provide assessment for any patient referred by nurses (community or practice), GPs, hospital staff on discharge, social workers, carers (either formal/employed or informal) or the patient themselves.

Referrers should be aware that the assessment may determine that provision of MDS is neither necessary nor appropriate and that alternative advice on improving the patient's adherence to their medication regime may be offered.

The community pharmacy/dispensing practice will complete the Compliance Needs Assessment using the tool in Appendix 4 and provide an MDS only if adherence problems cannot be addressed by other methods. The pharmacist/dispensing GP may offer alternative advice as to how any pharmaceutical care issues can be addressed. The pharmacist should annotate on the Pharmaceutical Care Record tool (in the Chronic Medication Service) that a compliance needs assessment has taken place.

If an MDS is to be provided, the pharmacist/dispensing GP must check that the patient can use the MDS device. If MDS is initiated for a patient, a check should be made after one week to ensure that the patient is coping with the device, again after one to two months, and then annually to determine if MDS is still necessary and appropriate. If used MDS units are returned to the pharmacy/dispensing practice, these should be reviewed to assess compliance. This may be part of the Chronic Medication Service of the Community Pharmacy Contract.

The pharmacist/dispensing GP will inform the referrer of the outcome of the assessment using the NHS Highland Compliance Needs Assessment Report (Appendix 5).

5.1b Housebound patients

Housebound patients may require a home visit from a community pharmacist/dispensing GP for a compliance needs assessment to be carried out.

Some patients may be able to visit the pharmacy/dispensing practice with support from carers.

5.1c Patients resident in care homes

MDS should not routinely be provided to care home residents.

Care home residents who self administer their own medicines may be assessed for suitability for MDS by a community pharmacist/dispensing GP. This should follow the same processes for patients living in their own homes, including reassessment to ensure that continued use of MDS is appropriate and necessary.

In situations where a patient is moved into a care home in an emergency, care home staff should use the patient's own medication (if assessed as being appropriate) until such time when the patient can be assessed for what support they will require with their medicines.

When patients are resident in care homes for short time periods eg, for respite, care home staff should use the patient's own medication (if assessed as being appropriate) for the duration of the patient's stay.

5.1d Hospital in-patients

Patients identified as having difficulty adhering to or managing their medication while in hospital should ideally be assessed during their in-patient stay.

Where patients are being assessed in hospital, pharmacy staff should use the NHS Highland Compliance Needs Assessment Tool (Appendix 4) for determining a patient's suitability for MDS.

There are a variety of potential solutions to compliance problems but, before initiating MDS for a patient, hospital pharmacy staff are required to ascertain that the patient's usual community pharmacy/dispensing practice will be in a position to provide continuity of supply using MDS. As being in hospital is not the patient's usual environment, it is important that the patient's community pharmacy/dispensing practice will provide on-going assessment of appropriateness of MDS use after discharge.

If in-patient assessment is not possible, eg in a community hospital where there is no pharmacy service, the patient should be referred to their community pharmacy/dispensing practice for assessment post discharge. This should be undertaken by a community pharmacist/dispensing practice GP using the NHS Highland Compliance Needs Assessment Referral Form (Appendix 3).

It is the responsibility of the hospital pharmacy service to ensure that any necessary interim measures are put in place to assist the patient, until a full compliance needs assessment can be carried out in primary care.

Hospital pharmacy staff should send a copy of the completed Compliance Needs Assessment Tool to the patient's community pharmacy/dispensing practice and GP practice (if not a dispensing practice). It is anticipated that co-ordination between the patient's community pharmacist and GP will enable the Emergency Care Summary (ECS) to be updated to reflect the outcome of the compliance assessment.

5.2 Medicines assessment

The removal of a medicine from its original packaging to repackage it is an unlicensed use of the medicine. In order to obtain a product licence, the manufacturer must demonstrate that the packaging provides the medicine protection against water vapour, air and light. Manufacturers are not required to demonstrate stability of their medicines when stored in MDS.

There is no up-to-date resource that provides data on the stability of medicines when removed from and stored out of the original packaging. Stability of a specific medicine will be determined not just by the active ingredient but also by excipients and the manufacturing process itself. Therefore, products with the same active ingredient but from different manufacturers may have different stability properties.

In addition, when different medicines are placed within the same blister in a MDS, the medicines can interact. This is particularly the case when tablets and capsules are combined.

5.2a Specific considerations

When considering the suitability of medicines to be dispensed in MDS, pharmacists should consider the following:

1. In order to determine whether a medicine can be dispensed in an MDS, reliable stability data should be referred to (eg, from the manufacturer) whenever available. It should be recognised that such data may be product specific. A summary of information available in 2006 was published in the *Pharmaceutical Journal* which may be a useful reference although slightly out of date (article available at: http://www.pjonline.com/libres/pdf/articles/pj_20060121_stable.pdf).

2. Where no stability data exist, pharmacists should use their professional judgement in deciding whether to dispense a medicine in MDS. This should be based on the risks and benefits to the individual patient.

3. The following are strong indicators that a medicine may not be appropriate for MDS:
    a. The medicine is sensitive to moisture. This may be stated on the packaging or may be indicated by the presence of a desiccant in the packaging.
    b. The medicine is sensitive to light. This may be stated on the packaging or may be indicated by the packaging being dark in colour.

4. Some medicines have particular characteristics that mean they may not be suitable for use in an MDS:
    a. Medicines that require refrigerated storage.
    b. Effervescent or dispersible products (particularly sensitive to moisture).
    c. Large tablets that are difficult to fit into a compartment in MDS.
    d. Buccal and sublingual tablets that should not be swallowed whole.
    e. Cytotoxic medicines
    f. Liquid medicines.

5. Some medicines have particular requirements for use that mean they may not be suitable for use in an MDS:
    a. Medicines with the directions “as required” or “as directed”.
    b. Medicines that require specific dose timings, eg, Parkinson’s medicines.
    c. Medicines whose dose will frequently vary depending on test results, eg, warfarin.
    d. Medicines that need to be taken in a specific way so need to be easily identifiable to the patient, eg, tablets to be taken with plenty of water or after food.
    e. Administration by routes other than the oral route.

When medicines are repackaged into an MDS, they will have a significantly reduced expiry date. See section 6 for further details.

6 Processes for the prescribing and supply of MDS

Before supply, all patients must be assessed for suitability of MDS as described in section 4.

6.1 Who should supply MDS

NHS Highland recommends that MDS should be dispensed, labelled, sealed and checked by a pharmacist or dispensing GP. This is in accordance with Royal Pharmaceutical Society and legal standards.

NHS Highland does not recommend that any other health professionals supply MDS i.e. except a pharmacist or dispensing GP. However, in very exceptional circumstances where supply of MDS from neither a pharmacy nor a dispensing GP is possible, in a short-term emergency situation only, a health professional eg registered nurse may decide to supply an MDS themselves. The health professional concerned should contact their professional lead and the operational unit lead pharmacist to discuss this prior to any supply being made. Long-term supply by a professional other than a community pharmacy/dispensing practice is not acceptable.

Any professional who is considering filling an MDS should be aware of the following:

a) The patient has the right to expect that the same standards will be applied to the dispensing and supply of MDS as would be applied if the patient were receiving MDS from a pharmacy or dispensing GP practice.
b) Supply and use of MDS carries a significant risk of error.
c) Legislation requires that each time a medicine is dispensed, a current dispensing label should be applied directly to the packaging in which the medicine is dispensed. Therefore, an MDS must be supplied with current dispensing labels.
d) Removal of medicines from original packaging into an MDS is likely to be outwith the medicine's licence and therefore will result in unlicensed use of the medicine, which has implications regarding greater responsibility.
e) The supplying professional will be responsible and accountable for determining the suitability of medicines to be dispensed in MDS. This may be discussed with the pharmacy or dispensing GP practice that originally dispensed the medicines to the patient, but responsibility lies with the supplying professional.
f) The supplying professional's employer must be made aware of this activity. In addition, it must be covered by a standard operating procedure (SOP). At the time of ratification of this policy there is no SOP in place in NHS Highland to cover the dispensing of medicines in MDS by staff other than pharmacy or dispensing GP practice staff.

6.2 Practicalities of MDS supply

This section covers the practicality of MDS supply once the patient and medicine assessments (see section 4) have been completed.

6.2a Patients living in their own home

1. When a patient has been assessed as suitable for an MDS, the pharmacist should contact the patient's GP to confirm that the GP is in agreement for MDS to be provided and to arrange for prescriptions to be issued.
2. When a decision is made to provide MDS, the patient should identify one community pharmacy/dispensing practice for the supply of all medicines to ensure any issues relating to the MDS (eg, changes to medicines) are identified.
3. Prescriptions for medicines to be dispensed in MDS should be written for a maximum of 28 days' supply and should be endorsed "dispense weekly". All medicines should be synchronised to a 28-day cycle to allow for ordering of all prescriptions at the same time.
4. The GP practice should identify on the patient's record that they are receiving MDS. This should include highlighting the fact that an MDS is being used on the patient's Emergency Care Summary using a defined Read code.
5. Prescribers should be mindful that interim prescriptions (ie, provided part-way through the 28-day cycle) cannot be put in MDS immediately. If changes to the patient's medicines require changes to be made to MDS, this should be directly communicated to the community pharmacy.
6. The community pharmacy/dispensing practice should ensure they have systems in place to identify MDS patients so that, if any interim prescriptions are received, the need to change the patient's MDS is easily identified.
7. The community pharmacy/dispensing practice should carefully consider how many weeks of MDS should be prepared in advance of supply. In particular, factors such as the likelihood of changes to medication and the stability of medicines should be considered.
8. The community pharmacy/dispensing practice should ensure they have systems in place to ensure that further repeat prescriptions are requested timeously.
9. If there is no longer a requirement for MDS for a specific patient, eg, patient moves into long-term care or dies, the GP practice should inform the community pharmacy.

6.2b Patients resident in care homes

1. MDS should not routinely be provided to care home residents.
2. If a patient moves into a care home on a long-term basis, their MDS should be discontinued. Refer to section 7 (discontinuing MDS provision).
3. If care home residents self-administer their own medicines, they may be assessed as requiring MDS. For these patients, follow the process (above) for patients living in their own homes with regard to prescribing and supply.

6.2c Hospital in-patients

On admission

1. Patients should be advised to take their MDS, and all other medicines, with them on admission to hospital (refer to hospital information leaflets for admission).
2. Patients using MDS at the point of admission are identified as part of the Medicines Reconciliation Process. MDS use pre-admission is annotated on the patient's kardex in order to flag up appropriate actions at discharge. In addition, supplementary flagging mechanisms may be used locally.
3. Community pharmacies/dispensing practices should be informed when patients are admitted to hospital in order to suspend provision of MDS. It should be documented in the patient's hospital notes that this has been done.
4. If a patient brings a MDS device with them on admission, refer to the NHS Highland Policy on Patients' Own Drugs (PODs) in Hospital.

During admission

1. As per the NHS Highland Policy on Patients' Own Drugs (PODs) in Hospital, medicines should not generally be administered to patients from MDS while they are in hospital. Refer to PODs Policy for further details.
2. Patients on self-administration schemes who have been assessed as requiring a MDS and are going on temporary leave from hospital should use their MDS unless this puts the patient, or others, at risk.

At discharge

1. If there is no longer a requirement for MDS for a specific patient, eg, patient moves into long-term care, the hospital pharmacy service should inform the community pharmacy involved in the patient's care.
2. Patients discharged with a MDS supply being provided from a community pharmacy /dispensing practice:
   An up-to-date copy of the patient's medicines on discharge (along with any changes since admission e.g. medicines stopped) should be communicated to the patient's community pharmacy/dispensing GP practice and GP practice (if not a dispensing practice). This needs to be organised in advance in order to allow sufficient time for prescriptions to be generated and dispensed in primary care prior to the patient being discharged from hospital.
3. Patients discharged with a MDS supply being provided from the hospital:
   This may occur after a compliance needs assessment or in the patient's best interest purely as an interim measure. The hospital pharmacy service will provide 7-days supply of medication in an NHS Scotland approved disposable MDS, as per local protocol.
4. Medication will not be dispensed in a MDS if the patient is being discharged to a care home.

6.3 Practical advice on the supply of MDS

6.3a Advice for patients and/or carers

1. Patients and carers should be advised not to make any changes to the content of the MDS themselves. If a change is required (eg, an interim prescription has been supplied), the pharmacy or dispensing practice should be contacted to arrange for the MDS to be changed.
2. If an MDS becomes damaged, the contents appear to have been changed, or the MDS is dropped and the contents spilled, the patient/carer should be advised to return the MDS to the pharmacy or dispensing practice with a view to a replacement MDS being provided. A replacement prescription and/or MDS may need to be provided in a short timescale, including out-of-hours in order that the patient can continue with their medication.
3. MDS should be stored out of children's reach because the seal may not be child resistant.

6.3b Guidance for pharmacies and dispensing practices

1. The MDS must have a current dispensing label attached for every medicine the MDS contains.
2. Patients receiving medicines in MDS should be provided with a patient information leaflet for each medicine dispensed.
3. An expiry date should be placed on the MDS. The expiry date will depend on the stability of the individual medicines that the MDS contains (see section 4.2). If none of the medicines have special storage requirements, then a maximum expiry date of eight weeks is suggested as best practice.
4. Single use MDS must be used, rather than re-usable devices.
5. The area in which the MDS is prepared must be clean and appropriate hand hygiene must be applied.
6. Medicines should not be placed in MDS without removing the original blister packaging. There have been some cases where a single tablet/capsule has been snipped off the original pack and placed into an MDS. This has resulted in the patient swallowing the packaging with detrimental effects.
7. If an MDS contains a Controlled Drug, the MDS must be stored in a Controlled Drug cabinet until it is collected by the patient/carer.

7 Review of MDS provision

1. All patients should be assessed by their community pharmacy/dispensing practice at least annually to ensure MDS is still necessary and appropriate. This review should consider changes to the patient's medication regime as well as the patient's ability to use a MDS. The frequency of review will depend on the patient's individual circumstances.

2. The necessity and appropriateness of MDS should also be considered when there are significant changes to a patient's medication regime (eg, following a polypharmacy medication review) and/or when there are significant changes in the patient's capacity to manage a MDS (eg, a decline in mental health or cognitive function).

3. The review process should be based on the NHS Highland Compliance Needs Assessment (Appendix 4) and an assessment of how the patient is managing the existing MDS. In pharmacies, the details should be recorded on the Pharmaceutical Care Record tool which supports the Chronic Medication Service.

8 Discontinuing MDS provision

1. In situations where MDS is considered no longer appropriate or necessary, provision of MDS should be discontinued and all medicines dispensed in manufacturers' original packs instead. Good communication between professionals as part of this process is vital.

2. In situations where the patient is not self-medicating and has a formal/employed carer, provision of MDS should be discontinued and all medicines dispensed in manufacturers' original packs.

3. When MDS has been discontinued, there is no longer a need to limit supply of medicines to 28 days' supply, nor is there a need to endorse prescriptions "dispense weekly." The patient's medication record should be updated to this effect.

4. If necessary, the patient's formal/employed carer should be trained to SVQ level 2 in Medicines Administration and, in the interim in accordance with the NHS Highland Home Carers' Administration of Medicines Policy, ie, covering the use of MAR charts and original pack dispensing.

5. For care homes currently using a MDS system, a planned transition to original pack dispensing should be agreed in conjunction with the community pharmacy/dispensing practice. The care home will be responsible for ensuring staff are informed of and appropriately trained on this transition.

6. During the transition period supplies of medicines already dispensed in MDS should be used up before moving to original packs. There is no need to return these.

9 Implementation plan for care homes

A number of care homes in NHS Highland have recently been supported to move away from the routine use of MDS to having all medicines dispensed in original packs. Based on the experiences of these care homes an information sheet (Appendix 7) has been developed to support other care homes to move to original pack dispensing.

The information sheet describes some areas and issues for homes and their supplying community pharmacy/dispensing GP practices to consider and agree before moving away from dispensing in MDS. It is essential that there is discussion and agreement prior to moving to original pack dispensing.

Appendix 1:

Help With Your Medicines

Managing medicines and using Monitored Dosage Systems (MDS)
Information for patients and carers

Managing your medicines

Taking medicines in the way that you and the prescriber agree is best for your health will help you stay as well and as independent as possible in your own home. There are many reasons why people are unable, or find it difficult, to manage or to take their medicines. If you can't or don't take your medicines as intended you will not get the most benefit from your medicines. Not taking medicines can also be a safety risk to you.

There are many ways that can help and support you to manage and take your medicines. Where at all possible, you will always encouraged to manage your own medicines, sometimes with support from a relative or carer.

Help with your medicines

Many people have problems managing and taking their medicines, particularly if they have to take a number of different medicines. If you are at all unsure about your medicines or are having problems taking your medicines you should talk to your pharmacist or GP who can help.

You shouldn't think that professionals are too busy to help, or be afraid or embarrassed to admit that you are having problems, such as:

- Trouble remembering to take your medicines or not wanting to take your medicines
- Not being able to read the labels on medicines
- Not being able to handle medicines or get them out of their packaging
- Trouble swallowing medicines
- Trouble using medicines such as inhalers
- Side effects to medicines

What can be done to help?

What will help one person may not help another. There are many different ways of helping people to take their medicines as intended. To see how you manage your medicines and to decide what would best help you will be assessed.

The assessments are normally done by a pharmacist (or GP from a practice that dispenses medicines) and will simply involve asking you some questions about your medicines and how you manage them. In deciding what will help, the pharmacist or doctor will always listen to what you think would help and any decision will always be agreed with you before anything is put into place.

There are many different methods of helping people to manage or take their medicines. Some of these include:

- Reducing the number of medicines or the number of times a day medicines need to be taken. You should not stop taking a medicine without discussing it with a pharmacist or doctor first.
- Having medicines supplied in medicine bottles with ordinary tops (rather than click-lock) or in bottles with tops that have winged caps to make them easier to open.
- Large print or colour coded labels on medicines.

- A reminder chart to help you remember what medicines to take and when.
- Taking medicines at the same time as other activities, such as mealtimes.
- Support from relatives or carers.
- Providing you with more information about your medicines.
- Having medicines dispensed in a Monitored Dosage System (MDS).
- Ordering all repeat medicines at the same time.

As well as these, you may have developed your own means to help you manage and take your medicines.

Monitored Dosage Systems (MDS)

MDS are also sometimes known as Dosette® boxes, compliance aids or blister packs. They are small trays, packs or boxes into which tablets and capsules are placed in spaces for times of the day and days of the week. Most MDS hold a week's worth of medicines.



An example of a MDS

MDS can help some people take their medicines but not everyone. Some people will put their medicines into a MDS themselves, or have their relatives or carers do this for them.

When a MDS is being prepared by a pharmacy or dispensing GP practice, it is recommended that people are assessed to find out whether a MDS is suitable for them and their medicines.

There are many situations when a MDS will not help a person with their medicines. In some cases MDS might make medicines taking more difficult or even dangerous for a person. This is why it is important that patients are assessed before using a MDS. There are many medicines that cannot be put in MDS such as inhalers, liquid medicines, eye drops etc. Many tablets and capsules cannot be put into a MDS because they need to be protected from moisture, air or light.

When are MDS useful?

MDS may help some people with their medicines, for example:

- When a number of medicines have to be taken
- When medicines have to be taken at a number of different times during the day
- When people have difficulty getting medicines out of their packaging
- When people have poor eye sight
- When people have learning difficulties
- When people sometimes forget to take their medicines or get confused about their medicines

MDS will not be useful or helpful when a person:

- Does not want to take a medicine
- Has difficulty getting medicines out of packaging due to handling problems or cognitive impairment
- Is taking medicines that cannot be placed in MDS
- Has their medicines and/or the dose of their medicines changed frequently

And remember… If you are at all unsure about your medicines or you are having problems taking your medicines, you should always talk to your pharmacist or GP who can help.

Appendix 2:

Managing Medicines and Monitored Dosage Systems (MDS)
Information for health and social care professionals and staff

This information sheet aims to summarise the key points in the Policy on the Use of MDS in NHS Highland. Professionals and staff should refer to the policy for further information. The policy sets out the ideal and exemplary standards for the use of MDS. It is recognised that making changes to current MDS provision will take some time to implement but, in the meantime, all professionals and staff should begin to work towards the standards in the policy.

What can be done to help people with their medicines?

There are many reasons why people are unable, or find it difficult, to manage or take their medicines. This has significant clinical, safety and financial implications. There are many different methods of helping people to manage or take their medicines. Some of these include:

- Reducing the number of medicines or the number of times a day medicines need to be taken.
- Having medicines supplied in medicine bottles with ordinary tops (rather than click-lock) or in bottles with tops that have winged caps to make them easier to open.
- Large print or colour coded dispensing labels on medicines.
- A reminder chart to help people remember what medicines to take and when.
- Taking medicines at the same time as other activities, such as mealtimes.
- Support from relatives or carers.
- Finding out reasons why people do not take their medicines and addressing them.
- Providing people with more information about their medicines.
- Having medicines dispensed in a Monitored Dosage System (MDS).

As well as these, individuals may have developed their own means to help them manage and take their medicines. People should always be supported to manage their own medicines where at all possible. Provision of MDS should only be considered after other alternatives have been explored.

Assessment

In order to determine what will best help a person manage and take their medicines it is strongly recommended that patients are assessed, particularly if use of MDS is being considered. Assessments are normally conducted by a pharmacist (or dispensing GP) and any health or social care professional or other member of staff can refer someone for an assessment. People can also refer themselves.

The assessment will look at how the person manages their medicines and what means/method of support is best for the individual. The assessment will also look at the medicines the person is taking. Not all formulations of medicine are suitable for inclusion in a MDS e.g. inhalers, liquids, etc. However, many tablets and capsules cannot be put in a MDS either e.g. if they are sensitive to light, air or moisture they can degrade quite quickly. In addition, when different medicines are placed next to one another, they can interact.

When a person first starts to use a MDS it is important that they are contacted one or two weeks after starting to check how they are managing with the MDS. Thereafter, people should be assessed at least annually to ensure MDS is still necessary and appropriate.

The necessity and appropriateness of MDS should always be considered when there are significant changes to a person's medication regime (e.g. following a polypharmacy medication review) and/or when there have are significant changes to a person's capacity to manage a MDS (e.g. decline in mental health or cognitive function).

Monitored Dosage Systems (MDS)

Whilst a MDS (also known as Dosette® boxes, compliance aids or blister packs) may help some people, the evidence to support this is limited. MDS are commonly recommended by health and social care professionals and staff to try to improve how a person manages and takes their medicines but they should never be seen as the answer for addressing all adherence problems.

There are many situations where the use of MDS is inappropriate or unnecessary. Not everyone benefits from a MDS, indeed people can come to harm if they use a MDS incorrectly. Also, there are some people who could benefit from the provision of a MDS that currently are unable to access such a service.

Issues and difficulties with MDS include:



An example of a MDS

- People and/or their carers should always be involved in decisions about their medicines. Use of MDS should always be discussed before being provided. Currently, this is not always the case.
- As above, people should be assessed before MDS is provided to determine if it is suitable for both them and their medicines.
- Frequently, other steps can be taken to help a person manage and take their medicines before MDS need be considered.
- Not all people have the manual dexterity or mental capacity to manage a MDS.
- Often, removing a medicine from the original packaging is unlicensed use of the medicine. As a result, those involved in the prescribing, dispensing and administration of such medicines take greater responsibility.
- Not all medicines are appropriate for MDS e.g. liquids, but also tablets and capsules that are sensitive to air, moisture or light. This often leads to more than one system of medicines administration being in place for one person.
- MDS can de-skill people and carers in managing medicines.

Appropriate use of MDS

MDS may help some people, such as those who:

- Have difficulty accessing medicines from original packaging
- Have difficulty following a medication regime due to factors such as:
    - Complex medication regimes due to the number and/or the frequency of medicines to be taken
    - Sight impairment
    - Confusion
    - Some situations of forgetfulness
    - Learning difficulties

Inappropriate use of MDS

The routine use of MDS is inappropriate for:

- People resident in care homes
- When MDS is being provided solely for the benefit of, or on the wish of, a formal/employed carer
- People who have not been assessed for suitability for MDS
- People with intentional non-adherence or poor motivation to take their medicines
- People who have difficulty using a MDS due to poor manual dexterity or cognitive problems.
- People who have their medicines changed frequently.

Prescribing and supply of MDS

The Policy on the Use of MDS provides detailed advice but some key points include:

- MDS should be dispensed, labelled, sealed and checked by a pharmacist or dispensing GP.
- It is not recommended that any other professionals or staff supply MDS, except a pharmacist or dispensing GP.
- For patients living in their own home:
    - Prescriptions for medicines to be dispensed in MDS should be written for a maximum of 28 days' supply and should be endorsed "dispense weekly".
    - Prescribers should be mindful that any changes made to medicines should be communicated to the community pharmacy so that changes can also be made to MDS e.g. if a medicine is stopped.
- For people resident in care homes:
    - MDS should not routinely be provided to care home residents.
    - It is recommended that the routine use of MDS in care homes is phased out and, instead, medicines are dispensed in their original packs.
- For people admitted to/being discharged from hospital:
    - People should be advised to take their MDS, and all other medicines, with them into hospital.
    - Community pharmacies/dispensing GP practices should be informed when people are admitted to hospital to suspend the provision of MDS.
    - Supply of MDS on discharge needs to be organised in advance with the MDS being supplied by either the hospital pharmacy or the patient's community pharmacy/dispensing GP practice, depending upon local circumstances.
- If a MDS contains a controlled drug that legally is required to be stored in a controlled drugs cabinet, the whole MDS should be stored in a controlled drugs cabinet.
- People and carers should always be advised never to make any changes to a MDS themselves. If a change is made or the MDS is damaged, it should be returned to the pharmacy/dispensing GP practice.

Appendix 3: Compliance Needs Assessment Referral Form

A community pharmacist/dispensing GP need to know a number of details in order to complete a full compliance needs assessment. The form can either be completed by the referrer, or the referral can be made by telephone and the pharmacist/dispensing GP can use this form to record the details. Referrals can be made by: nurses, GPs, hospital staff on discharge, social workers, carers or the patient.

NHS Highland/National Pharmacist Compliance Needs Assessment Package (NPCNAP)
Multi-agency Referral Form

Patient name:_____ DOB: _____

Address: _____

Telephone: _____ CHI Number: _____

Lives alone- Yes / No (circle) House bound- Yes / No (circle)

Informal carer input (if applicable):_____

Relationship to patient:_____ Telephone:_____

Contact address (if different from above):

Community pharmacy/dispensing practice: _____

Address:_____

Telephone number: FAX number:

Social Care/professional carer input (if applicable)**:**

Designation:_____

Address:_____

Telephone: Visit frequency: daily or times per week (*circle)*

General practitioner:_____

Address:_____

Telephone number:_____ FAX number:_____

Referral details

Patient referred by Contact number Date

Relevant Medical History: circle as appropriate

Stroke, arthritis, high blood pressure, cataract, glaucoma or history of falls/fractures

Other_____

_____

Current Medication:

If available please attach GP repeat medication slip/computer print-out of the home visit summary and attach to this referral form. Alternatively, complete the table below including non-prescription medicines.

Name of medication	Form	Dose	Times of administration

Reason for assessment: **Circle as appropriate**

1. Is patient taking their medication as prescribed? Yes No
2. Does the patient understand why they are taking medication? Yes No
3. Patient has difficulty opening bottles/foil pack? Yes No
4. Patient has difficulties with ordering repeat medication? Yes No
5. Patient cannot read labels/ patient information leaflets Yes No
6. Is the patient confused or forgetful? Yes No

Comments_____

_____

The pharmacist/dispensing GP assessor will contact patient/carer to arrange an appointment and will inform you of the result of the assessment.

Appendix 4: Compliance Needs Assessment Tool

This form should be used by community pharmacists/dispensing GPs/hospital pharmacists when completing a compliance needs assessment.

NHS Highland Compliance Needs Assessment		
Pharmacy/disp prac name Tel:	Assessor's name Signed Date	Duration of assessment Location of assessment Source of referral MDS provided Y / N

Patient consent before the assessment: I understand the purpose of the assessment and agree to participate		
Patient name	Signature	Date

Section 1: General information		
Patient name	CHI	GP
Patient address	Initial assessment Y/N	Review Y/N

Section 2: Medication details	
Number of regular medicines	
Number of times per day medicines are taken Can this frequency be reduced?	
Number of "as required" medicines	
Number of "as directed" medicines Can instructions be added?	
Is regimen stable? (eg, are any drugs being titrated?)	
Are all drugs suitable for inclusion in an MDS?	

Section 3: Ability to manage medicines

	Yes	No	Comments
1. Who orders repeat prescriptions?			
2. Who collects repeat prescriptions?			
3. Does your medication ever run out?			
4. Can you tell me what your medication is for?			
5. Can you tell me when you take your medicines?			
6. Do you ever forget to take your medicines? *(circle)*			Never frequently sometimes
7. Do you ever choose not to take your medicine? *(circle)*			Never frequently sometimes
8. Does anyone/thing help remind you to your medicines?			
9. Can you open child resistant tops?			
10. Can you open foil blisters?			
11. Can you read the labels/ patient information leaflets?			
12. Can you measure liquids? (if appropriate)			
13. Can you use inhalers/eye drops? (if appropriate)			
14. Can you swallow all of your medication?			

Section 4: Compliance aid assessment

Have the following methods of improving compliance been tried?	**Yes/no**
Simplifying medication regime	
Easier packaging	
Large font labels	
Memory aids (reminder charts, advice, new technology)	
Support from carers/relatives	
Weekly dispensing	

Section 5: Ability to use an MDS (if appropriate)	
Following a demonstration of an MDS:	**Yes/no**
Do you find it easier to take the tablets out of the MDS than the packets you have now?	
Do you know today's date? Can you identify each dose in the MDS? (eg, ask patient to find Tuesday lunchtime hole)	
Do you understand how to take medicines that cannot be put into the MDS?	

Section 6: Pharmacist/Dispensing GP recommendations	
The compliance assessment shows the patient requires:	**Tick as appropriate**
A simpler medication regime (please be specific on how existing medicines can be simplified)	
A memory aid (please specify, eg, reminder charts, advice, new technology)	
Easier packaging (please specify, eg, non-click lock bottles)	
Large font labels	
Weekly dispensing in original packaging	
Monitored dosage system	
Care at Home assisted support (please tick): Ordering/collection of medicines Prompting to take medicines Assistance to take/use medicines (specify assistance)	
Referral to GP for a Care at Home managed support assessment	
No further assistance	
Pharmacist/dispensing GP name and signature	Date
Date for follow up	

Patient consent after the assessment: I agree with the outcome and the assessment and agree for the outcome to be shared with other agencies (eg, GP, hospital, Care at Home service, carer, care home).		
Patient name	Signature	Date

If completed in hospital, a copy of this completed form should be sent to the patient's community pharmacy/dispensing GP practice and GP practice (if not a dispensing practice).

Please now complete the Compliance Needs Assessment Report Form, sending copies to the patient's GP and Care at Home Service (if appropriate).

Appendix 5: Compliance Needs Assessment Report

This form should be used by the pharmacist or dispensing GP who has assessed the patient for medicines compliance to report the outcome of a compliance needs assessment to the patient's GP and/or the person who referred the patient for assessment.

NHS Highland **Care at Home Needs Assessment Report**	
Patient name	Patient's GP
Address	Patient referred for compliance needs assessment by (name and designation)
CHI	

Dear (delete) Care at Home Service Manager/GP/Community Pharmacist/Other_____

A. I have identified that the above patient referred to me for medicines needs assessment has the following problem(s). This **will/ will not** require any action from you **please indicate if you agree to the proposed action and return to the pharmacy/dispensing practice.**

Medicines issue	Action taken or proposed action	Agreement Y/N

B. I have been **unable** to identify/resolve the patient's problems for the following reasons

Assessor details

Practice/pharmacy name: Address: Tel:	Assessor's Name: Signed Date:	For GP/Pharmacy/Care at Home use (Action, File, Patient to attend etc)

PLEASE ENSURE THE FOLLOWING PEOPLE HAVE A COPY OF THIS FORM:
GP / COMMUNITY PHARMACY / CARE AT HOME SERVICE (IF APPLICABLE)

Appendix 6: Template Patient Medication Reminder Chart

Please list all medicines including inhalers, eye/ear drops, patches, injections, etc. A new form must be provided each time medicines are changed.

Patient's name:_____ **Date form completed:**_____

Patient's date of birth:_____ **Pharmacy/dispensing practice name:**_____

Name of medicine (attach labels here)	Times of administration				Additional information (eg, what this medicine is for)
	Morning	Midday	Teatime	Night	

Appendix 7: Original Pack Dispensing in Care Homes – Information Sheet

Introduction

In line with national guidance NHS Highland now recommends original pack dispensing, as opposed to the routine use of Monitored Dosage Systems (MDS), for care home residents. The routine use of MDS in care homes is no longer recommended. This information sheet describes why this change is being made.

Background

In recent years a number of key national documents have recommended that medicines for people resident in care homes be dispensed in original packs. The Royal Pharmaceutical Society (Scotland) document Improving Pharmaceutical Care in Care Homes states that: "Due to concerns around safety, patient empowerment, effectiveness and efficiency, the RPS calls for the supply of medicines in original packs in care homes to be provided as standard."

The Care Inspectorate has been involved in the development of some of these national documents and supports the dispensing of medicines to care homes in original packs as standard.

NHS Highland has developed a Policy on the use of MDS in NHS Highland. This policy lists a number of issues related to the MDS. For care homes the issues of particular relevance are:

- Many medicines are not appropriate for MDS e.g. liquids. Also, not all solid oral dosage medicines are suitable for MDS e.g. medicines sensitive to moisture and light. This often leads to more than one system of medicines administration being in place – combining MDS and original packs.
- When removed from original packaging, the effectiveness of some medicines can no longer be guaranteed to meet that approved under the product's licence; use of an MDS is often unlicensed storage of a medicine. As a result, those involved in the prescribing, dispensing and administration of medicines take greater responsibility for medicines provided in MDS than if the medicines had been supplied in their original packaging.
- Use of MDS can lead to the wastage of medicines.

In addition:

- When dispensed in MDS best practice advises that medicines should be given a maximum expiry date of only eight weeks.
- When dispensed in original packs, medicines are much easier to identify so reducing the risk of errors.
- Medicines dispensed in original packs will come with the patient information leaflet which provides care staff with useful information about how the medicine should be taken or used and how it should be stored, as well as information on potential side effects, interactions and contraindications. This saves care homes having to keep file copies of these information leaflets.
- Having most of a person's medicines in one bag along with the up-to-date medicines administration record (MAR) chart makes checking-in of the medicines much more accurate, and so safer, and quicker for care home staff.

Recommendations

For the reasons mentioned above NHS Highland strongly recommends that care homes currently using a MDS system should plan, along with their supplying community pharmacy/dispensing GP practice, to move to dispensing of medicines in original packs.

With a significant number of medicines being unsuitable for MDS all care homes will already be handling and administering medicines that are dispensed in original packs. As a result most processes and procedures in managing medicines should not need to change.

NHS Highland has been working with a small number of care homes to pilot the move to original packs and, from this, we have listed below some considerations for care homes and supplying community pharmacies/dispensing GP practices to think about.

Considerations for moving to original pack dispensing
It is important to highlight that original pack dispensing is nothing new and all care homes will already be handling and administering medicines that are in original packs e.g. liquids, inhalers, eye drops etc.

This sheet gives some areas and issues for homes and their supplying community pharmacy/dispensing GP practices to consider and agree before moving away from dispensing in MDS. It is essential that there is discussion and agreement prior to moving to original pack dispensing.

Ultimately it is the responsibility of the Care Home Manager to ensure that all relevant staff within their service have access to and receive training in the management and administration of medicines, and are competent. Information and, if necessary, training on the move to original pack dispensing should be provided to all relevant staff. Community pharmacies may be able to provide support with training.

1. Avoiding waste
    - A start date for original pack dispensing will be agreed (see Process section below). As long as medicines are still prescribed for individuals and those medicines are within their expiry date, they should be used up before ordering new stock; this includes medicines packaged in a MDS. Medicines must not be returned/disposed of unnecessarily.
    - Stocks of medicines still being prescribed for individuals and still within their expiry date should be carried over into the next month. IT IS UNACCEPTABLE TO RETURN A MEDICINE FOR DESTRUCTION UNNECESSARILY AND, AT THE SAME TIME, REQUEST A NEW SUPPLY.
    - Prescriptions for regular medicines should be issued together in quantities limited to 28 days supply at a time. Prescriptions for “when required” medicines should be issued in reasonable quantities to cover 28 days treatment. It may be necessary to contact the GP practice to have prescription quantities synchronised.
    - All MDS packs have, once dispensed, an expiry date of eight weeks whereas original packs tend to have much longer expiry dates. Original packs from manufacturers will all have the expiry date printed on them. This will help reduce waste.

2. Process
    - The care home should discuss and agree a start date for original pack dispensing with their supplying community pharmacy/dispensing GP practice.
    - Most homes work to a 28-day cycle for medication. Where at all possible the same 28-day cycle should be maintained i.e. timescales for ordering, receiving and starting a new medication cycle.
    - There should be no need for 28-day medication cycles to change.

3. Storage of medicines
    - All medicines for an individual should be stored together. Exceptions to this are controlled drugs (CDs) that require secure storage in a CD cabinet, medicines that require to be stored in a fridge and bulky items.
    - There are a number of different ways to store medicines securely and a variety of storage equipment available. Common examples include:
        - Individual locked metal cabinets that are attached to a wall. These cabinets hold all medicines for one person and are commonly located in the person’s room.
        - A lockable metal trolley that can be secured to a wall when not in use. These are available to hold medicines for a number of people but in individual trays/boxes within the trolley.
    - Care homes should determine what system is most suitable and practical for them so that medicines can be dealt with safely and easily, whilst remaining secure. Factors such as the physical layout of the home and where individuals have their medicines administered to them e.g. in their own room, are important factors to consider.

4. Dispensing
    - All medicines for each individual person should be packaged in individual dispensing bags along with any new copies of printed MAR charts. Exceptions to this are controlled drugs (CDs) that require secure storage in a CD cabinet, medicines that require storage in a fridge and bulky items.

5. Checking in medicines
    - As above, community pharmacies and dispensing GP practices have been asked to dispense all medicines for each individual person in individual dispensing bags along with any new copies of printed MAR charts. Exceptions to this are controlled drugs (CDs) that require secure storage in a CD cabinet, medicines that require storage in a fridge and bulky items.
    - All medicines, by law, received into a care home have to be checked in and a record kept of what has been received. This is normally recorded on the MAR chart.
    - Having most of a person's medicines all together along with their new MAR chart will make the checking in process much more accurate, and so safer, and quicker.
    - Remember that some controlled drugs also require to be recorded in a controlled drugs register.