Monitored dosage systems: guidance

The information contained within this document is in line with the current Data Protection Act (DPA) requirements. This information may be subject to change upon implementation of the General Data Protection Regulations (GDPR) on 25th May 2018.

Introduction

The purpose of this guidance is to assist pharmacists in making decisions about the appropriate supply of a monitored dosage system (MDS) as an auxiliary aid for patients. This is applicable for the supply of an MDS to those who are eligible under the Equality Act 2010 or to patients who request an MDS for convenience. The guidance will also support pharmacists when assessing which medicines are suitable for inclusion in an MDS and outlines the requirements to be considered to ensure that medicines are dispensed safely. The term "MDS" used in this guidance covers dosette boxes, medicine trays, compliance aids, blister packs and pill dispensers.

When supplying medicines to patients in an MDS, the pharmacist must be satisfied that they are meeting the General Pharmaceutical Council (GPhC) standards outlined in the "*Standards of conduct, ethics and performance July 2012*" and "*Standards for registered pharmacies September 2012*".

Legislation

As well as meeting the GPhC standards, pharmacists providing medicines in an MDS must ensure that they comply with all legal requirements including those covering medicines legislation, health and safety, data protection and the Equality Act 2010. Relevant legislation includes:

- Equality Act 2010
- The Human Medicines Regulations 2012
- The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008
- The Misuse of Drugs Regulations 2001 and amendments
- The Misuse of Drugs (Safe Custody) Regulations 1973 and amendments
- The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (Schedule 4 Terms of service of NHS pharmacists)

Definition of disability

Disability is a physical or mental impairment that has a substantial and long-term adverse effect on the ability of a person to carry out normal day-to-day activities.

A disabled person is defined as "*a reference to a person who has a disability*".

The Equality Act 2010 requires pharmacists to determine what reasonable adjustments can be made within the pharmacy to overcome obstacles which prevent persons with a disability from receiving goods and services. The provision of an auxiliary aid such as an MDS is one way of providing an adjustment if this is deemed necessary, to ensure that a patient with a disability is not at a disadvantage compared to someone without a disability.

The Department of Health has commissioned a non-official, Disability Discrimination Act (DDA) resource kit with assessment forms that can be used by pharmacists; completion of these may help

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in determining whether, and what type of adjustment a patient requires, however completion of the assessment forms is not mandatory.

Prescriptions and payments

Pharmacists cannot charge patients with a disability (as defined under the Equality Act 2010) for the provision of any reasonable adjustments. Currently in Wales, Practice Payments payable to pharmacists include a contribution towards the provision of auxiliary aids for patients eligible under the Equality Act 2010. This means that these eligible patients should not be charged for the provision of auxiliary aids in Wales. In England, a Single Activity Fee incorporates payment for the provision of auxiliary aids.

NHS prescriptions ordering 28 days treatment should be dispensed on one occasion (except for instalment prescriptions); this also applies to medicines provided in an MDS. The Terms of Service of NHS pharmacists do not impose a requirement to dispense into an MDS or to dispense in instalments (other than instalment prescriptions for the treatment of substance misuse clients). Therefore, if a prescription is received for 28 days treatment, the pharmacist should supply 1 x 28 days in an MDS or 4 x 7 day MDSs on one occasion. The prescription would attract one professional fee only.

Occasionally, a patient may benefit from having their medicines dispensed at shorter intervals, for example, weekly. This may be because of the following:

- The stability of the medicines may only be guaranteed for short periods of time outside of the manufacturer's original packaging
- The patient is at risk of deliberate or accidental self-harm by taking all their medicines in one go
- There may be risk to the patient or others (for example, young children or animals) from having a large quantity of medicines in the home
- The patient may require a change in either dose and/or the medicines which they are taking (once the MDS has been dispensed, new medicines should not be added, nor unwanted medicines removed)
- The patient who may be regularly admitted into hospital possibly resulting in changes to the medicines

In these circumstances, where it is in the patient's best interests to do so, the prescriber should be contacted to arrange prescriptions with a shorter prescribing interval. It will, however, be the prescriber's decision if they choose to prescribe in this manner.

Patients may request for their medicines to be put in an MDS for convenience rather than because they are eligible to receive them in this way under the Equality Act 2010. Pharmacists are entitled to charge the patient in these circumstances. The pharmacist should also consider that medicines taken outside of the manufacturer's packaging will not be covered by the manufacturer's product licence and so the prescriber should be notified of the patient's wishes as they may wish to monitor the patient. In addition, the pharmacist should consider whether the prescriber would be willing to issue a new prescription should there be any changes to the patient's medicines part way through the prescription. The prescriber may not be willing to issue a new prescription in these circumstances.

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MDS suitability

Before supplying medicines in an MDS to a patient, either for convenience or under the Equality Act 2010, there are a number of factors that must be taken into account, taking into consideration both the patient and the medicine(s).

Patient characteristics

When dispensing medicines into an MDS, the aim is to encourage and support a patient's medicine adherence and compliance. However, an MDS may not be appropriate for all patients. Each patient identified to have compliance issues should be reviewed to understand the underlying causes for poor compliance on an individual, case-by-case basis. This may be achieved by conducting an annual or intervention Medicines Use Review (MUR) in England and Wales, for example.

Following a review process, it may be found that an MDS is not the most appropriate option for the patient and other supportive measures may be more suitable, such as;

- Adjusting the timings of doses to simplify the regime
- Using easy open or non-child resistant containers for those with arthritis
- Increasing the patients understanding on the importance of each medicine in regards to maintaining their health
- Using larger font labels to assist partially sighted patients
- Reducing the number of medicines the patient is taking
- Using reminder charts

Along with identifying current compliance issues and the contributing factors, information gained from a review may assist with the preparation of an MDS that is tailored individually for the patient. For example, by ascertaining the time of day the patient usually takes each medicine (following the prescriber's instructions), will allow the pharmacist to dispense the MDS in line with the patient's preference.

Others factors to consider before deciding whether to supply medicines in an MDS are shown in Table 1 below.

Table 1: Factors to consider before deciding whether to supply medicines in an MDS

Does the patient understand how to use an MDS?	Although an MDS may appear to be a simple system, some patients may not understand how to correctly follow the dosing schedule of an MDS. Therefore, an explanation of how the days and daily timings are set out should always be provided. If a patient is unable to understand and use an MDS correctly, this may not be an appropriate choice and could lead to incorrect administration.
Can the patient physically use the MDS?	The pharmacist should ensure that the patient has no physical impairment, for example, arthritis or manual dexterity issues that would prevent a patient from opening and safely accessing their medicines stored in an MDS. Consider providing larger MDSs that may be easier to handle and open.
Are there children in	Medicines can be supplied in a non-child resistant container, in accordance

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the household where the MDS is stored?	with a prescription by a practitioner under The Human Medicines Regulations 2012. However, this practice should only take place where it is not reasonably practicable to provide medicines in a child resistant container or to assist the use by a patient or carer. The pharmacist must review the possible risks of a child obtaining medicines from an MDS and should therefore advise the patient on safe storage of the MDS out of sight and reach of children.
How will medicines not stored in an MDS, such as those taken 'when required', or items to be stored between 2-8°C be managed?	Not all medicines will be suitable to be stored in an MDS. This may be due to physical properties of the formulation or medicines which are required to be taken on a 'when required' basis. In this situation the pharmacist would need to consider alternative ways to support the patient's adherence of these items and ensure they are taken correctly and safely. These medicines can be taken, alongside the medicines in the MDS, for example or by supplying a medicine administration record (MAR) chart.

Finally, as part of the General Pharmaceutical Council's document '*Standards of conduct, ethics and performance July 2012*', a pharmacist should encourage patients to participate in decisions about their care. By providing an explanation of all the options available to the patient, this allows them to make an informed decision about using an MDS.

Medicine characteristics

Before dispensing medicines into an MDS, each solid dosage form must be deemed suitable to be stored outside of its original packaging by the pharmacist; this applies to both branded and generic medicines. In most cases, manufacturers will not guarantee the stability of the medicines outside of the original packaging and storage of the medicine in an MDS is commonly viewed as being outside of the product licence. This has implications on the liability for both the prescriber and pharmacist if the stability or efficacy of a product is compromised while stored outside of the product licence and manufacturer's recommendations.

Based on the knowledge of the chemical and physical properties of medicines and storage requirements, there are certain dosage forms that are known to be unsuitable for storage in an MDS and these are shown in Table 2 (this list is not exhaustive).

Table 2: Dosage forms unsuitable to be stored in an MDS (this list is not exhaustive)

Formulation type/medicine properties	Reason	Examples
Dispersible/soluble tablets	Hygroscopic in nature and therefore susceptible to degradation when exposed to moisture	• Aspirin dispersible tablets • Prednisolone soluble tablets
Orodispersible/buccal tablets	Hygroscopic in nature and must be distinguishable from other tablets as they are not to be swallowed	• Zyprexa Velotab® orodispersible tablets • Prochlorperazine buccal tablets

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Cytotoxic medicines	Risk to pharmacy staff and/or patient/carer on exposure during handling	• Colchicine • Letrozole
Medicines requiring temperature control	Require storage between 2-8°C or have limited stability when stored at room temperature	• Nardil® (phenelzine) tablets (to be stored at 2-8°C unless during unavoidable excursions for short periods) • Fludrocortisone acetate tablets (can be stored for up to 30 days at room temperature/25°C)
Medicines packaged with a desiccant	Due to a formulation's hygroscopic nature, some original packs contain a desiccant which acts as a drying agent	• Nicorandil tablets (desiccant linked to each tablet in the blister strip) • Pradaxa® (dabigatran) hard capsules (desiccant is within bottle lid)
Medicine that cause skin reactions on handling	Risk of skin reactions to staff, patients and/or carers upon direct contact	• Creon® (pancreatin) Micro • Chlorpromazine tablets

Where available, manufacturer's stability data on storage outside of the original packaging or in an MDS should be utilised to make an informed decision on a medicine's suitability for storage in an MDS. UK Medicines Information (UKMI) provides general information on medicine stability in MDSs on the Specialist Pharmacy Service (SPS) website. This has been developed using manufacturer's information, including the Summary of Product Characteristics (SPC), for branded and generic medicines, known stability characteristics of medicines and available data on storage in an MDS. Although general information is provided, pharmacists should use their own professional judgement before deciding whether to store a medicine in an MDS.

The table below provides examples of risk minimisation strategies for storing medicines in an MDS.

Table 3: Risk minimisation strategies for storing medicines in an MDS

Risk factor	Risk mitigation advice
Light sensitive medicines	• Avoid exposure to direct light • Store in dark conditions • Store in a light resistant container
Moisture sensitive medicines	• Store in dry conditions • Avoid humid environments such as kitchens and bathrooms or next to heat sources
Heat sensitive medicines	• Store below 25°Cs/or at room temperature • Do not store near direct heat sources
Air sensitive medicines	• Minimise exposure to air • The MDS should be an airtight container, with individually opening compartments to reduce exposure to medicines in other compartments

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Pharmacists may choose to consider dispensing some medicines into an MDS with the blister or foil packaging still intact, so the product remains in its original packaging, maintaining its stability. However, undertaking this practice carries other risks, such as the patient mistakenly swallowing the medicine whilst still in the foil. Where this has occurred, there are reports of perforation of the stomach and serious harm to the patient; therefore the pharmacist must ensure the patient and/or carer(s) are aware that the blister/ foil must be removed prior to administration.

Table 4 below highlights key examples of medicines and their suitability for storage in an MDS.

Table 4: Examples of medicines and their suitability to be stored in an MDS

Example	Suitability	Reasons	Action/other considerations
Adcal® D3 chewable tablets	Suitable	Stability data available to support storage in an MDS	• Store for up to 14 days in an MDS • Ensure patient and/or carer(s) understand it is to be chewed not swallowed
Epilim® and Epilim Chrono® tablets (sodium valproate)	Only if benefit outweighs the risk	No stability data available but theoretical concerns	• Protect from moisture and humidity • Prepare on a weekly rather than monthly basis
Fosamax® tablets (alendronic acid)	Unsuitable	No stability concerns but dosage regimen makes it not suitable for administration from an MDS	Consider how a patient/ carer would identify the tablet from others (required to be taken on an empty stomach before other medicines and remain upright for at 30minutes after)
Janumet® tablets (metformin and sitagliptin)	Suitable	Stability data available to support storage in an MDS	Protect from light Can be stored in an MDS for up to 28 days
Madopar® capsules (co-beneldopa)	Only if benefit outweighs the risk	• No stability data available but theoretical concerns • Original pack contains a desiccant	• Protect from moisture and store in an MDS for a maximum of seven days • Complex regimens may deem it unsuitable but consider this against the patients needs
Madopar® dispersible tablets (co-beneldopa)	Unsuitable	Stability data available to confirm dispersible formulation is inappropriate for storage in an MDS	In addition to stability information, the patient must understand that the tablet is not to be swallowed
Persantin® capsules (dipyridamole)	Only if benefit outweighs the risk	No stability data available but theoretical concerns	Protect from air and light

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Proscar® tablets (finasteride)	Unsuitable	Tablets, particularly crushed or broken, should not be handled by pregnant women or those of child bearing potential due to teratogenic risks from exposure	• Store in original packaging to prevent exposure • If deemed necessary, risk minimisation procedures should be in place such as wearing protective clothing while handling
Risperdal® tablets (risperidone)	Only if benefit outweighs the risk	No stability data available but manufacturer does not recommend storage in an MDS	Lack of data to support storage outside the original packaging but there are no theoretical concerns
Marevan® tablets (warfarin)	Only if benefit outweighs the risk	No stability data available but theoretical concerns	• Protect from air, light and moisture • Possibly unsuitable due to complex dosing regimes, for example regular dose changes

MDS – further adjustments

Dispensing medicines into an MDS may not provide the full support for a patient to adhere to their medication regimen. Depending on patient need, a suitable MDS system with additional adjustments may be required. For example:

- Visually impaired patients may benefit from an MDS with larger font or Braille print
- Patients who have difficulties with reading and writing may require an MDS that is colour coded or use illustrations to represent the times of the day
- Some patients may require an MDS with removable days or portable systems if they are required to carry medicines themselves, for example, those who attend respite care for a day
- Patients with dexterity, motor or movement issues may benefit from a larger MDS that is easier to handle and open, for example, those patients with arthritis or Parkinson's disease
- Patients with memory impairment, such as dementia, may benefit from reminder charts or automated pill dispensers (that provides medication to a patient on the specified day at the pre-set time)
- Other reminder technologies include voice reminder alarms and vibrating watches to alert patients to when medicines are due to be taken

Practical guidance

Table 5 below highlights further practical points for consideration when preparing and supplying medicines in MDSs.

Table 5: Practical points for consideration

Controlled Drugs (CDs)	There are no legal restrictions on dispensing CDs in an MDS. If a pharmacist decides to supply CDs in an MDS there are a number of points to consider: ○ Ensure the supply meets all legal requirements for CDs as stipulated in The Misuse of Drugs Regulations 2001 and amendments

	○ If the MDS contained a CD which requires safe custody, the entire MDS would need to be stored in the CD cabinet until collection ○ The pharmacist should establish if storage in the CD cabinet is feasible, bearing in mind the size of the CD cabinet ○ For CDs which require CD register entries to be made, these are to be completed only when the MDS has been supplied to the patient or representative
Dispensing area and hygiene	• A designated area of the dispensary should be used solely for dispensing medicines into an MDS, which should be assembled one patient at a time to reduce the risk of cross contamination and dispensing errors • The designated area and all equipment, such as a reusable MDS and tablet counter, used in the MDS dispensing process should be cleaned before and after, following the manufacturer's maintenance directions • Medicines should not be handled without wearing gloves, in order to protect the dispenser from any harm due to direct exposure to the medicine and to maintain hygiene levels, minimising the risk of contamination to the patient's medicines
Labelling	• As stating in Regulation 258 and Schedule 25 Part 1 of The Human Medicines Regulations 2012, all medicines dispensed against a prescription must be labelled or have a notice relating to the package contents affixed, with the following details: ○ The product name or common name ○ Directions for use ○ Relevant precautions for use • Therefore, each individual medicine dispensed in an MDS must be labelled, each time a supply is made. The labels should be positioned on the immediate outer packaging or by securely attaching a backing sheet, which includes information that reflects the current prescription.
Medicine changes and adjustments	• Pharmacists are not contractually obliged under their NHS Terms of Service to make changes to medicines or to re-package an existing MDS once it has been dispensed. • If a patient has their medicines dispensed in an MDS and the prescriber changes or adds a medicine part way during the use of the MDS, it is up to the prescriber to issue a new prescription for all of the items • Where it is likely that a patient will need changes to their medicines or doses, the prescriber should be contacted to discuss whether they can provide prescriptions with a shorter prescribing interval, such as seven days
Medicine administration record (MAR) charts	• MAR charts are not only a useful reminder tool for patients but are sometimes a vital document utilised by carers to ensure medicines are administered to patients in accordance with the prescribers directions and to prevent dosing errors • It is not a legal requirement for a pharmacy to provide a MAR chart with an MDS, however, it is recommended that only competent and trained staff, create such a document, using the original prescription, to ensure accuracy and consistency is achieved between the prescriber's instructions and MAR chart

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	• Thus pharmacists are ideally placed to and should provide this service, where possible; it is important to check if there is any local guidance established in regards to the supply of MAR charts
	  ○ England: NHS England regional team
	  ○ Wales: NHS Wales Local Health Board
	  ○ Scotland: NHS Scotland Health Board
	  ○ Northern Ireland: Health and Social Care Trust
	• It is important to note that MAR charts should be produced at the point of dispensing using the original prescription; therefore pharmacists should not routinely provide MAR charts for medicines that have been dispensed by another pharmacy because they have not had sight of the original prescription

Patient information leaflets	• Regulation 260 of the Human Medicines Regulations 2012, it is a legal requirement for a patient information leaflet (PIL) to be supplied with every licensed medicinal product; this does not apply to unlicensed products • PILs are an essential written resource, alongside verbal communication, to support a patient's understanding of a medicine and advice for safe use • A patient or carer may consent to not receiving a PIL on every dispensing occasion, but the pharmacist must consider the possible implications of not providing a PIL; a record of consent gained should be recorded
Secondary dispensing	• This is where medicines are dispensed at one pharmacy and brought to another pharmacy to be placed in an MDS, without sight of the original prescription ○ For example, re-dispensing medicines supplied by another pharmacy into a patient's existing MDS would mean that the pharmacist re-dispensing the medicines would not be able to confirm the identity, source, storage condition of the medicines or the original prescription that the medicines were dispensed against • This practice is not advised and carries a number of risks; without sight of the original prescription, the pharmacist at the second pharmacy is unable to complete a clinical and accuracy check of the dispensed product; it is unclear where liability for dispensing errors therefore lies • Before participating in such practice, the pharmacist must consider other possible options to support patient adherence, such as; having the medicines supplied from the two pharmacies in separate MDSs and using them concurrently together, or using a reminder chart for the medicines not included in an MDS • If secondary dispensing is deemed necessary, it is recommended that the pharmacist has sufficient evidence that dispensing a medicine originally dispensed in another pharmacy into an MDS, without the original prescription, is essential for the patient's compliance and care, that robust SOPs are in place that attempt to minimise potential risks and ensure the responsibilities of each party involved are clear ! **Advice from professional indemnity providers should always be sought in advance**

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Training

There are no specific training requirements or courses for pharmacy staff to complete before dispensing medicines into an MDS. Pharmacists are responsible for ensuring that all relevant pharmacy staff are trained on, and are following, the relevant and up-to-date policies and procedures pertaining to the safe dispensing of medicinal products in an MDS. Training given to pharmacy staff should be relevant to the type of MDS used and appropriate to their levels of involvement in the preparation and supply of an MDS. The training provided should be on-going and documented.

Liability issues

Pharmacists should be mindful of the potential liability issues that may arise when a medicine is removed from the manufacturer's original packaging and dispensed into an MDS. Medicines that are transferred into an MDS become off licence, because they are no longer stored in accordance with the manufacturer's instructions in the SPC. The stability of the medicine may be affected when it is removed from the manufacturer's original packaging and the degree of instability may be unknown — pharmacists may be liable where medicines deteriorate in the MDS. Pharmacists should consider documenting any decisions made to dispense medicines into an MDS.

Robust SOPs for each stage of the preparation and supply of an MDS must be in place and adhered to. The NPA has produced a template SOP "*Monitored dosage systems: SOP*" and can be found on the NPA website. The checking process used must be thorough and robust, and include a procedure for establishing the identity of the medicine which has been removed from its original packaging. The correct medicine, correct strength and quantity in each compartment must also be checked, in addition to the medicine's expiry date. The final check should involve reviewing the prescription, against the label and against the products contained in the MDS. This requires the original packs of the medicines which have been included in the MDS to be available.

Although many steps in the MDS dispensing process can be completed by an appropriately trained member of staff, pharmacists have overall responsibility for the safe supply of medicines in an MDS. Therefore, an MDS should only be prepared in the dispensary under the supervision of a pharmacist as there is a responsibility for the pharmacist to personally oversee the entire process.

Refusal by carers to administer medicines not in an MDS

The Care Quality Commission (CQC) fundamental standards require service providers to train staff to be able to administer medicines. This could include administering medicines supplied in an MDS; however it does **not** require all medicines to be in an MDS for carers to administer. Where carers refuse to administer medicines unless they are in an MDS, the pharmacist will need to establish what service the carers have been commissioned to provide. If the service contract expressly states that medicines can only be administered if they are supplied in an MDS, whilst this is not ideal, the CQC would not intervene. The Local NHS Organisation may be approached for advice in these circumstances:

- England: NHS England regional team
- Wales: NHS Wales Local Health Board
- Scotland: NHS Scotland Health Board
- Northern Ireland: Health and Social Care Trust

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If there is no such requirement stated in the contract to only provide medicines in an MDS, and there are concerns that the care agency is not providing support and training their employees to administer medicines safely, whether they are in original packs or in an MDS, this should be reported to the CQC. The agency may be attempting to cut costs by not training care staff and advising them not to administer medicines unless they are in an MDS; this practice is unacceptable. Care workers are required to have the necessary skills and experience to assist the patient in the capacity in which they are employed. For carers administering medicines, they should be able to interpret written instructions.

Pharmacists should not enter into an agreement with the carer to dispense a patient's medicine(s) into a MDS to make administration of the medicine(s) to the patient more convenient for the carer; appropriate assessment of the patient and medicine stability should be used to determine whether an MDS should be provided.

The CQC can be contacted via their website or by telephone on 03000 616 161 where there are concerns over the support provided by carers to patients.

References and further reading

- Electronic Medicines Compendium: https://www.medicines.org.uk/emc/
- Equality Act 2010: http://www.legislation.gov.uk/ukpga/2010/15/contents
- National Institute for Health and Care Excellence "*Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence*": https://www.nice.org.uk/guidance/cg76
- National Institute for Health and Care Excellence "*Managing medicines in care homes*": https://www.nice.org.uk/guidance/sc1/resources/managing-medicines-in-care-homes-61677133765
- Primary Care Commissioning "*Disability Discrimination Act — a resource kit*": http://www.pcc-cic.org.uk/article/disability-discrimination-act-resource-kit
- Specialist Pharmacy Service: https://www.sps.nhs.uk/
- The Care Quality Commission: http://www.cqc.org.uk/
- The Human Medicines Regulations 2012: http://www.legislation.gov.uk/uksi/2012/1916/contents/made
- The General Pharmaceutical Council "*Standards of conduct, ethics and performance*" https://www.pharmacyregulation.org/standards/conduct-ethics-and-performance
- The General Pharmaceutical Council "*Standards for registered pharmacies*" https://www.pharmacyregulation.org/standards/standards-registered-pharmacies
- The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008: http://www.legislation.gov.uk/uksi/2008/2789/contents/made
- The Misuse of Drugs Regulations 2001 and amendments: http://www.legislation.gov.uk/uksi/2001/3998/contents/made

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- The Misuse of Drugs (Safe Custody) Regulations 1973 and amendments: http://www.legislation.gov.uk/uksi/1973/798/contents/made
- The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013: http://www.legislation.gov.uk/uksi/2013/349/contents/made

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