# MANAGEMENT OF MEDICINES POLICY

# Introduction

#### Aim

1. The aim of this leaflet is to provide policy and direction to all Ministry of Defence (MOD) personnel who procure, store, prescribe, supply, administer or dispose of medicines. It provides policy on the safe and secure use of all medicines, ensuring compliance with legislation and best practice, allowing each Command or unit to develop appropriate medicines management Standard Operating Procedures (SOPs).

# **Summary**

2. To date, the MOD has not had a comprehensive and current policy encompassing the entirety of the management of medicines. This leaflet supersedes JSP 340 (Joint Service Regulations for the Management of Medical, Dental and Veterinary Material and Equipment 2000) and fills the gap in medicines management and medical logistic policy. Details of the remaining medical logistic elements of JSP 340 can now be found in the Defence Logistic Framework (DLF) on the Defence Gateway1.

## Scope

- 3. This policy applies to all MOD personnel and contractors working in MOD Headquarters, units and Medical Treatment Facilities (MTF) in the UK and overseas. Breaches of this policy may lead to disciplinary action being taken against individuals, although it is accepted that breaches for operational reasons may be necessary, where UK standards cannot be met. This policy applies to all medical materiel controlled by <a href="The Medicines Act 1968">The Medicines Act 1968</a>, used within the MOD, and includes topical preparations, applications, injections and infusions, medical gases, medicated dressings, diagnostic agents and medical devices.
- 4. The MOD is committed to the safe, effective and efficient use of medicines to support the provision of high quality care to patients in line with the <u>Defence Medical Services (DMS) Strategy</u> and Medicines Optimisation Plan (to follow). This policy ensures the MOD directs compliance with the law, best practice and safe systems of working in relation to the management of medicines. It should be used in conjunction with the current edition of the British National Formulary (BNF) and all the other references listed.
- 5. There is no single definition of medicines management but in the MOD it encompasses the entire way medicines are used to optimise the contribution they make to informed and desired outcomes of patient care. This policy aims to provide suitable advice and direction for the complete journey of a medicine from procurement through to disposal. Legislation provides a full list of definitions, but those relevant to this policy can be found at Annex A. The policy is broken down into the following sections:
  - a. Central Procurement and Supply page 4
  - b. Transportation and Receipt of Medicines page 6
  - Security, Storage and Stock Management page 7
  - d. Prescribing page 10

<sup>&</sup>lt;sup>1</sup> From 23 Apr 15 policy in the JSP 886 became accessible via the Defence Logistics Framework (DLF). JSP 886 is still available but after a period of time of parallel running, the JSP 886 will be withdrawn.

- e. Supply and Administration page 21
- f. Dispensing page 25
- g. Disposal of Pharmaceutical Waste page 30
- h. Governance and Risk Management page 30
- i. Medicines Information page 32
- j. Training and Education page 33

## **Accountability**

- 6. The Surgeon General, as Defence Authority for healthcare and medical operational capability, has overall responsibility for the strategic and operational management of the DMS, which includes setting the policy, which complies with all legal and good practice guidance requirements. However, it is the responsibility of the Chain of Command (CoC) to ensure that appropriate SOPs, guidance and training are in place to cover all activities relating to medical materiel undertaken within their own Area of Responsibility (AOR). It is accepted that not all of the standards can be met on operations and exercises but every effort must be made to manage medicines as safely as possible, as far as is reasonably practicable, in line with this policy.
- 7. The management of medicines is the responsibility of everyone; those employed in the MOD that have contact with medicines or patients and the patients themselves. However, pharmacists are the subject matter experts on many of the issues highlighted in this policy. The on going management of medicines issues will be raised and discussed at the Senior Pharmacists' Group (SPG), where all Commands are represented. In the absence of a Command Pharmacist, support in the development of SOPs, training and guidance is available from pharmacy personnel identified at the DMS <a href="Pharmacy Webpage">Pharmacy Webpage</a>. Any major issues will be presented to the Drugs and Therapeutics Committee (<a href="DTC">DTC</a>), DMS Clinical Committee (<a href="DMSCC">DMSCC</a>) or Patient Safety Quality Improvement Group (<a href="PSQIG">PSQIG</a>). When required, <a href="PSQIG">PSQIG</a> will provide any actions and/or feedback to an individual or Command HQ.

# Legislation

- 8. The following legislation (and subsequent amendments) are mandatory regarding the use of medicinal products and where necessary are referred to in the policy:
  - The Medicines Act 1968.
  - The Human Medicines Regulations 2012.
  - c. The Misuse of Drugs Act 1971 and The Misuse of Drugs Regulations 2001.
  - d. The Controlled Drugs (Supervision of Management and Use) Regulations 2013.
  - e. The Health Act 2009.
  - f. The Poisons Act 1972.
- 9. The Human Medicines Regulations 2012 repealed, revoked or re-enacted most existing UK legislation regulating the authorisation, sale and supply of medicinal products for human use and consolidated their effect in one place and in rationalised form. The Human Medicines Regulations 2012 leaves some aspects of the Medicines Act 1968 in place, principally Part IV. Remaining medicines' legislation is awaiting consolidation.

- 10. In order to support the MOD's operational capability, exemptions to the legislation<sup>2</sup> allows for members of the Armed Forces to supply and administer medicines, under certain caveats. In order to ensure appropriate governance, MOD restricts the use of these exemptions. The following defines the situations and groups of MOD personnel who are authorised to supply and administer medicines.
  - a. All Service Personnel may possess and administer Morphine auto-injectors (MAI), Oral Transmucosal Fentanyl Citrate (OTFC), and Combopens to another person in accordance with MATTs, CCS or sS equivalent, in the course of their duties. All personnel are to be trained and tested to confirm their competence before being issued with MAI, OTFC or Combopens.
  - b. Appropriate Practitioners (Doctors, dentists, independent non-medical prescribers, community practitioner nurse prescribers and supplementary prescribers) may supply and administer medicines to their patients, in accordance with relevant legislation<sup>3</sup>, and are individually responsible for ensuring that they are competent to do so.
  - c. Pharmacists, registered health visitors, registered midwives, registered nurses, registered physiotherapists and registered paramedics may supply and administer medicines in accordance with a patient group direction (PGD) <sup>4</sup>, providing they have been assessed as competent to do so.
  - d. Defence Medics (Cbt Med Techs, RN Medical Assistants, RFA Med Techs and RAF Medics) should only supply and administer medicines under their sS ratified protocols, following completion of specific training and having been assessed as competent by a Medical Officer.
  - e. Personnel assigned to Specialist Military Units who have successfully completed and remain validated for the Patrol Medic Course are authorised to supply and administer GSL and P medications detailed in all the sS protocols referred to at para 10d. They are also authorised to supply and administer Prescription Only Medicines in accordance with MOD A Block protocols.
  - f. All other Service Personnel may only supply or administer medicines under the specific direction of a doctor, dentist or independent prescriber.

## Classification of medicines

- 11. Under the Human Medicines Regulations 2012 there are three classes of medicinal products:
  - a. **Prescription Only Medicines (POM)**. POMs are medicines generally subject to the restriction of requiring a prescription written by an appropriate practitioner. There are exemptions to requiring a prescription in some circumstances, such as using a Patient Group Direction (PGD).
  - b. **Pharmacy medicines (P).** P medicines are medicinal products that can be sold from registered pharmacy premises by a pharmacist or a person acting under the supervision of a registered pharmacist.
  - c. General Sales List medicines (GSL). GSL medicines are those that can be sold in

JSP 950 leaflet 9-4-2 Patient Group Directions.

JSP 950 Part 1 Lft 9-2-1 (V1.0 Dec 15)

<sup>&</sup>lt;sup>2</sup> Human Medicines Regulations 2012 (The Human Medicines (Amendment) Regulations 2014): Schedule 17, Part 3 and part 5. <a href="http://www.legislation.gov.uk/uksi/2012/1916/schedule/17/made">http://www.legislation.gov.uk/uksi/2012/1916/schedule/17/made</a>

<sup>&</sup>lt;sup>3</sup> Human Medicines Regulations 2012, Part 12 Chapter 2: <a href="http://www.legislation.gov.uk/uksi/2012/1916/regulation/214/made">http://www.legislation.gov.uk/uksi/2012/1916/regulation/214/made</a>

registered pharmacies but also other lockable retail outlets such as supermarkets and does not require the supervision of a pharmacist.

Some medicines can be classified under more than one category and this can depend upon formulation, strength, quantity, indication or marketing authorisation. Collectively GSL and P medicines are known as Over The Counter (OTC) or non-prescription medicines.

12. There is an additional control imposed on some medicines that are liable to misuse or abuse and these are called Controlled Drugs (CDs). Due to the complex legislative requirements for CDs, a comprehensive guide on their management is at Annex B.

# **Standard Operating Procedures**

- 13. All Commands are to have in place SOPs, which as a minimum, will:
  - a. Cover all areas of medicines management ie procurement, prescribing, dispensing, supply, distribution, storage, administration and disposal.
  - b. Be clear and unambiguous, and provide detail on who is authorised to use them.
  - c. State any equipment, facilities and requirement for data capture associated with the process.
  - d. Specify the written and/or supporting information or instructions for referral up the CoC.
  - e. Include any FMEDs or appropriate references to ensure correct documentation is used.
  - f. Be in place to manage CDs.
- 14. This policy does not provide all the detailed guidance but the overarching policy under which SOPs can be prepared. To assist in the development of medicines management SOPs, the following additional policies are to be used:
  - a. Defence Logistic Framework (DLF).
  - b. JSP 473 Joint Service Regulations for the Engineering Support of Medical, Dental and Veterinary Equipment Part 2: Guidance.
  - c. JSP 315 Accommodation Scales.
  - d. JSP 950 Medical Policy.
  - e. Defence Primary Health Care (DPHC) SOPs and Guidance Notes.
  - f. sS Medicines Management policies (Royal Navy, AP1269 and AP1269A).
  - g. Summary of Product Characteristics or Data Sheets (for specific medical items <u>eMC</u>, HSIS JSP515 The MOD Hazardous Stores Information System).
  - h. BOC Medical Cylinder Storage and Handling and Data Sheets. <u>JSP 319 Safety</u> Regulations for the Storage and Handling of Gases and BOC Safety Datasheets.

In the absence of a SOP, DPHC SOPs should be referred to as standard practice.

# **Central Procurement and Supply**

- 15. **Procurement**. Procurement covers the activities through which medicines are acquired for or on behalf of MOD. It is essential that there is an auditable trail for all medical materiel from their ordering and receipt to their destruction or supply. The following key messages relate to the supply of medical materiel:
  - a. All medicines for use within the MOD must be sourced from approved suppliers through the MOD Delivery Partner, (<u>Team Leidos</u>), and be appropriate and legitimate for their intended use. Routinely these should have a UK Marketing Authorisation. Refer to the <u>DLF</u> and <u>JSP 332 Low value purchasing manual</u> for further guidance.
  - b. Type 1 (operational) and Type 2 (primary care) customers have different ordering procedures for medicines, and whilst there is some overlap for operational requirements, each type should only use their designated system. These are:
    - (1) **Type 1 customers**. All demands for medical materiel are to be processed through the Joint Supply Chain, using MJDi or equivalent system. Entities within Team Leidos, the MOD Delivery Partner, awarded responsibility for the procurement, storage and supply of MOD medical materiel, each hold a Wholesale Distribution Authorisation (WDA) for medicinal products (also known as wholesale licence). A WDA allows only authorised personnel to procure, store and supply medicinal products. For the purpose of wholesale dealing, MOD units are the authorised demander (2012DIN04-146 Authority to demand prescription only medicines under Wholesale Dealers License.). Type 1 units are only entitled to demand and hold medicines against their Medical Equipment Table (MET) or against agreed modules for a specific tasking from the Front Line Command (FLC). These are to be accounted for in accordance with the DLF.
    - (2). **Type 2 customers**. The majority of demands for medical materiel are to be placed by the e procurement automated system (currently Purchase to Payment (P2P)) and accounted for on their primary care electronic prescribing system. Some medical materiel is not available on the e procurement system and separate instructions for how to order these items is issued by <u>Team Leidos</u>, and in the DPHC SOP <u>Chapter 2</u>.
  - (c). Non-formulary items. These items require specific information to be submitted to the Regional, Command, Lead Pharmacist and/or HQ SG Medicines Management Lead Pharmacist to approve the supply prior to procurement. Further information available at this link.
- 16. **Unlicensed medicines**. Where the supply of a medicine with a UK Marketing Authorisation has been interrupted because of a manufacturing or supply problem, or there is not one available for a specific therapeutic use, the MOD has a process<sup>5</sup> in place to authorise the use of a UK unlicensed or specials manufactured product within the DMS. The use of unlicensed medicines is not to be routine practice unless required for operational use and authorised by Headquarters Surgeon General (HQ SG) after review by the DTC and the <u>Advisory Group on Military and Emergency Response Medicine</u> (AGMERM)<sup>6</sup>
- 17. **Parallel Imports (PI)**. The UK operates a Parallel Import (PI) Licensing Scheme, allowing medicinal products authorised in other EU member states to be marketed in the UK, provided the imported medicinal products have no therapeutic difference from equivalent products authorised in the UK. The importer must submit a Parallel Import Licence application to the MHRA's Parallel Import Section before the proposed importation. This system is controversial as there is a risk of

<sup>&</sup>lt;sup>5</sup> JSP 950 Leaflet 9-3-3 under review – link to follow

<sup>&</sup>lt;sup>6</sup> Routine firm base primary care activity where DPHC Pharmacists make decisions on an individual patient basis requirement do not require AGMERM approval.

counterfeit medicines entering the supply chain, resulting in a threat to patient safety and compromising the security of drugs supply. The use of PIs is only to be used when all other avenues of supply have been exhausted and where no appropriate generic or brand is available eg stock shortages. PIs are not to be procured under any circumstances as preferential products or when the supplier does not hold a product licence parallel import marketing authorisation from the MHRA.

- 18. **Local Purchase (LP).** LP for medicines is only to be considered if a reputable source of the product is used, where the quality of the product can be assured. LP is only to be used when all other procedures have been exhausted and there is an unacceptable delay to patients' treatment. Advice should be sought from the command, regional or deployed pharmacist. LP processes are clearly explained in the <u>DLF</u>.
- 19. Morphine Auto injectors (MAI) / Oral Transmucosal Fentanyl Citrate (OTFC) on operations. These products are only authorised for operational analgesia<sup>7</sup>. MAI or OTFC are often included in medical modules, and there is an expectation to receive these in the UK. However, they are not to be routinely used for exercises or medical support in the Firm Base unless the Competent Medical Authority has authorised their use in the relevant medical support plan, where a requirement exists which cannot be met through routine non-military medical support. Medical Treatment Facilities (MTFs) are not to issue operational analgesics to Individual Augmentees (IA) this is the responsibility of the local Type 1 supply unit. Those MTFs providing airfield cover are authorised to receive MAI or OTFC in First Aid Kits (10 man disaster). Any other issues must be authorised by either the Command Pharmacist or SO1 Pharm HQSG.
- 20. **Training stocks**. Units are only to demand, hold or use medicines for Collective Performance Training on the authority of their Command Pharmacist or SO1 Pharm HQSG. This includes out of date stocks. This is to prevent unnecessary wastage but also to avoid expired/damaged drugs being used on real casualties or patients. **The risk to patients is not to be underestimated**. Where training stocks have been authorised they must be clearly segregated from deployable modules or "live" medical materiel and each individual package marked as "FOR EXERCISE USE ONLY. TRAINING STOCK ONLY. NOT FOR CLINICAL USE". Controlled and Accountable Drugs are never to be used for training. In the event of a real casualty during training, they are to be dealt with by systems completely outside of the training event/exercise (eg 999 or MTF) to remove the risk of using damaged or expired medicines. Where possible, the use of 'dummy' or placebo medicines and devices should be encouraged.
- 21. **Illicit substances**. The Misuse of Drugs Act 1971 (Section 8) deems it a criminal offence for the occupier/manager of any premises knowingly to allow the unlawful production, use or supply of substances controlled by the Act (Controlled Drugs) within them. Appropriate action will be taken by the MOD wherever this is discovered or suspected. It is not the responsibility of DPHC or deployed MTFs to destroy illicit substances/evidence on behalf of the police. Service Police are to destroy 'unknown' substances or controlled drugs by witnessed incineration.

# **Transportation and Receipt of Medicines**

## **Transportation**

22. **Environmental control**. Transportation includes the delivery of medical materiel from a wholesaler but also the transfer of medicines between MOD sites (eg between clinics, MTFs and an outside location). It is essential that environmental control (as per manufacturers' instructions) is maintained throughout all of the transportation of medical materiel to retain their integrity and licensed storage conditions. A temperature monitoring device should be included to provide

<sup>&</sup>lt;sup>7</sup> OTFC is licensed for and therefore also permitted to treat breakthrough pain in patients receiving opioid therapy for chronic cancer pain. See JSP 950 lflt 9-4-4 Operational Analgesia – link to follow.

assurance temperatures during transportation have been in accordance with manufacturer's instructions. Items requiring refrigerated storage, such as vaccines, should be transported in separate containers (eg validated cool bags/boxes) to maintain environmental control. For hazardous material, reference must be made to the relevant data sheets and a risk assessment undertaken. Where practicable, all medicines should be transported in a securely sealed or tamper evident container.

23. **Personnel**. Staff engaged in transportation of medicines should be identified, authorised, and appropriately trained (refer to <u>DLF</u>; training requirements should cover environmental control and hazardous material) and are responsible for the safe delivery to the correct location.

# Receipt

- 24. Staff in receipt of medical materiel must:
  - a. Ensure that temperature control requirements have been met during delivery, and that the items are unpacked, checked and placed **immediately** in the designated medicines fridge/storage area.
  - b. Ensure that the delivery and delivery note has not been tampered with or damaged in transit.
  - c. Sign the appropriate delivery note (and retain for 2 years) to acknowledge receipt of the delivered goods, checking:
    - (1) Correct drug.
    - (2) Correct formulation.
    - (3) Correct strength.
    - (4) Correct quantity.
    - (5) Shelf life / expiry date of product.
    - (6) Storage requirements.
    - (7) Condition of the product.
    - (8) Requirements for safe handling.

Unpack medicines and store in a secure environment as soon as possible after receipt (particularly CDs). Entries into the CD/AD Register (BMed 12/13) must be made on the day the stores are received or the following day (within 24 hours). See Annex B.

d. Report any discrepancies immediately to the supplier, and/or the CoC if necessary.

# **Security, Storage and Stock Management**

### General

25. All medical materiel should be stored securely in accordance with the manufacturers' marketing authorisation, Summary of Product Characteristics (SPC), and manufacturer's product storage instructions, in appropriate, secure storage that has been specifically designed for this purpose.

# Storage<sup>8</sup>

- 26. Rooms, cupboards (<u>BS 2881</u>) or refrigerators for the storage of medical materiel must be sited where they are convenient for staff, allow adequate space to permit surveillance and afford maximum security against unauthorised entry. Specific considerations are:
  - a. Medicines should be stored securely in either a lockable room/cupboard, or a medicine trolley, which can be secured to a wall when not in use. They should be stored out of direct sunlight in a dry, clean, secure, well ventilated and temperature controlled environment in accordance with the medicine's marketing authorisation (normally under 25°C).
  - b. Medicines for internal use must be stored separately from medicines for external use. Under no circumstances should medicines be transferred from one container to another (except for recognised containers when dispensing). They must not be taken out of their original container and left loose.
  - c. Intravenous and sterile topical fluids and bulky materiel are to be stored in designated locked clean areas. Storage is to be raised from the floor and the ambient temperature should not exceed 25°C.
  - d. Medicines for resuscitation are to be stored in the appropriate pre-identified locations in MTFs.
  - e. Reagent cupboards must be sited in areas where testing is carried out.
  - f. Controlled and Accountable Drugs are to be stored in bespoke cabinets complying with the Controlled Drugs, Misuse of Drugs (Safe Custody) Regulations. The cabinet should be reserved solely for the storage of CDs and ADs. Further detail on the management of CDs is at Annex B.
  - g. Medicines and vaccines that require refrigeration MUST be stored in an approved dedicated medicines fridge that is temperature monitored to maintain the stability of the medicines. Medicines are not to be stored together with food or pathological specimens, but in a separate locked fridge. The fridge should be of a suitable size, which is dependent on the volume of refrigerated medicines to be stored, and should be serviced and calibrated every 2 years, or sooner if product failure or fault identified.
  - h. In secondary care, patients' own medicines are to be stored in appropriate lockable cabinets. Their location, size, security and structure are to be considered as part of a risk assessment.
  - i. All other materiel, including devices, consumables, medical gases and hazardous materiel, is to be stored in accordance with the <u>DLF</u> and their relevant data sheet, with appropriate signs to identify them.
  - j. Heavy items are to be placed on the bottom shelves of storage racks or on pallets near the entrance. The location of such materiel shall not obstruct the movement of materiel or safe passage of personnel employed within the storage facility. Items of irregular shape should be positioned to prevent any trip hazard.

<sup>&</sup>lt;sup>8</sup> Further guidance can be obtained from Royal Pharmaceutical Society's document "The Safe and Secure Handling of medicines – a Team Approach", often referred to as The Duthie Report. <a href="http://www.rpharms.com/support-pdfs/safsechandmeds.pdf">http://www.rpharms.com/support-pdfs/safsechandmeds.pdf</a>. Accessed 30 Jun 15.

#### **Environmental control**

27. **Temperature control**. The routine temperature ranges for the storage of medical materiel are: below -20°C (frozen), +2 to +8°C (refrigerated), and +8 to +25°C (ambient), as directed by the manufacturer and marked on the packaging. It is essential that vaccines and other injectable products are stored correctly and are never used if there is any doubt to their integrity, especially if frozen. Further guidance for vaccines can be found at HPA Vaccine Incident Guidance<sup>9</sup>.

# 28. Temperature monitoring.

- a. **Routine practice.** It is important to monitor temperature in all locations where temperature sensitive medical materiel is stored to maintain their integrity. It is mandated to monitor refrigerator temperatures on a daily basis. <sup>10</sup> Ambient temperatures should be monitored as good practice, but this is only mandated in those areas where temperatures are extreme and outside of normal temperate ranges. Records of temperature monitoring should be retained in accordance with JSP 950-1-2-11 Defence Health Record.
- b. **Operational environments**. In operational locations, it is not always possible to achieve adequate temperature control, particularly for ambient goods. If temperatures exceed 25°C then the products should be marked and replaced after the end of a 6 month period or expiry date of the product if this is sooner. This stock is classed as unlicensed and the prescriber should be made aware that the liability for the product rests with the MOD and the prescriber rather than the manufacturer. Specialist advice is to be obtained from the deployed or command pharmacist regarding risk and impact on patient safety prior to use.
- 29. **Actions on temperature control failure**. If Medical Materiel with a Shelf Life (MMSL) is not stored between the recommended temperatures of the drug's marketing authorisation, the manufacturer may disclaim responsibility for any apparent failure and render the medicine an unlicensed product. It is therefore recommended that any product knowingly stored outside of their recommended temperatures should not be used unless its stability, and any changes to subsequent storage requirements and shelf life has been verified by the manufacturer in writing.
- 30. On failure of a power unit, air conditioning unit or refrigerator, an investigation should take place, noting timeframes, temperatures and the reasons for exposure. A refrigerator is not to be opened, except for emergencies until this investigation has occurred.
- 31. Affected stock is to be guarantined.
- 32. Medicines are to be marked with the date of exposure and reduced expiry date where it shortens the manufacturers printed product expiry date.
- 33. DPHC regional or deployed pharmacist (Command pharmacists where no pharmacist is deployed) are to be informed and an assessment is to be made on the risk versus benefits of retaining the materiel.
- 34. As a patient safety incident, a Significant Event (SE) report is to be raised to learn and share any lessons to prevent reoccurrence. In situations that the medicine has to be used, as there is no alternative, then the responsibility and liability rests with the prescriber and the MOD.

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<sup>&</sup>lt;sup>9</sup> https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/326417/Vaccine\_Incident\_Guidance.pdf. Accessed 30 Jun 15

<sup>&</sup>lt;sup>10</sup> Monitoring does not normally take place when MTFs are closed.

## Security

- 35. All access to medicines will only be by authorised personnel. The practitioner in charge is responsible at all times for the safekeeping and secure storage of medicines in their service, and ensuring that all medicines are stored according to national legislation and local policy.
  - a. The keys for the medicine cupboard, internal medicine cupboard, medicine trolley, medicine refrigerator and pharmacy transport box must be kept together on one key ring reserved solely for these keys. The keys must be clearly identified. The keys for the CD cupboard are to be kept separate.
  - b. The keys are to be kept in a safe or on the person of the designated practitioner during working hours and stored securely when the clinic or base is closed. In the event of no designated practitioner being on duty in a ward or department, the keys should be handed to the practitioner in charge.
  - c. At bases where a number of designated practitioners may require access to the medicine cupboards at different times, a secure system must be agreed and enforced. Where keys are issued to staff, the MTF is to maintain a control log to record when the keys were issued, to whom and when they have been returned.
- 36. Dispensaries are to be secured at all times, even when occupied, to prevent access by unauthorised personnel. Only dispensary staff or those responsible for dispensing medicines are to have access to the dispensary during normal working hours. Access out of normal working hours is to be in accordance with para 30c above. Any unauthorised access to keys is to be reported to the Practice Manager and an SE report raised as part of the investigation process.

# Stock management

- 37. **General**. In primary care and on operations, where possible, DMICP or an equivalent system is to be used to account for and manage stocks. MTFs are to keep stock levels to a minimum and monitor expiry dates carefully to avoid wastage.
- 38. **Stock rotation**. Personnel storing items in a location are to ensure that package labels are facing forward and clearly visible. MMSL items are to be stored, with the expiry date clearly visible, to allow the issue of shortest dated stock first following the First Expiry First Out (FEFO) rule.
- 39. Stocktaking and financial control. Stock taking is to be undertaken in accordance with the DLF and stock deficiencies must be investigated by the practice manager or Officer in Charge (OIC) of the medical stores account and managed in accordance with the process and Material Loss Codes (MLC) in the DLF. Where there is a suspicion of medicine misappropriation or abuse (MLC 1 or 2), the OIC of the medical account must be informed and report it to the Defence Fraud and Analysis Unit. The senior clinician must be informed if there is suspicion that medical staff are involved. For CDs refer to Annex B. Medicines that have time expired or have deteriorated in store (eg from over provisioning or incorrect storage) are to be written down in accordance with the DLF. Incidents valued at £250 or more will be subjected to the MOD 2260 process. Single trivial losses below £250 are not to be recorded on the MOD F2260 but aggregated and entered onto a single line in the losses register. In peacetime primary care, the stock figure is to be removed from the electronic stock management system with an appropriate and full explanation.

# **Prescribing**

### General

40. **Medicines optimisation**. Medicines optimisation encompasses all aspects of medicines use, from the prescribing of medicines to the ways in which medicines are taken or not taken by

patients. It seeks to maximise health gain through the optimum use of medicines. Medicines optimisation encompasses medicines management in a number of ways but most importantly it focuses on outcomes and patients rather than process and systems. This focus on improved outcomes for patients is likely to help ensure that patients and the MOD get better value from the investment in medicines. The MOD is committed to ensuring that all our patients are at the centre of all decisions made about their care to ensure that they get the right medicine, at the right time.

- 41. **Best practice**. The MOD has a responsibility to ensure that medicines are used safely and effectively. This includes safe and effective prescribing. All DMS prescribers (including Non-Medical Prescribers (NMP)) are to follow good prescribing practice. The National Prescribing Centre<sup>11</sup> (now an integral part of National Institute for Health and Clinical Excellence (NICE) has issued a Single Competency Framework for all prescribers which provides an outline of common prescribing competencies that, if acquired and maintained, can help all prescribers to become and remain effective prescribers in their area of practice. Further detailed guidance is issued from each of the professional regulatory bodies<sup>12</sup> and the policy for NMPs is detailed within JSP 950 Part 1 Lft 9-3-2 Independent Prescribers in the DMS.
- 42. **Evidence Based Medicine (EBM)**. The most widely cited definition of EBM is from Sackett et al<sup>13</sup>, stating that it is: 'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research'. The MOD has a responsibility to ensure that EBM is taken into consideration in all aspects of patient care. All guidelines, policy and formularies will be developed using the best possible clinical evidence combined with advice and recommendations from subject matter experts.
- 43. **Guidance**. Prescribing is to be guided in the first instance by the most appropriate DMS guidelines for the clinical setting [Defence Primary Care Formulary (DPCF), medical modules or Clinical Guidelines for Operations (CGOs)]. Non-formulary prescribing should be limited only to instances where the clinical need of an individual patient dictates a drug not listed. Certain situations may call for the use of an unlicensed product or a product used 'off-label', meaning that the product is being used outside of the marketing authorisation granted by the MHRA. The prescribing of unlicensed products and off-label medications must be carefully considered and their use recorded correctly on the appropriate DMS forms (link to new unlicensed policy to follow).
  - a. **Defence Primary Care Formulary (DPCF).** The <u>DPCF</u> provides an evidence-based prescribing framework for use in the DMS. Further guidance on prescribing and the DPCF can be found within <u>JSP 950 Part 1 Lft 9-3-1 Defence Primary Care Formulary</u>. Compliance with the formulary is expected but it is understood that certain patients may require nonformulary drugs to continue or start appropriate therapy. These additional drugs will be reviewed by the Drugs and Therapeutics Committee for possible inclusion in the DPCF, where appropriate. Where initiation of treatment or continuation of supply necessitates procurement and supply outside of a formal DTC decision the Regional Pharmacist and/or Lead Pharmacist should consult with the HQ SG Deputy Chief Pharmacist to make an out of DTC decision.
  - b. **Medical Modules**. A Medical Equipment Table (MET) is a ratified sS document conferring entitlement to hold, use and account for a specific scale of medical materiel by Medical Modules and Kits. On operations or exercise, all prescribers are to prescribe within the confines of the contents of the modules available unless there is a clinical necessity to prescribe an item which is not available within the module. Prescribers wishing to prescribe

<sup>&</sup>lt;sup>11</sup> NICE National Prescribing Centre guidance on medicines and prescribing.

<sup>12</sup> GMC, GDC, NMC, HPC and GPhC Guidance.

<sup>&</sup>lt;sup>13</sup> Sackett D L, Rosenberg W M C, Gray J A M et al 1996 Evidence-based medicine: what it is and what it isn't. British Medical Journal. 312;169–171.

a product not present in the MET should be mindful of the supply and logistic implications of such action. The prescribing of non-scaled items places a higher burden on the medical logistic facilities, may result in extended supply times and carries the risk of non-delivery. Any recommendations for changes to modules must be sent to the appropriate Defence Consultant Advisor and agreed at the Clinical Equipment Advisory Group (CEAG). Requests for urgent or critical non-scaled items are to be raised using a not-in-vocabulary (NIV) request form.

- c. Clinical Guidelines for Operations (CGO). CGOs provide deployed personnel with guidance as to best medical practice in the view of DMS subject matter experts. It is not intended to be an all-encompassing textbook of Military Medicine and Surgery. Neither should the guidelines be viewed as mandatory practice clinical judgement must be used at all times. However, CGOs act as a guide and aide-memoire for clinicians in the field encountering conditions that they do not often see in their UK employment or the management of which is changed by the deployed environment. CGOs also provide an audit framework against which treatment can be measured and assured.
- 44. Drugs and Therapeutics Committee (DTC). The role of the DTC is to:
  - a. Promote high quality, appropriate and cost-effective prescribing through the management of a range of medicines specified in the DPCF and other Defence formularies as appropriate.
  - b. To provide a forum in which to debate changes to treatment with medicines at both the primary care and secondary care level and monitor the ways in which medicines are managed in the DMS.
  - c. To provide a focus for tri-Service clinical input to the pharmaceutical range management and e-cataloguing functions of the DE&S delivery partner.
  - d. To be adaptable to the changing needs of the DMS with respect to prescribing and medicines management, both in primary and secondary care, at the interface and on operations.

The DTC has authority under the DMSCC to review and authorise any DMS policy related to prescribing and monitors SE trends and shares lessons as appropriate.

- 45. **Personnel who can prescribe.** There are two groups of healthcare professionals who are legally able to prescribe Medical and Non-Medical Prescribers.
  - Medical prescribers.
    - (1) **Fully registered doctors.** They may prescribe any medicine for any medical condition, but not those listed in Schedule 1 of the Misuse of Drugs Regulations 2001.
    - (2) **Fully registered dentists.** Dental Officers (DO) may issue a prescription for any drug listed in the JSP 950 leaflet 9-3-1 <u>Defence Primary Care Formulary</u> (dental chapter pending) or British National Formulary (BNF) to meet the dental needs of patients. However, a DO has an ethical responsibility to restrict prescribing to areas in which he/ she is competent and to medicines that have a dental effect. Prescribing in accordance with the Defence Primary Care Formulary facilitates best practice for DMS delivered primary dental care.

- b. **Non-medical prescribers**<sup>14</sup>. Non-medical prescribing is the term used to describe prescribing by health professionals other than doctors and dentists.
  - (1) Independent non-medical prescribers. These can prescribe any medicine for any medical condition, including most CDs, within agreed competencies. Nurses, pharmacists, physiotherapists, podiatrists and optometrists may become independent prescribers. Independent nurse and pharmacist prescribers may prescribe unlicensed and off label medication, providing it is within their clinical competence and accepted good clinical practice. This includes CDs except Schedule 1, 2 and 3 including Phenobarbital). Physiotherapists and podiatrists may prescribe off label medication providing it is for any medical condition within their clinical competence and accepted good clinical practice. This includes CDs except Schedule 1, 2 and 3 including Phenobarbital). Optometrist independent prescribers may prescribe any POM for conditions affecting the eye and tissues surrounding the eye, including off label, providing it is within their clinical competence and accepted good clinical practice. They may not prescribe CDs or unlicensed medicines.
  - (2) **Community practitioner nurse prescribers**. These may prescribe a limited set of items from the non-medical prescribers' formulary in the BNF. They may not prescribe CDs and may not prescribe medicines 'off-label' (except nystatin for oral thrush in neonates).
  - (3) **Supplementary prescribers**. This is a partnership between a medical prescriber (doctor or dentist) and a supplementary prescriber. The supplementary prescriber may prescribe any medicine for any medical condition (including CDs and unlicensed medicines), in accordance with an agreed patient-specific, written Clinical Management Plan. Supplementary prescribing may be undertaken by nurses, pharmacists, podiatrists, optometrists, chiropodists, radiographers and physiotherapists.

All prescribers are reminded that central to prescribing is the assurance that practitioners work within their own competence, in line with robust education, training and governance arrangements (refer to policy leaflet JSP950 Part 1 Lft 9-3-2 Independent Prescribers in the DMS).

- 46. **Prescribing responsibility**. The clinical responsibility for a prescription remains with the prescriber who has signed the prescription, regardless of who has recommended that particular therapy. When a clinician issues a prescription for any medicinal product, the clinical and legal responsibility for the outcomes of the treatment remains with that clinician. In the case of an adverse event, it will be the prescribing doctor or non-medical prescriber who will be held liable in the first instance. Prescribers are required to ensure they are clinically competent or confident to prescribe medicines and have sufficient information and training to be able to prescribe safely. This is particularly pertinent in prescribing between hospitals and primary healthcare. NHS Policy EL(91)127 (responsibility for prescribing between hospitals and General Practitioners (GPs)) and EL(94)72 (Purchasing and Prescribing) make it clear that where prescribers accept prescribing responsibility, they should have all the information and support that they need to prescribe and monitor their patients and, as a consequence, shared care agreements must include a prescribing treatment protocol (see JSP950 Part 1 Lft 9-3-4: Transfer of Prescribing from Secondary to Primary Care).
- 47. **Medicines reconciliation**. Medicines reconciliation is defined as 'being the process of identifying the most accurate list of a patient's current medicines (including the name, dosage, frequency and route) and comparing them to the current list in use, recognising discrepancies, and

<sup>&</sup>lt;sup>14</sup> Nurses, pharmacists, podiatrists, optometrists, chiropodists, radiographers and physiotherapists.

documenting any changes, thus resulting in a complete list of medications, accurately communicated'. The benefits of reconciliation include:

- a. Reducing prescribing errors.
- b. Reducing hospital admissions and re-admissions due to harm from medicines.
- c. Reducing the number of missed doses and improving the quality and timeliness of information available to clinicians, thereby leading to improved therapeutic outcomes.
- d. Increasing patient involvement in their own care promoting better concordance and reducing waste.

The importance of medication reconciliation has been highlighted in recent guidance from the NICE and the National Patient Safety Agency (NPSA), the Care Quality Commission (CQC) and the National Prescribing Centre (NPC). Medicines should be reconciled at the transfer of care between different settings eg hospital admission (planned and emergency), hospital discharge, movement between settings step-up, step-down and ward/department transfer. The responsibility for medicine reconciliation rests with all individuals involved with the transfer of care between different settings both within and external to the DMS.

- 48. **Traffic light systems.** Traffic Light systems are agreed lists of specialist drugs that are suitable for prescribing under certain circumstances, within a specific health economy. Red drugs are considered unsuitable for prescribing within primary care and prescribing responsibility will remain with the initiating specialist. Amber drugs are those that are initiated or recommended by a specialist clinician and can then be prescribed within primary care under the auspices of a shared care agreement, where appropriate. Primary care prescribers are advised not to accept responsibility for prescribing these medicines unless they have been adequately informed in writing of their responsibilities with regard to monitoring, side effects, contra-indications and interactions, and are happy to accept the prescribing responsibility. Refer to JSP950 Part 1 Lft 9-3-4 Transfer of Prescribing from Secondary to Primary Care Specialist Drugs for further details. Additional clarification and support should be obtained from the Deputy Chief Pharmacist at HQ SG.
- 49. **Shared Care Agreements**. Effective Shared Care Agreements (ESCAs) are a conduit to ensuring that responsibilities are defined, understood, and provide seamless provision of care in the best interests of the patient. They allow the transfer of prescribing to a primary care clinician, while the consultant/specialist retains overall clinical responsibility for the care of the patient. Refer to <u>JSP950 Part 1 Lft 9-3-4 Transfer of Prescribing from Secondary to Primary Care Specialist Drugs.</u>
- 50. Additional policy on prescribing.
  - a. **Self-prescribing**. Prescribers are reminded that all professional and regulatory bodies recommend that they are not to prescribe for themselves, members of their family, friends, or members of staff directly employed or working in the MTF, unless they are a specifically registered patient. If this situation arises, it is good practice to refer the person to their own doctor.
  - b. **Repeat prescribing**. The decision to transfer a drug from an acute prescription to a repeat prescription should always be made by the prescriber after an informed discussion with the patient and careful consideration of whether the drug has been effective, well tolerated and is required long term. The patient should be seen, or at least spoken to, at this stage, to ascertain the above and to check compliance and adherence. For recommended prescribing intervals see para 52.
  - c. **Generic prescribing**. The term 'generic prescribing' describes the prescribing of a non-proprietary title for a pharmaceutical preparation. It allows any suitable drug, rather than

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a particular brand of drug to be dispensed. It is anticipated that approximately 80% of prescriptions will be prescribed as generic. There are situations, however where it is more appropriate to prescribe a drug by its proprietary (brand) name. Reasons for this include differences in bioavailability between different brands of drugs, confusion for patients or a non-proprietary title does not exist. The BNF often indicates in the individual drug monographs when a specific trade name is advised. Examples of situations where the generic name should **NOT** be used are as follows:

- (1) Where there is a particularly narrow therapeutic index eg lithium carbonate, ciclosporin, aminophylline.
- (2) Certain modified release preparations eg diltiazem, isosorbide mononitrate, nifedipine, mesalazine, methylphenidate.
- (3) Some compound preparations eg topical emollients and creams.
- (4) Certain combined preparations eg Hormone Replacement Treatment (HRT), oral contraceptives.
- (5) When the same drug is used for different and separately branded or licensed indications eg Prochlorperazine Buccastem M® for nausea and vomiting in previously diagnosed migraine only and Indoramin as Doralese® for urinary incontinence.
- (6) When the same drug is formulated to give different potency eg Qvar ® inhalers, dry powder inhalers.
- (7) Other miscellaneous drugs eg insulins, vaccines, wound products, stoma care and appliances.
- d. **Prescribing drugs not available on the National Health Service (NHS).** MOD prescribing endeavours to reflect prescribing in the NHS. Medicines that are not routinely available to be prescribed in the NHS (ie Blacklisted drugs)<sup>15</sup> are not to be prescribed in the MOD. If a medicine is required for a clinical reason, the prescriber may write a private prescription for the patient who should present to a civilian retail pharmacy to have it dispensed. Any costs incurred **cannot** be claimed back via Joint Personnel Administration (JPA). Similarly, only the dressings and equipment listed in the Drug Tariff are allowable at NHS/MOD expense.
- e. **Erectile Dysfunction**. New legislation recently introduced has removed the restrictions on the prescribing of **generic sildenafil** for the management of erectile dysfunction. Generic sildenafil may now be prescribed, where clinically appropriate, to any man requiring treatment for erectile dysfunction. **All** other products for treating erectile dysfunction, including branded sildenafil (Viagra®), continue to be restricted both in terms of eligibility for prescriptions and quantities in line with NHS regulations provided by the Department of Health (DH). Private prescriptions can continue to be provided for patients who do not meet DH criteria and for whom generic sildenafil is unsuitable.
- f. Advisory Committee on Borderline Substances (ACBS). Whilst this is an NHS requirement, MOD prescribing should follow the same principles. Therefore, prescribing of borderline foods and dietary products should comply with the recommendations of the ACBS: 'Prescriptions for such products on FMed296 are regarded as drugs for the treatment of specified conditions. Doctors should satisfy themselves that the products can safely be

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<sup>&</sup>lt;sup>15</sup> These are drugs that are listed in Section XVIIIA of the Drug Tariff and are not permitted on an NHS or MOD prescription. For full details of the drugs on this list, click <u>here</u>.

prescribed, that patients are adequately monitored and that, where necessary, expert hospital supervision is available.' In such cases, the prescriber must endorse the prescription with 'ACBS'. A complete list of conditions can be found in the BNF or <a href="Drug Tariff">Drug Tariff</a> Part XV. Most conditions are included in the following categories:

- (1) Metabolic disorders.
- (2) Liver disease.
- (3) Dysphagia.
- (4) Malnutrition (disease-related).
- (5) Renal Failure.
- (6) Malabsorption states.
- (7) Specific skin disorders.
- (8) Gastrectomy.
- (9) Inflammatory Bowel Disease.

There are several areas where prescriptions for dietary products do not comply with the above recommendations and responsibility lies with individuals prescribing clinician who may use their judgement to make exceptions to the above recommendations. This may occur following recommendations from a dietician or for a medical condition requiring nutritional support for a defined period of time. An example would be a patient having had maxillofacial surgery, being discharged from hospital with a wired jaw and requiring nutritional support for 6 – 8 weeks post-operation. Such a patient would be unlikely to receive adequate nutrition from a manageable volume of liquidised foodstuffs.

- g. **Drugs that may be ordered only in certain circumstances.** The Selected List Scheme (SLS) details items that may only be prescribed under certain conditions. Prescriptions must be marked 'SLS' by the prescriber. **Please note** there are separate lists for English and Welsh prescribers to follow. Examples of drugs that are under this scheme include clobazam, all erectile dysfunction drugs except generic sildenafil<sup>16</sup>.
- h. **Drugs of limited clinical value**. These drugs (eg cough preparations, decongestants, topical NSAIDs (except formulary approved choices, in-line with NICE)), peripheral vasodilators and drugs for minor ailments should not be prescribed routinely. For further details, refer to JSP 950 Part 1 Lft 9-3-1 DPCF.
- i. **Prescriptions generated outside dispensing medical centres**. On occasions, external prescriptions that have been generated elsewhere are presented to dispensing medical centres. There are significant risks associated with this practice including breach of policy, transfer of clinical responsibility (see para 41) and error in transcription. These fall into three categories:
  - (1) **External NHS prescriptions**. If an individual patient presents to a medical centre with an NHS prescription, this should not be transcribed by the dispensing medical centre. The individual should be advised to return to the hospital pharmacy (for hospital prescriptions) or a community pharmacy. If this is not possible, they are to

<sup>&</sup>lt;sup>16</sup> For further details, please refer to section XV111 of the Drug Tariff.

make an appointment to see their Medical Officer (MO)/nurse prescriber who can then review the patient and if necessary prescribe the drug appropriately in accordance with any guidance or shared care agreements (see para 44).

- Signed FMed296 from another medical/dental centre in Global Queue. If the prescription is in the Defence Medical Information Capability Programme (DMICP) Global Queue, then this prescription can be dispensed as prescribed and there is no requirement to transcribe the prescription by the dispensing medical centre. In such cases, the responsibility for the prescribing remains with the original prescriber whilst the dispensing process lies with the dispensing medical centre. If a SMO is not willing to accept this responsibility, then they should see the patient as a new consultation.
- Signed FMed 296 from another medical/dental centre no electronic record. If an individual patient presents to a medical centre with a signed FMed 296 but it is not in the DMICP Global Queue<sup>17</sup>, this should not be transcribed by the dispensing medical centre. The individual should be advised to make an appointment to see their own MO/nurse prescriber who can then prescribe the drug appropriately.

It is important to note that if the prescriber authorises transcription, the responsibility for the prescription and the clinical condition is transferred to the transcribing prescriber. Under no circumstances are pharmacy technicians or other healthcare professionals to transcribe without a prescriber's authority or transcribe internal handwritten prescriptions when DMICP has failed. 18 If a pharmacy technician is in doubt about the authenticity of the FMed 296, this is to be clarified with the prescriber at the originating medical centre concerned.

- Prescribing overseas and implications. In accordance with JSP 770 The Tri-Service Operational and Non-Operational Welfare Policy, 'the management of some chronic conditions could be compromised by an assignment, especially overseas. Before deploying overseas, the assigned is to contact Movement Support Services to obtain a medical screening form and make a declaration concerning the health of their dependants'. All long term medical conditions and any medicines/treatment 19 are to be declared in accordance with single Service procedures in order to allow the receiving theatre to make an informed decision as to whether a chronic condition can be appropriately managed locally. Consideration should also be given to JSP 820 - Tri-Service Disability and Additional Needs Policy.
- Off-label and Unlicensed medicines. Refer to unlicensed policy, JSP 950 Part 1 Lft 9-3-3 Off-label prescribing - Prescribing Licensed Medicines outside of the Terms of their License:
  - Off label. Medicines that are used outside the conditions of their UK/European a. marketing authorisation ('licence') are referred to as being used off licence or off label. Independent non-medical prescribers can prescribe off label where it is accepted clinical practice or alternatively where there is clear justification for prescribing outside the licensed indications or doses.
  - **Unlicensed.** An unlicensed medicine is one that does not have a valid UK marketing authorisation (licence) which defines the medicines terms of use. Independent non-medical prescribers can prescribe unlicensed medicines on the same basis as other independent prescribers.

<sup>&</sup>lt;sup>17</sup> This can be a problem where a patient has been prescribed a drug onboard ship that is not available through the Supply Chain and the patient takes the prescription to a dispensing medical centre. DMICP (Deployed) may not have sychronised so the prescription will not show and transcription by an MO will be necessary

<sup>18</sup> It is acknowledged that current deployed hospital care laydown and interoperability of Med IS systems may make transcription

necessary, in order to computer generate dispensing labels.

19 This is particularly important to ensure that patients declare any specialist or secondary healthcare drugs that may not be available at the new assignment.

Both **off-label** and **unlicensed** prescribing is to take place within the framework of MOD policy for prescribing such products. This MOD policy has been developed and approved through the Medical Policy Steering Group and specifies the need for authoritative clinical evidence and guidance to support prescribing decisions in this area and includes an indication of where liabilities and responsibilities lie. The policy refers to the relevant professional bodies' standards and requirement for patient consent where appropriate. Prescribers accept full professional, clinical and legal responsibility for off-label prescribing.<sup>20</sup>

53. **Controlled Drugs**. Due to the complexities of prescribing, supplying and administering CDs, more detail is to be found at Annex B.

# **Prescriptions**

- 54. **General.** A prescription is a verbal or written authorisation by a prescriber for the supply of medication by an authorised third party to a named individual or their representative. Any verbal instruction must be followed up by appropriate written documentation as soon as is practicable. DMS prescribers are to use an FMed 152 Inpatient Drug Chart or FMed 296 (or Role 3 equivalent) for all internal prescribing. Records made on DMICP do not conform to 'electronic prescribing' and therefore an FMed296 must be printed and signed in all circumstances when using DMICP. It is essential to record drug sensitivities/allergies on patient records and if necessary, written documentation.
- 55. **Prescription requirements.** Several pieces of essential information must be present for a prescription to be considered legal and written in line with national best practice. Prescriptions must include:
  - a. The name and contact number of the prescriber responsible for giving the prescription.
  - b. Identifiable prescriber code as appropriate.
  - c. Date of issue.
  - d. Signed indelibly in ink, by the prescriber.
  - e. For dentists, GPs, and practice-employed non-medical prescribers include the name, address, and telephone number of the practice.
  - f. Such particulars as to indicate whether the practitioner is a doctor, dentist, or other type of prescriber.
  - g. Full name of the patient, their address, and age if under 12 (and date of birth).
  - h. Generic name of the medicine is to be used noting exceptions at Para 45c.
  - i. The full name of a drug and preparation must always be used. Unofficial abbreviations must NOT be used as they may be misinterpreted, putting patients at risk.
  - j. A clearly stated dose. Prescribers should specify the dose by using mg, micrograms, or nanograms (micrograms and nanograms should be written in full). The unnecessary use of decimal points is to be avoided wherever possible (eg 3mg, NOT 3.0mg). Quantities of 1g or more are to be written clearly in units (eg 1g, 2g). Quantities less than 1g are to be written in milligrams (eg 500mg NOT 0.5g). Quantities less than 1mg are to be written in

<sup>&</sup>lt;sup>20</sup> JSP 950 leaflet 9-3-3 contains a list of drugs and specified conditions which have been specifically authorised by SG for unlicensed or off label use within DMS activity.

micrograms (eg 100 micrograms, NOT 0.1mg). When decimals are unavoidable a zero is to be written in front of the decimal point where there is no other figure (eg 0.5ml, NOT .5ml). The word "units" is to be used and not the abbreviation "U".

- k. The quantity to be supplied (or dose and duration of treatment).
- I. Frequency of administration and route is to be clearly stated. 'As directed', 'as required' or other non-specific dosage instructions should not be used as standalone instructions.
- m. For topical preparations, the precise area to be covered is to be specified eg face.
- n. Prescriptions for controlled drugs listed in schedule 2 or 3 of the Misuse of Drugs Regulations 2001 must be written in accordance with those regulations stated at Annex B.

Prescriptions must be legible, indelible, signed and dated<sup>21</sup>.

- 56. **Recording the Prescription**. A record of the prescription must be entered onto the electronic patient record as soon as is practicable if not generated on the integrated electronic health record.(iEHR).
- 57. **Recommended prescribing intervals and validity**. The quantity supplied on a prescription should be appropriate to the medical needs of each patient. For acute prescribing, or where medication adjustments have been made, it is recommended that no more than 1 months supply is made. For ongoing, stable medical conditions where repeat prescriptions are issued, it is recommended that up to 3 months supply is prescribed at any one time. Prescriptions are valid for 6 months. Prescriptions for CDs are valid for 28 days. For those personnel travelling overseas, prescribers should adhere to the following:
  - a. **Operations**. Unless the supply of medication can be guaranteed on the operation, prescribers should supply enough medication for the length of tour, usually to a maximum of 6 months supply. Consideration should be given to the potential storage conditions in theatre (eg for the contraceptive pill, insulins), the reliability of the supply chain, and the ability to store large quantities of medicines.
  - b. **Overseas Travel (including expeditions and holiday)**. Prescribers should supply enough medication to cover the length of the trip overseas and any associated leave.
  - c. **Travel on assignments**. Prescribers should supply enough medication to cover the length of the trip overseas and transition to a different MTF. This should be to a maximum of 3 months.

MTFs are to advise patients that if they are concerned about running out of medication then they are to contact the MTF responsible for their primary care at the earliest opportunity and on their return to their unit for continued supply. Where there is any doubt to the validity of the request, reference is to be made to any supporting information eg joining or mounting instructions.

- 58. **Types of MOD prescriptions**. The following are the only types of prescription that are to be used in DMS MTFs:
  - a. **FMed 296.** This is the standard MOD prescription and is to be used in all primary care settings, including on operations, unless there is a recognised alternative identified below. This FMed may also be used to record the supply of a medicine against a protocol or PGD

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<sup>&</sup>lt;sup>21</sup> For further information see the British National Formulary.

particularly when an electronic record is unavailable <sup>22</sup>. There are two versions of the FMed 296 that can be ordered via MILLIE:

- (1) Loose pad (091LAN1368849).
- (2) DMICP template (091LAN1368848).
- b. **FMed 152.** The FMed 152 is the MOD's inpatient medication chart developed primarily for use on operations. However this is also to be used in any area where patients are bedded down eg Medical Reception Station (MRS), Defence Medical Rehabilitation Centre (DMRC). Only one prescription chart should exist for a patient at any one time and all associated supplementary charts (eg epidural charts) should be clearly annotated as such. All errors and queries relating to these prescriptions are to be referred to the prescriber in the first instance. These are obtained on MILLIE using the code: MSN 091LAN1369641.
- c. **FP10 (PCD)**<sup>23</sup>. This is an NHS prescription required to prescribe Schedule 2 and 3 CDs when the dispensing process is not carried out in MOD MTFs. CDs will not be dispensed in community pharmacies unless they have been prescribed on these prescriptions. The DMS has obtained authority from the NHS Business Services Authority to have a unique Prescriber Code allocated to each of the DPHC Regions to allow tracking and audit. They are pink in colour and supply is coordinated via NHS England London Region to Regional Pharmacists. Regions are to ensure that these forms are accounted for and secured correctly.

Examples of these prescriptions to aid recognition are at Annex C.

- 59. **Handling and Security of Prescription Forms**. Prescriptions are controlled stationery and must be obtained, stored securely and controlled at MTFs. Local SOPs must be in place to ensure that prescriptions cannot be misplaced, misused or misappropriated. The risks of not managing the security of prescription forms are well documented<sup>24</sup> and whilst the MOD cannot adhere to all the recommendations and will tolerate a degree of risk, we must develop a prescription security awareness culture amongst all personnel<sup>25</sup>. The following guidance is to be followed:
  - a. All healthcare delivery organisations and commands are to:
    - (1) Prevent theft and misuse through secure storage and control.
    - (2) Develop an organisational SOP outlining individual roles and responsibilities.
    - (3) Develop local protocols outlining what actions to take in the case of loss, theft or missing prescription forms.
  - b. Practice Managers and those responsible for administration are to ensure that they:
    - (1) Order as normal through MILLIE online. Prescriptions should not be stockpiled and should only be re-ordered to maintain a reasonable working level of stock.
    - (2) Secure deliveries as soon as possible (locked room in a locked cabinet) and restrict access. Deliveries should be checked for missing serial numbers.

<sup>&</sup>lt;sup>22</sup> The MOD has introduced a tick box at the top of the FMed 296, identifying the form as a record of supply against a PGD or protocol. <sup>23</sup> Equivalent prescription forms in Wales, Scotland and NI can be found <u>here</u>. The prescriptions for CDs are usually allocated to individual prescribers but for the MOD they are allocated to DPHC regions and subsequently to the MTF.

NHS Business Authority - Security of prescription forms guidance.

<sup>&</sup>lt;sup>25</sup> The MOD has now introduced serial numbers onto the base of the FMed 296 prescription form. It is not as complicated as the NHS serialisation but provides a mechanism to record and monitor usage.

- (3) Maintain a central stock control record that records the receipt, issue and destruction of the serialised prescriptions in an auditable way. This is to be retained for 3 years.
- (4) Ensure prescribers store prescriptions securely when not in use or at end of clinical sessions. Any prescriber finishing employment at the MTF should return all unused prescriptions to the Practice Manager/pharmacy technician who will amend the records.
- (5) Conduct random checks on the prescriptions in circulation at the MTF.
- (6) Report up the CoC all cases where prescriptions are known to be lost or stolen.
- (7) All prescriptions that are damaged or contain errors and therefore not issued to patients should be disposed of appropriately by shredding or burning.
- (8) Report any misuse, loss or theft of prescription forms through the CoC and to the military police quoting which serial numbers are affected. The MTF log should be annotated to reflect which serial numbers have been suspected of being lost / stolen and an SE raised as part of the investigation.

# **Supply and Administration**

- 60. **General**. There are several routes whereby patients may legally receive medicinal products. Once a medicinal product has been prescribed and dispensed or supplied to an individual, the drug is the individual's own property. If this medicine is used for or given to another individual this could be treated as a criminal offence. It is important to complete the patient record immediately (or as soon as is practicable) after a drug has been supplied or administered to a patient.
- 61. **POMs**. Prescription Only Medicines (POMs) may ONLY be supplied or administered under the:
  - a. Directions of an appropriate prescriber.
  - b. Under the terms and conditions of a valid PGD.
  - c. Human Medicines Regulations 2012 Exemptions (where they apply to specified health professionals, Service Personnel (SP), Masters of Ships and Commanders of Aircrcaft) <sup>26</sup>.
  - d. As an 'emergency supply' by a Community Pharmacy (non-MOD).
  - e. When some medicines are used in an emergency for the purpose of saving life or to prevent ill-health when it is not practicable for another person who is legally entitled to supply a POM to do so.
- 62. **Non-prescription medicines**. P and GSL medicines are only to be supplied or administered to individual patients in accordance with the directions given by a prescriber for that specific patient or in accordance with a PGD or medic protocol. This does NOT include patient's own 'over the counter' medicines, which may have been supplied directly to the patient by a community pharmacy or other retail outlet.

<sup>&</sup>lt;sup>26</sup> SI 1997 No 1830 HMR 2012 Part 5 Schedule 17.

- 63. **Drug administration**. All reasonable endeavours will be made to gain the patient's consent before administration is undertaken in line with DPHC's <u>Guidance Note 03/15</u>: <u>Consent for Treatment</u>. The following principles are to be applied when administering drugs to patients:
  - a. Medicines will be administered by appropriately qualified and competent persons with documented authority.
  - b. Only medicines of assured quality, efficacy, and safety will be administered. Before any administration of injectable medicines, infection control principles in accordance with JSP 950 Part 1 Lft 7-2-1 Guidance on Risk Assessment and Immediate Management of Needlestick/Sharps/ Blood/ Body Fluid and Tissue Exposure Incidents must be applied and all calculations, expiry dates, dose and route are to be confirmed by 2 people.
  - c. Medicines should only be given by injection when the practicality and appropriateness of other routes of administration has been excluded.
  - d. All medicines prepared for administration should be prepared by appropriately trained healthcare professionals and administered immediately by the person who has prepared the medicine or in their presence. Exceptions on operations include Intensive Care Unit (ICU), where syringes are permitted to be prepared in advance.
  - e. When only part of the preparation has been used, the remainder is to be discarded in an appropriate waste container and not used for another patient.
  - f. No one should administer a parenteral POM, unless they are an appropriate practitioner or are acting in accordance with the directions of an appropriate practitioner. However, a number of medicines are exempt from this restriction when administered in an emergency for the purpose of saving a life, or for self-administration.
  - g. Each member of staff that administers a medicine that may cause anaphylaxis will have ready access to adrenaline (epinephrine) injection of the necessary strength and quantity, as part of a resuscitation trolley and have had appropriate training to ensure competence in treating anaphylaxis.
  - h. Special instructions for administering medicines must be read prior to administration. If in doubt about any route of administration the prescriber or a pharmacist should be contacted.
  - i. Mixing of medicines and enteral feeding is to follow <u>NEWT Guidelines</u> (or recognised equivalent).
- 64. Patient Specific Directions (PSD). A PSD is used once a patient has been assessed by an independent prescriber, and that prescriber, (doctor, dentist or non medical prescriber), instructs another healthcare professional or Defence Medic in writing to supply or administer a medicine directly to that named patient or to several named patients. This could be demonstrated by a simple request in the patient's notes or an entry on the patient's drug chart. It may also take the form of a list of patients' names and addresses attached to a direction to supply or administer a certain medicine (eg patients on a clinic list). Regardless of how the detail is recorded, a permanent record must be included in the patient's iEHR. In general, PSDs are a direct instruction and do not require an assessment of the patient by the healthcare professional instructed to supply and/or administer the medicine, unlike a PGD. Full responsibility and accountability lies with the independent prescriber who has written the instruction and must have conducted an assessment of each individual patient. These are useful for large numbers of patients having the same medication (eg unit deployments).
- 65. **Patient Group Directions (PGD).** A PGD is a written direction that allows the supply and/or administration of a specified medicine or medicines, by a named and authorised health

professional, to a well-defined group of patients requiring treatment for a specific condition. Supply cannot be delegated to any other person under a PGD, regardless of their profession or level of training because such delegation is not allowed by medicines legislation. In order to supply medications under a PGD, a professional must have stocks available of appropriately labelled products conforming in accordance with the specific directions of the PGD. See also <u>JSP 950 Part 1 Lft 9-4-2</u> Patient Group Directions.

- 66. **Protocols**. Those personnel within the MOD not entitled to prescribe medicines or supply/ administer under a PGD can be authorised to supply medicines in accordance with a ratified protocol. These protocols are to define scope of practice and procedures for each aspect of a treatment. Examples include Army Cbt Med Tech protocols, RAF Medic Treatment Protocols, RN Medic Issuing Protocols and MOD A Block protocols.<sup>27</sup> Personnel are only authorised to use these protocols following completion of specific training and when they have been assessed as competent by the supervising MO. Medicines issued under protocols are to be labelled in accordance with the specific directions of the protocol.
- 67. **Recording of supply on the electronic health record.** It is essential to record all instances when medicines are supplied against a PGD, PSD or protocol. Templates should be used when available. If they are not available, then the consultation, along with any medicines supplied, is to be recorded onto the system, as "issued" on the "Medication" screen. The batch number and expiry date is to be entered into the patients' notes as free text. This allows the medicine to be supplied to the patient as "issued" and then deleted from the dispensing queue, but recorded in the medication history.
- Overlabelling. To allow patient packs to be supplied safely to patients under a PGD, PSD or protocol, there is a need to prepare pre-labelled packs to reflect the dose exactly as authorised in the these protocols, as if it were being dispensed against a prescription. <sup>28</sup> Labels must include all the standard labelling requirements, leaving a space on the pack for the patient's name, date of dispensing and address of the supplying service to be added at the time of supply. In NHS practice, medicines supplied are often in packs that are pre-labelled by a licensed manufacturing unit. Legislation allows for low-scale overlabelling for an organisations' own use without the need for a licence. The MHRA have agreed that for the MOD, this is 25 packs per product per month per region and these are to be prepared under the supervision of a pharmacist. Operationally, every effort should be made to label medicines correctly but it is accepted that RN platforms and Role 1 units may not be able to over label. 69. The unlicensed administration of medicines. The Summary of Product Characteristics (SPC) for licensed medicines includes the storage and administration recommendations for that product. Deviation from the SPC makes the use of the product "off label" or unlicensed. Examples of this are crushing tablets, cutting unscored tablets, cutting patches, opening capsules, adding liquid medicines to food or drink, adding thickening agents to liquid medicines and giving medicines by unlicensed routes (eg giving intravenous fluids by a subcutaneous route). There are legal, professional and clinical considerations to be made when administering medicines using an unlicensed method and advice should be sought from a pharmacist where possible.

# Charging policy for the supply of medicines

70. **UK primary care**. All medicines are supplied or administered to Service Personnel (SP) at no cost to the individual (except for those on private prescriptions). Where a supply of medicines is made to a dependant or entitled civilian who is not normally exempt<sup>29</sup> from NHS prescription

<sup>&</sup>lt;sup>27</sup> Army Cbt Med Tech Protocols, RN Medic Issuing Protocols (MIPs), RAF Medic Treatment Protocols and Medication Issuing Protocols and MOD A Block protocols.

<sup>&</sup>lt;sup>28</sup> If the dose and maximum of duration of treatment is less than the smallest commercially available pack size, the label should include the maximum duration of treatment and directions to discard the remainder. No splitting of manufacturers original packs is to occur.

<sup>29</sup> For details on who is entitled to free prescriptions and how much NHS prescription charges please click <a href="here">here</a>. Also note that there are no prescription charges in Wales, Scotland and NI.

charges, arrangements must be made to collect the national prescription charge<sup>30</sup>. No charges are applied to medicines supplied under a PGD, except for those travel vaccinations not normally received free on the NHS (prescription charge to be applied).

- 71. **UK secondary care**. All prescriptions issued in UK hospitals should be dispensed in the hospital pharmacy. These prescriptions are not to be dispensed in DPHC MTFs. Any costs incurred by SP are to be claimed back on JPA.
- 72. **Overseas**. The policy governing the entitlement to medical care overseas and associated charges is held in JSP 770 The Tri-Service Operational and Non-Operational Welfare Policy.<sup>31</sup>

#### Overseas travel

- 74. **Holiday or non-duty overseas travel**. All travel requires a competent travel risk assessment.
  - a. **Regular military personnel**. For regular military personnel, all travel medicines, as recommended by recognised travel medicine information sources<sup>32</sup>, will be supplied against prescriptions issued by MTFs at no charge to the individual, irrespective of whether the travel is duty-related or not. This does not extend to instances where the travel will occur after the individual leaves the Service, but does include career breaks. In the event of non-availability or supply restrictions at DMS MTFs, Service personnel should be advised to obtain the necessary items via civilian travel clinics and reclaim the costs via JPA, against parent-unit budgets.
  - Reserve military personnel. Reserve personnel are not normally entitled to DMS primary care in the UK, but they are entitled to DMS care when on exercise overseas (JSP 770 - The Tri-Service Operational and Non-Operational Welfare Policy, Chapter 4). Defence is responsible for their medical support when they are deployed or undertaking officially sanctioned military activity be it sporting, adventurous training or military training, up to the point where the individual is fit to be discharged home to the care of their own GP in the home base. For official travel, Reserve Personnel will be seen at a DPHC medical centre prior to their deployment. The medical centre staff will complete a travel risk assessment (example at page 28-29 of the RCN guidance on travel health nursing)<sup>33</sup>, record any consultation on the iEHR and provide any required vaccinations and medicines. Medical facility staff should complete the risk assessment in conjunction with any relevant operational medical information in accordance with JSP 950 leaflet 7-1-1 Immunisation of Entitled Personnel, para 6. If the MTF are unable to provide these, the Reservist is to be advised to obtain travel medicines and vaccinations from their own GP or travel clinic and reclaim any costs on JPA. A summary of the consultation is to be given to the individual for onward transmission to their own civilian GP.
  - c. **Entitled civilian patients**. Registered dependants and other entitled non-military patients (including MOD employees) may not be prescribed or supplied travel-related medicines or other products against public funds, unless they are accompanying service personnel on official duty or posting. Individuals requiring routine travel medicines are to be referred to a civilian travel clinic and informed that there may be charges levied for the

http://www.rcn.org.uk/\_\_data/assets/pdf\_file/0006/78747/003146.pdf. Accessed 30 Jun 15.

JSP 950 Part 1 Lft 9-2-1 (V1.0 Dec 15)

<sup>&</sup>lt;sup>30</sup> This includes outsourced medical centres where they will pay on collection.

<sup>&</sup>lt;sup>31</sup> Prescription charging is in place in Germany and FI, where equivalent NHS exemptions and prepayment certificates are available.

NaTHNaC or Travax.

services they receive. Those vaccinations offered free in the NHS can be administered in the medical centre. Alternatively, the individual may be given a private prescription, which they should present to a civilian Pharmacy for dispensing and for which they will be charged an appropriate fee by the pharmacy<sup>34</sup>. Parenteral products (eg vaccines) supplied through the external pharmacy may be administered by MOD clinical staff with no charges being raised for the service<sup>35</sup>.

- d. **Civilian MOD employees**. MOD-employed civilians may be supplied relevant travel medicine requirements (for duty travel purposes only) via an MOD MTF. If these are supplied from a civilian source then the costs can be claimed back from the MOD. A summary of the consultation is to be given to the individual for onward transmission to their own civilian GP.
- e. **Dependants (unregistered).** When accompanying service personnel on official duty or assignment, non-registered dependants should be advised to obtain any necessary medicines and vaccinations required for travel through their NHS GP or travel clinics and reclaim the costs, via the Service person's parent unit as a JPA claim for relocation expenses.

# **Dispensing**

- 75. **Responsibility**. Dispensing is distinguished from supply or administration of medicines if the patient or carer is intended to use the medicine other than under the direct supervision of the practitioner. For most patients medicines are obtained by means of a prescription, which has been issued by an appropriate prescriber for the medical treatment of that individual. The prescription is then dispensed by, (or under the supervision of), a pharmacist or dispensing doctor, according to national legislation before being supplied to that patient. Defence MTFs, except for those where a pharmacist is employed, are the equivalent to NHS dispensing practices and therefore the responsibility for the dispensing function rests with the SMO or equivalent. On operations, where there is no direct supervision by an MO, the responsibility lies with the CO. However, clinical decisions and issues of POMs are only to be authorised by a MO.
- 76. **Process**. Dispensing includes such activities as checking the validity of the prescription, appropriate dosage method for an individual patient, the assembly and labelling of the product (including the addition of appropriate cautions, providing information leaflets and necessary counselling for the patient). All dispensing procedures must comply with the Human Medicines Regulations and EEC Directive 92/27 with regard to their packaging, labelling and package leaflets. Handling of medicines must comply with any relevant Control of Substances Hazardous to Health (COSHH) risk assessment.
- 77. **Pharmacy standards**. Patients have the right to expect that dispensing will be carried out with the same care and to the same standard they might reasonably expect if it was carried out by, or under, the supervision of a pharmacist. The **Pharmacy Standards** state in particular:
  - a. There must be SOPs in place covering all aspects of dispensing which all staff are to follow.
  - b. Medicines must be supplied as original manufacturer packs or in pre-packs prepared under the supervision of a pharmacist.
  - c. The medicines must have a sufficiently long expiry date to cover the course of treatment.

<sup>&</sup>lt;sup>34</sup> No charges are to be levied for these consultations by MTF staff.

<sup>&</sup>lt;sup>35</sup> There is no mechanism to deal with non-NHS standard charges through MOD dispensaries. Private prescriptions issued for travel-related products are not to be dispensed or otherwise supplied by DMS MTFs.

- d. The medicine must be labelled correctly.
- e. The patient or carer must be supplied with the manufacturer's information leaflet and provided with counselling where necessary. Any information provided to patients is to be in a format that the patient can understand.
- 78. **IT infrastructure**. Where possible an electronic prescribing and dispensing system is to be used. This is currently DMICP. It is to be used to account for all medicines and to record the issue and administration to patients in primary care. It is not a legal requirement to print or computer generate prescriptions but this is regarded as best practice by all the professional and regulatory bodies. Hand written prescriptions are only to be generated when absolutely necessary. The legal requirement is for the prescription to be signed by the prescriber. This is prior to the patient receiving their medication ie at the point of prescribing.
- 79. **Dispensing environment**. Dispensary infrastructure, including fixtures, fittings, shelves, containers for dispensing and work surfaces must be fit, appropriate and clean for purpose. A sink with hot and cold running water is to be available and the dispensary is to remain tidy at all times. Full details can be found in <u>JSP 315</u>, <u>Scale 28</u>. Personnel should also maintain a high level of personal hygiene, wear appropriate clean clothing, and cover broken skin. Eating and smoking are not permitted in the dispensary environment. Staff are permitted to drink non-alcoholic beverages providing these have been prepared elsewhere.
- 80. **Ordering against a prescription**. When ordering and selecting medicines to supply or administer to a patient, the following is to be considered as the order of priority in line with paras 15-18:
  - a. **First line**: Generic products (except for those products that have to be specifically prescribed as a brand, as identified in the BNF).
  - b. **Second line**: If a particular generic product is not available, then MTFs are to identify the next available generic from a different manufacturer if possible.
  - c. **Third line**: If there are no generic products available then a suitable branded product may be selected.
  - d. **Fourth line**: Parallel Imports (PI) or unlicensed products may be considered where **NO** appropriate UK marketed generic or brand is available. Under no circumstances are PIs to be used as preferential products and ordered routinely.
- 81. **NHS** prescriptions. NHS prescriptions are not to be dispensed in MOD MTFs unless absolutely necessary. Patients presenting with NHS prescriptions are to be referred to the nearest civilian retail pharmacy (if a green FP10 form is used) or the originating hospital (for pink FP10 or HS10 forms see also para 66). Any incurred costs are to be recovered via JPA. Transcription onto the iEHR is strongly discouraged (see para 45i).
- 82. **Labelling**. Medicines supplied must be mechanically labelled according to the requirements of Legislation, European Directives and Royal Pharmaceutical Society (RPS) best practice and must specify:
  - a. The name, form and strength of the medicine.
  - b. Number of dose units or volume of medication.
  - c. Directions for use.
  - d. The patient's name.

- e. The date of supply/dispensing.
- f. The name and address of the supplying MTF.
- g. The phrase 'Keep out of the sight and reach of children'.
- h. The phrase 'For external use only' if appropriate.'
- i. All appropriate cautionary, warning labels and special storage instructions.

In the event of mechanical failure, labels can be produced by typewriter or pre-prepared labels (including the FMed series). As a last resort, labels can be neatly hand written with indelible ink. These labels should be checked by a pharmacy professional or senior clinician before supplying to a patient. Guidance on the correct cautionary labels is available at Appendix 3 to the BNF.

# 83. Dispensary manning and roles.

- a. **Responsibility.** The responsibility for medicine management and the safe dispensing of medication lies with the Principal Medical Officer (PMO)/ Senior Medical Officer (SMO) (or CO on sea going vessels with no MO borne). The responsibilities of all personnel involved with the management and working practices of the dispensary are to be clearly defined in Medical Standing Orders and TORs. Patient safety is of paramount importance when considering the dispensing of medication. It must be ensured that the correct patient has the correct medication in the correct quantity, in the correct form, at the correct dose, with the correct instructions and counselling.
- b. **Clinical check**. The responsibility for the 'clinical check' rests with the prescriber shared by the pharmacist (if available), to ensure that the medication, dose and frequency of use are appropriate for the specific patient's medical condition. It is the dispensary staff's responsibility to ensure that the prescriber's wishes and directions are correctly translated from the prescription and relayed to the patient and that the correct medications with appropriate labels (including warning and cautionary labels where necessary) are supplied.
- c. **Delegation.** The task of dispensing is delegated by the PMO/SMO to other personnel. In these cases, the PMO/SMO is to confirm the competency of all staff undertaking dispensing duties. Where an individual is not considered suitable for such duties, On Job Training (OJT) is to be given to ensure competence. All such personnel are accountable to the PMO/SMO for their actions.
- d. **Dispensing personnel.** Dispensing may be undertaken by a range of personnel within an MTF:
  - (1) **Pharmacists**. Pharmacists are qualified to Degree or Masters Level in Pharmacy and registered with the General Pharmaceutical Council (GPhC).
  - (2) **Pharmacy Technicians**. Pharmacy technicians must be qualified to NVQ Level 3 in Pharmacy Service Skills (or previous equivalent) and registered with the GPhC.
  - (3) RN Medical Assistants (MAs) / Army Combat Medical Technicians (CMT) / RAF Medics. Collectively and in the future, these cadres will complete the Defence Medic Training Pathway. SP working in the dispensary should be trained to the equivalent<sup>36</sup> of NVQ Level 2 in Pharmacy and are to be supervised by Pharmacy

<sup>&</sup>lt;sup>36</sup> NVQ L2 in Dispensing Services (or equivalent eg Buttercups) or has completed the Common Core/Defence Medic pharmacy module and the DPHC workplace competency framework for dispensary staff (available here), and deemed competent by the SMO.

Technicians where possible. The MOD is developing a Dispensing Assistants' course and this forms part of the standard training package for Defence Medics in the future.

- Registered nurses. There is no legal barrier to nurse dispensing but the Nursing and Midwifery Council (NMC) Standards of Proficiency for nurse and midwife prescribers requires that there is local policy in place to endorse the registrant's actions. A nurse should only dispense medication if they feel professionally competent to do so. The NMC recommends that nurses ensure that they are covered for vicarious liability by the employer and seek appropriate indemnity insurance for authorised and agreed dispensing.
- **Doctors**. There is no legal barrier to doctors dispensing, however any dispensing errors may risk the doctor's registration with the GMC. It is not considered good practice for a doctor to dispense medications that they have prescribed, unless there is another healthcare professional available to second check.
- Second checkers. Wherever possible, two members of staff should be involved in the dispensing process. One person is to act as the 'dispenser' and one to act as the 'checker'. It is best practice to have a register of signatures for dispensers and second checkers. The importance of the second 'checker' cannot be over emphasised and they must diligently carry out this duty.
- f. Out of hours dispensing. In the absence of a pharmacist/pharmacy technician, outside of normal working hours, an authorised prescriber may dispense medication providing another member of authorised healthcare staff is present to check and countersign the prescription in order to reduce any delay commencing patient treatment. MTFs are to have a clear SOP in place to allow for the signing out of keys/release of door codes, and who is authorised to have access to the dispensary. A record of who has entered the dispensary is to be available to dispensary staff at the beginning of the next routine shift for audit and accountability purposes. Access is to be restricted to duty personnel only.
- Concerns regarding performance. Where the SMO/clinical lead has concerns about an individual's competence or performance, a supportive approach should be taken. If after such an intervention, concerns are still present then further action is to be taken, with advice from the Head of Career Employment Group (CEG) or professional lead. Further details can be found in JSP950 Part 1 Lft 5-2-4 Managing Clinical Performance Concerns of Practitioners Within the DMS.
- Outsourced dispensing. Ideally all dispensaries should be managed by a full time pharmacy technician, registered with the GPhC. Where this is not possible due to manning gaps, illness or long term absence and where an MTF is unable to dispense safely with competent and trained personnel, the following contingency plans are recommended:
  - For very short term absence, an appropriately trained Combat Medical Technician (Cbt Med Tech) /Medic/Nurse<sup>36</sup> and a second checker.<sup>37</sup>
  - b. Longer term cover by a locum pharmacy technician.
  - Outsourcing to a community pharmacy within the extant MOD contract (DPHC SOP). C.
  - d. Independent outsourcing to another community pharmacy as a temporary solution.
  - Temporary closure, referring patients to a nearby dispensing medical centre. e.

<sup>&</sup>lt;sup>37</sup> This is for operational environments only.

- 86. **Generic substitution**. Legal and professional requirements dictate that pharmacists in the community must dispense prescriptions in accordance with the directions of an appropriate practitioner. This precludes a pharmacist from substituting a product for a named product without the approval of the patient and the prescriber. However, generic substitution has been carried out routinely for many years. In all but a few cases, pharmacists can dispense a brand rather than a generic. The legal basis for this is s58(2)(b) of the Medicines Act 1968, which states that "no person shall administer (otherwise than to himself) any medicinal product unless he is an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner".
- 87. **Parallel Imports**. A PI can be dispensed when a prescription has been written generically. It can also be dispensed when a prescription has been written using a UK brand name, but only when the import has the identical brand name. Further information on PIs is at Para 17.
- 88. **Packing down**. Units are not to pack down original packs unless absolutely necessary and is only to occur under the supervision of a pharmacist. Units are not to pack down or over label medicines in their own unit lines (see para 63).
- 89. **Patient Information Leaflets (PIL)**. It is an EC Directive (92/27) that every issue of a dispensed or supplied medicine should be accompanied by printed information specifically written for the patient. In order to meet the requirement, medicines are to be supplied in patient packs where possible. Approved PILs for split packs of medicines can be obtained from <a href="https://www.Medicines.org.uk/emc">www.Medicines.org.uk/emc</a> or direct from the manufacturer where one is not available at this website. When it is not possible to provide an approved PIL (eg on operations), the patient should be fully counselled.
- 90. **Unlicensed medicines**. Prescribers and pharmacy staff should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label. These risks may include: adverse reactions; product quality; or discrepant product information or labelling (eg absence of information for some unlicensed medicines, information in a foreign language for unlicensed imports, and potential confusion for patients or carers when the Patient Information Leaflet is inconsistent with a medicine's off-label use). Refer to para 47 and 64.
- 91. **Cytotoxic drugs**. Cytotoxic drugs are hazardous substances, as defined by the Control of Substances Hazardous to Health Regulations 2002 (COSHH). Under <u>COSHH</u>, employers must assess the risks from handling cytotoxic drugs for employees and anyone else affected by this type of work, and take suitable precautions to protect them. More specific information can be found in the <u>COSHH Approved Code of Practice (ACOP</u>). The toxicity of cytotoxic drugs means that they can present significant risks to those who handle them. Occupational exposure can occur when control measures are inadequate. Exposure may be through skin contact, skin absorption, inhalation of aerosols and drug particles, ingestion and needle stick injuries. Cytotoxic drugs are to be stored in a dedicated and segregated section of the dispensary and have dedicated dispensing equipment.
- 92. **Extemporaneous dispensing**. An extemporaneous preparation is a pharmaceutical formulation that is not available as a licensed product and can be obtained from a 'specials' manufacturer. Extemporaneous dispensing is not to occur in any MTF. Any requests for these products are to be referred to Regional or Command Pharmacists.
- 93. **Interventions**. All personnel employed in a dispensary are very well placed to make appropriate clinical and process interventions, and have the potential to play a significant role in delivering public health messages. Key areas for interventions are in prescribing (dosage and strengths of medication) and administration, and these are proven to improve patient care and avoidance of hospital admissions. Interventions should be recorded and analysed on a regular basis to improve prescribing and administration.

- 94. **Counselling**. All healthcare personnel have a responsibility to counsel patients to assist with medicines optimisation. Adherence is a key factor in achieving good clinical outcomes in patients undergoing treatment (Medicines Adherence NICE Guidance CG76). Meeting and talking to patients is fundamental in educating them on correct drug use, and recommending dietary and lifestyle changes.
- 95. **Retention of records.** Annex A to <u>JSP 950 Leaflet 1-2-11 Defence Health Record</u> provides the <u>Retention Periods</u> of all medical documentation including those that are related to pharmacy and medicines management.

# **Disposal of Pharmaceutical Waste**

- 96. **General.** Medicinal waste encompasses all expired, unused and spilt pharmaceutical drugs and any containers (eg bottles, vials and ampoules) with left-over residue, and products contaminated from the use of handling pharmaceuticals. Pharmaceuticals are not to be placed in normal refuse bins but should be disposed of via local waste disposal contracts which must include the requirement for pharmaceutical waste. The majority of pharmaceuticals should be placed in a yellow bin with a blue lid (leak proof container). Ideally, solid and liquid medicines should be separated and any container for liquid medicines must have an absorbent pad. Sharps<sup>38</sup> should be disposed of in specific yellow sharps bin with yellow lid (UN 3291 or approved) unless they fall into the categories below.
- 97. **Specific guidance.** This can be obtained from the Department of Health's <u>Safe</u> <u>Management of Healthcare waste</u> but as a specific guide:
  - a. **Cytotoxic/Cytostatic Medicines**. These are classed as hazardous waste (under the Hazardous Waste Directives) and must be disposed of correctly in an appropriate yellow bin with a purple lid (leak proof container).
  - b. Controlled Drugs. For information on the disposal of CDs refer to Annex B.
- 98. **Patient Returns**. To avoid the risk of misuse and stockpiling of patient returned medicines, patients can return unused or unwanted medicines to their local Community Pharmacy. If these medicines are returned to MTFs they must not be put back into stock or used for any other patient, but disposed of as above in para 91 and 92. It is essential that excessive returns should be noted and patients' medication reviewed to ensure that they are not receiving excessive medicines. To comply with the <a href="Data Protection Act 1998">Data Protection Act 1998</a> and patient confidentiality regulations, all patient details must be obscured or removed from packaging prior to disposal.

# **Governance and Risk Management**

#### **Medication errors**

- 99. **Definition**. A medication error is a preventable incident (or near miss) associated with the use of medicines that, or could have, resulted in harm to a patient. Such incidents may be related to any step in the medicines use process. This includes the prescribing, dispensing, storage and administration of medicines as well as the transfer of information. The wellbeing of the patient is of prime importance following a medicine incident and potential safeguarding implications must be given due consideration when an incident involves a child or a vulnerable adult.
- 100. **Reporting**. All Healthcare Professionals must be familiar with <u>JSP 950 Part 1 Lft 5-1-4 DMS</u>
  <u>Healthcare Governance and Assurance</u> which provides guidance on the identification and

 $_{\mbox{\scriptsize 3}}$  Medicinally contaminated syringes, needles and broken  $\overline{\mbox{\scriptsize glass medicinal ampoules.}}$ 

management of patient safety related risk and the use of the DMS Automated Significant Event Reporting (ASER) system. Following an incident, individuals are to immediately report the incident to their line manager and complete a Significant Event (SE) form on the ASER system or equivalent on operations. This is to allow incidents to be investigated and any risk to be assessed. Any learning (which is anonymised) is shared with colleagues and action plans can then be developed and implemented to prevent future recurrence.

101. Investigations. Incidents involving the administration or supply of medicines require thorough and careful investigation, which takes full account of the circumstances and context of the event and the position of the practitioner involved. Where an administration error has occurred, the patient/carer and the GP in charge of the patient must be informed in line with JSP 950 Part 1 Lft 5-1-6 Duty of Candour (waiting for publication).

# Adverse Drug Reaction (ADR) reporting

- 102. Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance. In particular, prompt reporting should be carried out for any suspected adverse reactions to new drugs and vaccines under intense surveillance (given the symbol of an inverted black triangle (▼) in the BNF).
- 103. Healthcare professionals have a responsibility to help monitor the safety of medicines in clinical use through submission of suspected, serious or unusual adverse drug reactions to the MHRA and Commission on Human Medicines (CHM) via the Yellow Card Scheme.<sup>39</sup> Such reporting is equally important for unlicensed medicines 40, those used off-label, and those medicines obtained by patients over the counter and herbal medicines. The patient's GP must be informed of any adverse reaction to a drug or dressing prescribed by a non-medical prescriber. All staff should also report any adverse drug reactions through the ASER system.

### **Counterfeit Medicine and Defective Product Reporting**

- 104. Counterfeit medicines are those medicines that are described as 'deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products. Counterfeit products may include products with the correct ingredients or with the wrong ingredients, without or insufficient active ingredients, or with fake packaging'41.
- 100. A defective product is a product that is supplied by the manufacturer but not to the expected standard. Defects may involve inadequate or incorrect labelling, ineffective packaging. contamination, discoloration, breakage, and incorrect contents.
- 105. In all cases, counterfeit and defective products are to be reported to the supplier via Team Leidos and also to local pharmacy personnel who may raise a report on the ASER system. To report a product/equipment failure that may require technical investigation, please use the Faulty Product Form and email it to DESMedGS-Inv1aGroup@mod.uk.

### Healthcare Safety Alerts and Drug/Device Recalls

106. General. Occasionally medical products are not manufactured, labelled or prepared in accordance with their Marketing Authorisation (MA) or are reported to have side effects or problems previously unidentified. In such cases, updated information or a recall of products is the responsibility of the MA holder. When defects represent a significant hazard to health, the

<sup>41</sup> MHRA guidance on counterfeit medicines.

<sup>39</sup> Further guidance on reporting reactions can be found in the BNF, along with a paper copy of the yellow card.

<sup>&</sup>lt;sup>40</sup> Additional reporting requirements for unlicensed medicines are in JSP 950 Leaflet 9-3-3 (to follow).

Medicines and Healthcare Products Regulatory Authority (MHRA) will issue a 'drug alert' via the Central Alerting System (CAS).

- 107. **Central Alerting System (CAS)**. CAS is a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information and guidance to the NHS and others, including the MOD. These alerts originate from all the regulatory agencies and professional bodies and are cascaded automatically through the MOD. The alerts include safety alerts, Chief Medical Officer (CMO) messages, drug alerts, Dear Doctor letters and Medical Device Alerts and are available on the CAS website.
- 108. **Alert Actions**. CAS alerts are received at HQSG and auto forwarded to a predefined<sup>42</sup> list of recipients. These Commands are then responsible for ensuring that all alerts are cascaded through the MOD, acknowledged and **actioned** at all levels. Each alert has a different timeframe for action, depending on the type of alert and level of risk, but it is vital that all relevant alerts reach the end user within the stated timeframes. The Commands are also to ensure that there is an audit system (eg as part of the Common Assurance Framework) in place to confirm that appropriate action has been taken at all levels. Any concerns relating to medicines should also be referred to the Medication Safety Officer, SO1 Pharmacy HQSG, if necessary.

# Supply, storage or environmental issues reporting

109. All issues relating to the storage, supply or environmental control of medicines are to be reported up the CoC. This is in order to inform all those involved in setting the policy and delivering the services, so that the MOD can improve systems in place. If the issue is related to patient safety then DMS personnel should report via the <u>ASER</u> system. For non-DMS personnel or when the issue is logistic-related, this should be via the appropriate MOD report<sup>43</sup>. Also, any lessons that have been identified that will benefit the rest of Defence are to be reported via the Defence Lessons Identified Management Systems (<u>DLIMS</u>). Any reports raised must be cross referenced with any SE where one has been raised.

### Audit – Medicines management and optimisation

- 110. Medicine Management carries an inherent high risk. Commands and their MTFs must carry out internal audits against the standards in this policy and develop action plans as a result. Internal dispensary and medicines management audits have been developed over the last 10 years to assist in improving process and dispensary management. An example from DPHC can be found <a href="here">here</a>. These audits should be routine practice and will support the <a href="Common Assurance Framework">Common Assurance Framework for Role 1</a> and any external inspections from the Care Quality Commission (CQC).
- 111. The Senior Pharmacist Group, along with the DTC, has the responsibility for monitoring compliance with this policy. HQSG will provide an annual report, in conjunction with Defence Statistics to the DTC to include a summary of prescribing analysis, compliance of formulary and details of non-formulary prescribing using their dashboards. The report will be reviewed by the group and reviews of processes and changes to this policy will be recommended by the group and reported back to the Commands.
- 112. All healthcare professionals have a responsibility to conduct clinical audit. Prescribing data is presented to Commands in the form of dashboards, owned by Defence Statistics. Regional and Command Pharmacists should use this data, in conjunction with Medicines Optimisation training and NICE guidelines, to develop and apply the principles of high quality, cost effective, rational and evidence based prescribing across the MOD.

<sup>&</sup>lt;sup>42</sup> HQSG, FLCs, DE&S, PJHQ, DPHC. Individuals are able to register with the website to receive individual alerts.

<sup>&</sup>lt;sup>43</sup> DE&S Customer Complaint Procedure, or Discrepancy Reporting. Guidance on the production of EFRs for medical equipment (including MAI) is held in JSP473 Joint Service Regulations for the Engineering Support of Medical, Dental and Veterinary Equipment Part 2 paras 49-60.

# **Medicines Information**

- 113. A specialised Medicines Information (MI) service is available from Guys and St Thomas' NHS Trust, (GSTT) managed by the Defence Medical Library Service (<u>DMLS</u>) in conjunction with HQSG. Requests for information are only to be made via pharmacists in the CoC, as access is restricted on the contract to 50 queries a year.
- 114. Before an MI query is sent to GSTT, every effort should be made to investigate internally first using available resources. HQSG can advise and support MI queries if Regional or Command pharmacists are unable to access the right information in a timely manner. The most common resources open to the DMS include:
  - a. The library at DMS(W).\*
  - b. National Poisons Information Service (NPIS).\*
  - c. My Athens<sup>44</sup>. \*
  - d. TRAVAX or NaTHNaC.\*
  - e. MEDUSA.
  - f. MICROMEDEX.
  - g. TOXBASE.
  - h. NICE Evidence.\*
  - UK Medicines Information.\*

Some of these resources are open to all DMS personnel (\*) and all pharmacists have access to the remainder.

# **Training and Education**

# General

- 115. All staff involved in the handling of medicines should be appropriately trained with regard to safety and security of medicines, and safeguarding themselves (and those under their supervision) from any risks posed by medical materiel. They should also be trained to ensure understanding of the need for risk management in relation to drug products and procedures. All DMS personnel should understand their scope of practice and work within their own level of professional knowledge and competence and those professionally registered are accountable for their own actions. They are responsible for maintaining their own CPD, and seeking updates when alerts arise. The MOD will provide direction to suitable resources if appropriate. Specifically:
  - a. **Medical Prescribers**. In accordance with their relevant codes of practice.
  - Registered Nurses. Registered Nurses must act according to the following:
    - (1) NMC (2015) Code of Professional Conduct: Standards for Conduct, Performance and Ethics.

<sup>&</sup>lt;sup>44</sup> My Athens currently holds the following useful publications: Martindale, BNF, Stockley's Drug Interactions.

- (2) NMC (2006) Standards of Proficiency for Nurse and Midwife Prescribers.
- (3) NMC (2008) Standards for Medicines Management.
- (4) NMC (2006) Standards for Nurse Prescribing.
- c. **Pharmacists and Pharmacy Technicians.** Pharmacists and pharmacy technicians must act according to the <u>GPhC Standards</u> of practice. It is vital that both pharmacists and pharmacy technicians are employed correctly at all times and maintain their clinical skills. This is critical when employed at field units where they must maintain clinical exposure and use their skills to train others in the management of medicines.
- d. Allied Healthcare Professionals (AHP). AHPs must act according to the Health Profession Council (2008) Standards of Conduct, Performance and Ethics. Furthermore AHPs must abide by their respective Standards of Proficiency.
- e. **Single Service Medics.** The majority of medics are not professionally registered but are governed by the sSs and are limited to supplying or administering medication by appropriate training in accordance with agreed protocols.
- 116. All staff (where appropriate) should ensure that the following training is kept updated:
  - a. Anaphylaxis (mandatory, and must be undertaken annually).
  - b. Immunisation and Vaccination Update (Compulsory for staff carrying out immunisation and vaccinations). This is to be updated on an annual basis. Newly qualified staff should have completed a recognised course before undertaking immunisations and vaccinations for the first time.
  - c. Medicines Management Training. The Command Pharmacists are responsible for ensuring the provision of safe and effective medicines management training across the MOD, covering the management of CDs and the cold chain.

### Annexes:

- A. Glossary.
- B. Controlled and Accountable Drugs.
- C. Examples of MOD prescriptions.

# **GLOSSARY**

**ACBS:** Advisory Committee on Borderline Substances whom provide advice on certain conditions where some foods may be classed as drugs.

**Accountable Drug (AD):** A term used in the MOD to describe all drugs in Schedule 3 and 4 of the MDR plus specific drugs designated in this policy.

**Administer:** To give a medicine to a patient either by introduction into the body, (eg orally or by injection) or by external application (eg cream, ointment or application of a patch) or to hand to the patient for immediate supervised use.

Allied Health Professional (AHP): Healthcare professional working in an occupation which is registered with a professional body and is covered by the remit of the Department of Health Chief Allied Health Professions Officer. This includes pharmacists and pharmacy technicians registered with the General Pharmaceutical Council.

**Assemble:** Putting a medicinal product in a container which is labelled before the product is sold or supplied. If the medicinal product is already in the container in which it is to be sold or supplied, assemble means labelling the container before the product is sold or supplied. The legal definition of assemble can be found section 132 of the Medicines Act 1968.

**Black Triangle** (▼): This is a symbol assigned to medicines that require Intensive Monitoring. The EU Pharmacovigilance Risk Assessment Committee (PRAC) is responsible for deciding if a product requires a Black Triangle.

**Civilian Medical Practitioner (CMP):** Non-military doctor registered with the General Medical Council with a licence to practise and prescribe medicines, employed by the MOD.

**Clinical Governance (CG):** Quality assurance activities which ensure that pre-determined clinical standards that have been set, are seen to be maintained by practitioners, and are evident within health care settings.

**Cold chain:** The 'cold chain' is the system of transporting and storing medicines within the temperature range of  $+2^{\circ}$ C to  $+8^{\circ}$ C (refridgerated) and below  $-20^{\circ}$ C (frozen) from the place of manufacture to the point of administration.

**Competence:** The requirement for a healthcare professional to properly perform their role. It is a combination of skills, knowledge, character and health.

**Continuing Professional Development (CPD):** The process by which healthcare professionals keep up-to-date through learning.

**Controlled Drug (CD):** Legally these are all drugs listed in Schedules 1-5 of the MDR. In the MOD, these are substances listed in Schedule 2 of the MDR and referred to as CD.

**Dentist:** A person trained and licensed to practice dentistry and registered with the General Dental Council.

**Dispense:** To prepare a clinically appropriate medicine for a patient for self-administration or administration by another usually against a written prescription. The act of dispensing includes supply to the patient and also encompasses a number of other cognitive functions (eg checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly of the product, labelling and advice on safe and effective use). These functions are usually performed under the supervision of a pharmacist or under the authority of the SMO.

**Doctor:** Medical Practitioner with registration with General Medical Council and a licence to practice that permits prescribing of medicines.

**Essential Shared Care Agreements (ESCA):** These are locally agreed documents which allow the transfer of prescribing and monitoring of a limited number of specialist medicines which are rated as Amber under the local Red/ Amber/ Green (RAG) list to a GP while the Consultant or specialist team retains overall clinical responsibility for the care of the patient. MOD ESCAs are approved by the Drugs and Therapeutics Committee (DTC).

**Fit to practise:** Practitioner holds and demonstrates the skills, knowledge, character and health to do their job safely and effectively. This should not be confused with being fit to work.

Independent/Supplementary Prescriber (ISP): A first level registered Nurse, Registered Pharmacist or AHP who is qualified to prescribe drugs, medicines and appliances as an Independent or Supplementary Prescriber. A prescriber who is legally permitted and qualified to prescribe and takes the responsibility for the clinical assessment of the patient, establishing a diagnosis and the clinical management required, as well as the responsibility for prescribing, and the appropriateness of any prescribing.

**Inpatient services:** For the purpose of this policy inpatient service refers to a unit on which patients are admitted for the provision of health care and/ or rehabilitation. It includes DMRC, operations and MRSs.

**Licensed manufacturing unit:** All medicines manufactured in the UK must be produced on a site that holds an appropriate manufacturer's licence. Any person or organisation wishing to wholesale deal (defined as selling, supplying or procuring to anyone other than the end-user) medicinal products within the EU must hold a wholesale dealer's licence.

**Manufacture:** Includes any process carried out in the course of making a medicinal product. The legal definition of manufacture can be found in section 132 of the Medicines Act 1968.

**Marketing authorisation:** Previously known as a 'product licence'. This normally has to be granted by the MHRA before a medicine can be prescribed or sold. This authorisation, which confirms that medicines have met standards for safety, quality and efficacy, considers all of the activities associated with marketing medicinal products.

**Medical device:** Means an article which is intended to be used for human beings or animals for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process, or; control of conception and does not achieve its purpose by pharmacological, immunological or metabolic means. The legal definition of medical device can be found in section 132 of the Medicines Act 1968.

**Medical logistics:** The science of planning and provisioning materiel required for effective medical support to a force. Medical Logistics comprises two main areas:

- a. Inventory Management (determining the medical materiel requirement, codification, cataloguing, monitoring and tracking).
- b. Provisioning (acquisition, storage, movement, distribution and maintenance).

**Medical Materiel Short Life (MMSL):** Medical items that have a specific expiry date, with a shelf life up to 60 months. These can encompass a large range of medical materiel but are primarily pharmaceuticals and clinical consumables. MMSL products must be used/consumed before the given expiry date by the demanding unit only as the Wholesale Distribution Authorisation (WDA) prevents the return or re-issue of these items to other units. However, operational units are

permitted to transfer MMSL between units provided there is evidence that it has been stored appropriately and the PMO/SMO is happy to accept the stock.

**Medical materiel:** Medicines, chemicals, blood products, dressings, surgical and medical instruments, devices and appliances, imaging and other diagnostic equipment, laboratory requirements, rehabilitation equipment, specialised hospital supplies, clinical training equipment and dental and veterinary supplies required in Ministry of Defence medical, dental and veterinary establishments, ships and units.

**Medical Officer (MO):** A military doctor employed by the MOD. The following designations refer to their seniority and level of authority: Senior Medical Officer (SMO), Principal Medical Officer (PMO), General Duties Medical Officer (GDMO).

**Medicinal products:** Any substance or article (which is not a medical device) which is given to human beings or animals for a medicinal purpose. This includes prescription only medicines (POM), pharmacy medicines (P) and general sales list medicines (GSL) and all medicines listed as controlled drugs (CD). Pharmacy medicines and general sales list medicines are sometimes referred to as 'over the counter' medicines (OTC). The legal definition of medicinal products can be found in section 132 of the Medicines Act 1968.

**Medicinal purpose:** Treatment or prevention of disease; diagnosing disease; ascertaining the existence, degree or extent of a physiological condition; upholding standards and public trust in pharmacy; contraception; inducing anaesthesia; or otherwise preventing or interfering with the normal operation of a physiological function. The legal definition of medicinal purpose can be found in section 132 of the Medicines Act 1968.

**Medicine:** Any substance or combination of substances presented for treating or preventing illness. Also, any substance or combination of substances which may be administered with a view to making a medical diagnosis or restoring, correcting or modifying physiological or psychological functions. In this policy, the term medicine has the same meaning as medicinal products in the Medicines Act 1968.

**Medicines Healthcare Products Regulatory Agency (MHRA):** The UK's regulator of medicines, medical devices and blood components for transfusion, responsible for ensuring their safety, quality and effectiveness..

**Near miss:** An error or mistake made during a process prior to supply or administration to a patient.

**Non Medical Prescriber (NMP):** A first level Registered Nurse, Pharmacist or AHP who has successfully completed a validated Prescribing Training Programme and whose name is recorded on the appropriate professional register as an Independent Prescriber.

Patient Group Directions (PGD): A specific and detailed written direction for the administration or supply of named medicines, including those classified as Prescription Only Medicines (POM), by a named nurse, pharmacist or other authorised healthcare professional, in a specific clinical situation. PGDs are developed within the MOD, by a multi-disciplinary group and are approved by the PGD Executive Group.

Patient Information Leaflet (PIL): Data sheets found in all dispensed medicinal products which should be brought to the patient's attention on supplying, dispensing or administering the medicinal product.

**Patient:** A person or animal who receives care or treatment from a health professional.

**Patient Specific Direction (PSD):** Written instructions from a doctor, dentist or non-medical prescriber for a medicine to be supplied or administered to a named person. This could be demonstrated by a simple request in the patient's notes or an entry on the patient's drug chart.

**Pharmacist:** A pharmaceutical chemist currently registered to practise with the General Pharmaceutical Council (GPhC).

**Pharmacy professional:** A pharmacist or pharmacy technician registered with the General Pharmaceutical Council.

**Pharmacy services:** The activities, advice, products, treatment or care that is provided in a registered pharmacy.

**Pharmacy Technician:** A qualified Pharmacy Technician currently registered to practise with the General Pharmaceutical Council (GPhC).

**Practitioner:** General term used within the Medicines Policy to describe a qualified medical practitioner, Registered Nurse, Pharmacist, AHP or other authorised employee.

**Prescribe:** To authorise (in writing), by full signature, the supply and administration of a medicine.

**Registered Nurse (RN)**: A nurse currently registered with the Nursing and Midwifery Council (NMC).

**Repeat prescribing:** A partnership between patient or client and prescriber that allows the prescriber to authorise a prescription so it can be repeatedly issued at agreed intervals, without the patient or client having to consult the prescriber at each issue.

**Shared decision making:** A process in which clinicians and patients work together to select tests, treatments, management or support packages, based on clinical evidence and the patient's informed preferences. It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and a system for recording and implementing patients' informed preferences.

**Summary of Product Characteristics (SPC):** Information on medicinal products dispensed may be found at the Electronic Medicines Compendium.

**Supplementary prescribing:** A voluntary partnership between an independent prescriber (doctor or dentist) and a supplementary prescriber, to implement an agreed patient or client-specific clinical management plan with the patient or client's agreement.

**Training provider:** An organisation responsible for the delivery, assessment and award of qualification for a programme approved by the MOD, or an organisation approved by an awarding body to deliver and assess a qualification included in a national qualifications framework approved by the MOD. This can be a college or private training provider.

**Transcribing (transposing):** Any act by which details of medicinal products are re-written based on one form of direction to administer, to another is 'transcribing'. Including discharge letters, transfer letters, copying illegible patient administrations chart onto new charts (whether handwritten or computer-generated).

**Unlicensed medicines:** This term refers to medicines that are not licensed for any indication or age group in the UK. Reasons why a drug may not be licensed include: the drug is undergoing a clinical trial, has been imported, has been prepared extemporaneously or prepared under a special manufacturing licence, does not hold a marketing authorisation or is not a medicine but is being used to treat a rare condition.

#### Annex A

**Yellow Card Scheme:** If a patient experiences an adverse drug reaction to a medication the healthcare professional should record this in the patient's notes, notify the prescriber (if they did not prescribe the drug) and notify via the Yellow Card Scheme immediately. Yellow cards are found in the back of the BNF and online on <a href="https://www.mediately.com/www.yellowcard.gov.uk">www.yellowcard.gov.uk</a>. For further information read the BNF or access the MHRA website <a href="https://www.mhra.gov.uk">www.mhra.gov.uk</a>.

#### **Controlled and Accountable Drugs**

#### Introduction

- All pharmaceuticals require appropriate handling to prevent misuse. Some pharmaceuticals, due to their potential for abuse, are subject to additional storage, record keeping, prescribing controls and audit activities above those which may be imposed by their 'Prescription Only Medicine' (POM) or other legal status. This applies equally to both human and veterinary licensed pharmaceuticals.
- The Misuse of Drugs Act (MDA) 1971 controls drugs that are 'dangerous or otherwise harmful', sets a framework within which criminal penalties are set, and specifies the levels and nature of controls which apply to these substances. These drugs are referred to as controlled drugs. The Misuse of Drugs Regulations 2001 (MDR) regulate the availability of these controlled drugs according to their legitimate use and places them in schedules 1 to 5 to the Regulations. The following policy adheres to the Act and subsequent Regulations and gives direction on the application of these within the MOD environment. This is to be read in conjunction with the JSP 950 Part 1 Lft 9-2-2 The Supervision of the Management and Use of Controlled Drugs.
- The Home Office, as legislative authority over controlled drugs, has stated that the MOD benefits from Crown Immunity and may lawfully possess controlled drugs during the course of its duties by virtue of Section 2(3) to the MDR 2001. 45
- 4. The MOD identifies a number of other products that are subject to less stringent controls within the current legislative framework and these are termed 'Accountable Drugs' (AD). Due to structural and procedural differences between MOD and the civilian healthcare sector, MOD control exceeds that required by current legislation for these products in some areas.

#### **Exceptions**

- **Defence Medical Group (DMG) units.** DMS personnel employed in DMG units are to comply with the host Trust's policies regarding controlled drugs, other than DMRC who should have their SOPs complying with this policy.
- Multinational medical facilities. Where UK Service Personnel (SP) are employed in a 6. multinational MTF, HQSG (in conjunction with other partner nations) will designate a lead nation to determine the legal basis for any dispensing or supply operations within the joint facility. Once determined, personnel are to follow the lead nation regulations regarding the levels of control and accounting procedures to be employed within the facility.
- Overseas locations and long exercises. In overseas locations (other than Joint Command Overseas Support (JCOS) areas) and on long exercises overseas where the Armed Forces operate by invitation or consent of the host nation, more stringent national requirements may be in place and may need to supersede these instructions 46. Advice should be sought through the Embassy, Consulate or another appropriate local source.
- Designation of substances as controlled or accountable drugs
- Within the MOD, two levels of control are imposed for the purposes of prescribing, accounting and storage. For the purposes of these instructions, the designation of substances as CDs or ADs is as follows:

<sup>&</sup>lt;sup>45</sup> This Crown Immunity does not include the activities of contracted commercial partners, who should comply with all relevant legislation and have Home Office Issued CD licenses.

46. For instance, there are strict national regulations on the import of codeine into Brunei; in Canada, national regulations restrict access

to dispensaries.

- a. **CD.** A CD is any substance which falls into Schedule 2 of the Misuse of Drugs Regulations (MDR) 2001 unless specified otherwise.
- b. **AD.** An AD refers to a substance which falls into Schedules 3 to 4 and other POMs that are deemed to be attractive or liable to abuse in the MOD.

Pharmaceuticals that fall into the categories of CD and AD are at Appendix 1.

9. Local Commanders or an appropriately senior member of clinical staff may temporarily add products or substances to the AD list in response to locally identified problems of misappropriation or abuse or where, for reasons of patient safety, it is felt that a higher level of control is required. No item may be removed from the CD or AD list without specific authority from HQSG.

#### Responsibilities

- 10. **Individuals.** Individuals responsible for managing CDs or ADs, including the maintenance of any records in relation to the supply of these substances and products, are responsible for their own actions and will be held accountable for failure to comply with these instructions. This policy is to be read in conjunction with <u>JSP 950 Part 1 Lft 9-2-2 The Supervision of the Management and use of Controlled Drugs.</u>
- 11. **Chain of Command (CoC)** The CoC, up to and including the Commanding Officer, is responsible <sup>47</sup>, through the management checks detailed within these regulations, for ensuring that individuals are meeting their obligations with regard to the management and accounting for CDs and ADs. Individuals within the command chain will be held culpable for any failures to exert appropriate management control within their areas of responsibility. A named account holder (and, in their absence, a deputy) is to be identified for each location in which CDs and ADs are managed using a BMed 12 / 13. In this context, the account holder is the individual who is responsible for the correct management of CDs and ADs <sup>48</sup>.

#### Safe custody

- 12. **General.** All CDs and ADs are to be stored securely when not required for immediate use. In view of the range of infrastructure types within the MOD it is not possible to lay down precise specifications for storage facilities that will cover all eventualities. However, the guiding principle must be that storage is to be as secure as is reasonably practicable, in the context of any other physical security arrangements that may be present within the location concerned. The requirements for storage media are to be determined by Unit Security Officers, following the risk management approach outlined in the <u>JSP 440 Defence Manual of Security</u>, and take into account any specific requirements, as detailed in the following paragraphs. Certain specific storage requirements are detailed in the following paragraphs and further advice can be obtained from SO1 Pharmacy HQSG, DPHC or sS Command Pharmacists.
- 13. **Deployed operational units**. Where units are deployed into temporary accommodation or under canvas it may not be possible or economically feasible to meet the storage requirements detailed in UK legislation. Under these circumstances, CDs and ADs are to be stored in lockable, sturdy containers that are to be secured to a suitable static fixing point or heavy item of furnishing, in an area which is permanently manned or which can be secured when unmanned. CDs and ADs may be stored in the same container but should where practicable be segregated from one another within that container. Fixed storage facilities which meet the requirements of the Regulations are

<sup>&</sup>lt;sup>47</sup> The Queen's Regulations for the Royal Navy (BR 2), Army (Amdt 29) and RAF (Amdt List 20) all state that the Commanding Officer is effectively responsible for the management of all functions within the ship, unit, station or establishment.

<sup>&</sup>lt;sup>48</sup> At Role 1, this is likely to be the Medical Officer or another healthcare professional in charge of a detachment; at Role 2 / 3 this may be the OC of the medical supply account or pharmacist in charge; in peacetime primary care this should be the MO in charge or a pharmacist employed in a dispensing role but may be dictated by sS policy. For non-medical units this may the OC, QM or SNCO Stores.

to be obtained as soon as reasonably practicable following occupation of any long-term accommodation. Where there is any doubt regarding the security of CD / AD storage media, units are to approach the military police, Command pharmacist or a pharmacy technician for advice on appropriate security measures.

- 14. **Non-deployed units**. For static and non-deployable medical facilities and units, both in the UK and overseas, the mandatory requirements that apply to safes, cabinets and rooms where CDs are kept are to comply with Schedule 2 to the Misuse of Drugs (Safe Custody) Regulations 1973 (the Safe Custody Regulations) or any future amendments. Within the context of these regulations the following broad principles are to be adhered to:
  - a. **Stores.** CDs and ADs are to be stored separately in a locked room or cupboard set apart for this purpose. Storage facilities for CDs and ADs must be of an adequate size to accommodate the maximum anticipated stock-holding level.
  - b. **Dispensaries.** CDs and ADs in dispensaries are to be kept separately within a locked cupboard fitted in accordance with the Safe Custody Regulations referred to above. Essentially, this is a metal cabinet or safe with suitable hinges, locked with a key and fixed to a solid (preferably internal) wall or floor with rag bolts that are not accessible from outside the cabinet.
  - c. Wards and departments. All CDs and ADs are to be stored in a locked cupboard reserved solely for the storage of these items. Ward CD cupboards should conform to the British Standard reference BS2881. This is a minimum security standard and may not be sufficient for areas where there are large quantities of drugs in stock at a given time, and / or where there is not a 24-hour staff presence, or difficulties relating to control of access. In this case a security cabinet that has been evaluated against the SOLD SECURE standard SS304<sup>49</sup> should be used.
- 15. **Secure storage exemptions**. In certain cases it may not be possible to comply fully with the requirements for secure storage identified above. The following sub-paragraphs detail those circumstances where variance from the 'Secure Storage' requirements is permitted.
  - a. **Refrigerated storage.** CDs or ADs that require refrigerated storage in order to meet manufacturers' stated storage conditions are to be held in a suitably secure refrigerator reserved for the storage of pharmaceuticals. When CDs in this category are held by wards and departments, stocks are not to exceed a realistic minimum of one pack or 5 days' supply, whichever is the greater.
  - b. **Drug trolleys.** CDs and ADs are not to be stored in drug trolleys between rounds; they may only be held on trollies when being issued to patients during rounds.
  - c. **Personal issue modules and ambulances.** CDs or ADs contained in modules issued to individuals are to be either retained with the individual or secured in an appropriate location. A locked vehicle is not a secure location unless the module container is itself lockable or the vehicle contains a lockable storage facility complying with <a href="Paragraph 12">Paragraph 12</a>. Due consideration should be given to the maintenance of any necessary environmental conditions whilst the item(s) are stored in the vehicle. A local risk assessment should be undertaken to identify and mitigate against security and storage issues.
  - d. **Security in transit between units outside the Joint Supply Chain (JSC).** CDs and ADs are to be maintained as securely as reasonably practicable whilst in transit. The consignor is responsible for determining the most cost-effective mechanism, based on the

<sup>&</sup>lt;sup>49</sup> See <u>www.soldsecure.com.</u>

volume of the consignment and the potential for diversion of the contents. Measures that may be employed include personal carriage or the use of courier or other secure parcel delivery services. Wherever possible, duplicate consignment notes should be forwarded separately to the receiving unit. Operational consignments are to be packaged and marked in accordance with any relevant NATO Standards (STANAGS 2128, 2060).

- e. Morphine Auto-Injectors (MAI) and Oral Transmucosal Fentanyl Citrate (OTFC) issued on personal loan. It is the responsibility of the individual to ensure the security of CDs held on personal loan, particularly during those periods when they are not in their possession eg whilst participating in sports or training.
- f. **General Practitioners' (GP) bags.** Storage of CDs within GPs' bags for peacetime primary care out-of-hours cover are to comply with the guidance referred to in <a href="Paragraph 63b">Paragraph 63b</a> of this Annex. .
- 16. Access to keys. Keys that allow access to CDs and ADs are to be held on the person of a designated custodian (or locked away with restricted access) at all times during normal duty periods. Key-holders (who are to be kept to a minimum) are to be nominated, in writing, by the account holder and will generally be the individual in charge of the ward / department / dispensary plus a nominated deputy. Account holders are to make provision for the safe custody of keys outside of normal duty hours. Duplicate keys are to be permanently deposited in safe custody in a sealed envelope. Active and duplicate keys are to be rotated regularly (at least every 12 months). It is essential that an SOP is in place to cover the security of both CDs/ADs and access to the keys. This must be sufficiently robust that, at any particular time, the individual who has access can be identified. The Unit Security Officer and / or military police are to be consulted to ensure that this is the case and to make sure that all SOPs relating to access to the medical centre, the dispensary and in particular to CDs and ADs, minimise the risk of inappropriate access.

#### Ordering and receipting of CD and AD

- 17. **Process**. CDs and ADs required as stock for dispensaries, wards, departments or stores or to replenish module / kit contents are to be demanded / receipted as follows:
  - a. **Type 1 (operational) customers**<sup>50</sup>. Demands are to be submitted electronically through the authorised Log Information Systems (Log IS) or manually on a separate AF G8620 or other single-Service demand forms. For electronic demands, a paper demand on AF G8620 is to be generated and used as authorisation for the onward transmission of the electronic demand having been signed by the QM or another individual identified as an authorised demander in accordance with 2012DIN04-146 Authority to demand prescription only medicines under Wholesale Dealers License. CD and AD supplies for veterinary Type 1 customers are obtained direct from the contractor via e-mail or fax. On receipt, **all** CDs and ADs (including morphine auto-injectors and fentanyl lozenges) are to be brought on charge to the unit account (including as part of a module) and registered in a BMed 12/13. All further transactions must be recorded in the BMed 12/13. The validity of the demand is to be ensured by the appropriate use of management bans<sup>51</sup> by Team Leidos.
  - b. **Type 2 (DPHC) customers.** Generally, CD and AD supplies are obtained direct from trade, under Team Leidos managed contracts. Demands are placed directly on trade suppliers through Purchase to Payment (P2P) or, where P2P is unavailable, other forms of communication (eg by signal, fax or hard-copy) to the Team Leidos customer services cell or Medical Provisioning Point (MPP), who will process the demand on behalf of the originating unit. For Type 2 customers using P2P all demands for CDs and ADs are to be approved at order manager level. Demand formats acceptable to Team Leidos are specified in their

<sup>&</sup>lt;sup>50</sup> Includes units demanding through 84 Medical Supply Squadron on operations.

<sup>&</sup>lt;sup>51</sup> A 'management ban' is a mechanism used by Team Leidos to control demands for particular items.

instructions to customers (Team Leidos website). On receipt, all CDs and ADs are to be brought on charge on DMICP and recorded in the unit BMed 12. All further transactions are to be recorded in the relevant BMed 12 / 13 as appropriate. It is essential that the CDs and ADs are receipted onto either P2P or confirmation of receipt is sent to Team Leidos.

- Internal supplies within DMS run facilities. Subunits and departments within DMSrun facilities may demand CDs and ADs from their unit medical store and / or dispensary in accordance with local policy. Demands for department replenishment may be submitted using Ward Controlled Drugs Order Book (Reference 90-500). A copy of the signature of each authorised signatory is to be held by the medical store and dispensary.<sup>52</sup>
- Minimum information for demands. With the exception of electronically transmitted demands, all demands for CDs and ADs must clearly show the following minimum information:
  - Full address of demanding unit (including UIN), to include any sub-unit designation. a.
  - Demand reference number. b.
  - Description of the item. If not known, the minimum information must include the generic drug name, form (tablet, injection etc) and strength.
  - Demand authorisation details. d.
  - Quantity required<sup>53</sup>. e.
  - Name, rank and appointment, in block capitals, of demander. 54 f.
  - NATO Stock Number (NSN) if known and for Type 1 customers only. g.
- Electronic demand formats. The information required for demands submitted through Log IS will vary depending on the construction of the system. Log IS must be constructed in such a way that demand details for CDs and ADs cannot be altered in any way once transmission is initiated and provide a method of tracking from demand to receipt and onward accounting (Permanent (P) or Limited (L) Class accounting rules apply).
- Personnel authorised to demand CDs and ADs. Demands for CDs and ADs are only to be authorised by the account holder<sup>55</sup> or an individual nominated by the account holder. The account holder is to retain and maintain a record of authorised demanders who are to be registered healthcare professionals, pharmacy technicians or Senior Non-Commissioned Officers (SNCO) or above. For P2P this role is undertaken by appointed Order Managers.
- Confirmation of receipt. A signed receipt is to be obtained for all supplies of CD and AD. In the case of supplies processed through the central JSC Warehouse, only the account holder (or nominated deputy) is to return the confirmation of receipt form; no other signatory will be accepted. The confirmation of receipt is to be returned within 7 days. In all other cases, a signature is to be obtained on handover of the goods to the recipient.

<sup>&</sup>lt;sup>52</sup> The registered nurse, midwife or ODP in charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of Controlled Drugs for use in that area and can delegate the task of preparing a requisition to another, such as a registered nurse or ODP.

53 For bulk stocks required for stores or dispensaries, the quantity required is to be expressed in terms of the number of dosage forms in

that nominal unit of issue (2 x pack of 28, 4 x 100ml bottle etc). For demands generated within clinical areas this is the number of dosage forms eg tablets, capsules etc.

<sup>&</sup>lt;sup>54</sup> Authorised Demander are to provide and a contact tel number in the "special instructions" box on the demand including the authority the demand is raised against (eg module replenishment; authorised by Command Pharmacist, Medical Officer)

55 MOD Materiel Account Holder is responsible for the safe custody of materiel and stores and is to ensure that materiel and stores are

used in an appropriate manner and solely in the public service. JSP 886, Vol 4, Part 1 (to be replaced by DLF)

Prescribing, dispensing and administration of CDs and ADs for individual patients or animals

- 22. **Prescribing.** Schedule 2 and 3 controlled drugs are to be prescribed for the treatment of named individuals, specific animals or for group administration to a herd as follows:
  - a. **CD.** CDs intended to be dispensed for individual patients are to be prescribed by authorised healthcare professionals or veterinary officers on FMed 296<sup>56</sup> or FMed 1063 Discharge Prescription (for patients in a Role 2 / 3 facility being discharged or transferred). They may be typed, completed in the prescriber's own handwriting (in indelible ink) or computer-generated and must contain the following<sup>57</sup>:
    - (1) Number, rank and full name, if a service patient, or title and full name, if a civilian patient. For veterinary prescriptions, the name, rank and service number of the handler of the animal(s) for whom the item(s) are prescribed, the species, microchip number and number of animals for which treatment is intended and details of the premises at which the animals are kept.
    - (2) Hospital and ward or full unit address, if a Service patient, or full postal address if a civilian patient<sup>58</sup>.
    - (3) The name, form and, where appropriate, the strength of the preparation with either:
      - (a) The total quantity of the CD to be supplied in both words and figures.
      - (b) The total quantity of the dosage units to be supplied in both words and figures.
    - (4) If a prescription is to be dispensed by instalments, the prescription must specify the total number of instalments that may be dispensed, the intervals to be observed when dispensing and the amount of the instalments of the total amount which may be dispensed. Repeat prescriptions are only permitted for Schedule 4 and 5 drugs.
    - (5) The dose to be taken or directions for use if not to be taken internally. The instruction 'as directed' is insufficient.
    - (6) Prescriptions written by Dental Officers are to bear the words 'for dental treatment only'. Prescriptions written by Veterinary Officers are to bear the words 'for veterinary treatment only'.
    - (7) The prescriber's usual signature (handwritten) and the date on which the prescription is written.
    - (8) Prescriber identifier (professional registration number).
    - (9) The name and address of the prescriber.

<sup>&</sup>lt;sup>56</sup> Reference to the FMed 296 in this context includes any of the electronic variants.

<sup>&</sup>lt;sup>57</sup> Pharmacists may make certain amendments to Schedule 2 and 3 CD where there are minor typographical errors, spelling mistakes or may add the words or the figures if these have been omitted. In these circumstances the prescription may be amended in ink and the amendment initialled by the pharmacist. Refer to the RPS guide on Medicines, Ethics and Practice.

<sup>58</sup> In the case of a prescription for a local civilian on ops, the lack of an address (or a name for detainees) should not prevent the

on the case of a prescription for a local civilian on ops, the lack of an address (or a name for detainees) should not prevent the prescription from being dispensed and the originating ward / dept / unit or detainee reference number should be inserted.

(10) For veterinary prescriptions, a declaration to state that the CD is being prescribed for an animal under their care and that the product is for administration 'under the cascade' 59.

Prescribers are not to prescribe or administer CDs for themselves, family, friends or colleagues, except under exceptional circumstances and are to document the circumstances comprehensively.

- b. **CD / AD prescribed for administration to in-patients.** CDs and ADs prescribed for the treatment of persons or animals temporarily resident for treatment within MOD establishments are not normally dispensed, but are supplied as ward / department stock for subsequent administration by ward or theatre staff. Prescriptions for such individuals are to be written on an FMed 152 (In-patient Medicine and Administration Record), or other equivalent local form. The relevant entry is to be signed and dated by the prescriber, who is also required to annotate the strength, specify one route of administration, and for an 'as required' prescription, the minimum interval for administration and the maximum quantity to be administered in a 24hr period.
- c. **AD.** ADs intended to be dispensed for an individual patient are to be prescribed on FMed 296 or FMed 14. Prescriptions for AD must meet the standard prescription requirements but do not need to meet the additional requirements for a CD prescription.
- 23. **Prescribing CDs and ADs in non-dispensing medical centres.** DMS prescribers operating from medical centres that outsource their dispensing or wish to prescribe CDs that are to be dispensed in a National Health Service (NHS) community pharmacy will require an appropriate prescription form **FP10 (PCD).** The DMS (for England) has obtained authorisation to have a private prescriber code for each DPHC region and the Regional Pharmacist has authority to obtain FP10PCD from NHS England and allocate them to Medical Centres, enabling access to FP10PCD for prescriber on duty as per the DPHC SOP. These forms are for use in DPHC medical and dental facilities only. Prescribers who need to prescribe CDs in other circumstances need to make arrangements to obtain a personal private prescriber number and personal forms independently.
- 24. **Period of validity.** Prescriptions for Schedule 2, 3 and 4 CDs remain valid for a maximum period of 28 days. Quantities owed from partially-dispensed prescriptions cannot be dispensed after the 28 day period and patients should be advised accordingly.
- 25. **Length of supply.** Prescribers employed in DMS medical centres are to restrict prescribing of Schedule 2, 3 and 4 CDs to a maximum of 30 days. In exceptional circumstances, where the prescriber believes a supply in excess of 30 days is clinically indicated and would not pose an unacceptable risk to patient safety, the patient's notes are to be annotated with the justification. To avoid unnecessary queries from dispensing staff it is suggested that the prescription is also annotated, for instance by initialling the quantity, to alert staff to the fact that a decision has been made to prescribe greater than 30 days supply.
- 26. **Prescribing by other healthcare professionals.** Changes in the Misuse of Drugs Regulations 2012 mean that appropriately qualified nurses and pharmacists will now be able to prescribe controlled drugs<sup>60</sup>. Nurse and Pharmacist Independent Prescribers (IPs) are now authorised to prescribe any controlled drug listed in schedules 2-5 for any medical condition, except diamorphine, cocaine and dipipanone for the treatment of addiction (IPs will be able to prescribe other controlled drugs for the treatment of addiction). The authority to prescribe any controlled drug is given on the basis that IPs, as set out in professional guidance, must only

<sup>&</sup>lt;sup>59</sup> 'Under the cascade' refers to the cascade to be used when a licensed veterinary product is unavailable.

<sup>&</sup>lt;sup>60</sup> Home Office circular 009/2012, Circular: nurse and provisions pharmacist independent prescribing for Schedule 4 Part II drugs (accessed 10 Feb 15).

prescribe within their competence. Supplementary prescribers may prescribe CD only within the confines of a patient-specific clinical management plan.

- 27. **Supply and administration of CD or AD to individuals under Patient Group Directions.** The administration or supply to patients of a CD or AD from ward or department stock under the auspices of a PGD is to be recorded in clinical documentation in accordance with local procedures, as specified within the relevant PGD. The inclusion of a CD in a PGD under any other circumstances other than those listed below is to be endorsed by HQSG. CDs may only be supplied or administered in the following circumstances:
  - a. Nurses or pharmacists, when acting in their capacity as such under a PGD, are now authorised to supply, or offer to supply diamorphine and morphine where administration of such drugs is required for the immediate, necessary treatment of sick or injured persons (excluding the treatment of addiction).<sup>61</sup>
  - b. Any healthcare professional authorised to supply / administer within a PGD may, when acting in their professional capacity, supply and / or administer any Schedule 5 CD in accordance with a PGD.
  - c. Any healthcare professional authorised to supply / administer within a PGD may supply and / or administer any Schedule 4 Part 1 CD and Midazolam in accordance with a PGD provided that it is not a drug in parenteral form for the treatment of addiction.
- 28. **CD** and **AD** consumed from personal issue modules and kits. CDs and ADs which are administered by medical personnel to casualties from personally issued emergency treatment modules or kits are not 'prescribed' and an FMed 296 does not need to be generated. However, in order to support any demand for replenishment stock or to account for any discrepancies when the module is returned to the issuing authority at the end of the loan period, supporting evidence of the reason for consumption of the CD or AD must be provided. FMed 296s may be used for this purpose, however they only need to meet the general requirements for any prescription and do not need to meet the additional requirements for a CD prescription as detailed in Para 22<sup>62</sup> above. In these circumstances the FMed 296 is a record of supply / administration, not a prescription.

#### **Accounting for Controlled and Accountable Drugs**

- 29. All CDs and ADs are to be formally accounted for until either issued to a unit in response to a demand, issued to a patient against a prescription, administered to a patient or certified as destroyed by a competent person and / or formally written off. All receipts, issues and destruction of CD and AD, including MAI and OTFC, are to be recorded in relevant registers, in addition to any other materiel accounting procedures required<sup>63</sup>. Any person authorised to supply CDs and ADs is required to maintain a register.
- 30. Records are to be made of all returned CDs and ADs, including patient returns. These entries are to be made at the back of the register and should include:
  - a. The date of return.
  - b. Name, quantity, strength and form.
  - c. Name and signature of person receiving.

<sup>61</sup> Circular: nurse and provisions pharmacist independent prescribing for Schedule 4 Part II drugs - Publications - GOV.UK.

<sup>&</sup>lt;sup>62</sup> FMed 296s will continue to be used as a record of the supply of a CD or AD administered from modules and kits pending the introduction of a new CD register for this purpose.

<sup>&</sup>lt;sup>63</sup> Dispensed CD / AD delivered to a ward / dept prior to discharge need not be entered into the BMed 13 but should be stored in the CD cupboard.

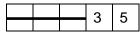
- d. Name and address of patient.
- e. The role of the individual returning the drug.

Returned CDs and ADs are subject to the same checks and storage / disposal requirements as other CDs and ADs but are to be segregated to ensure they cannot be dispensed in error.

- 31. **BMed 12 / 13 Management**. For stores accounts and dispensaries a BMed 12 is to be maintained. For wards and all other clinical areas a BMed 13 is to be maintained. Examples of correctly completed transactions are at <u>Appendix 2</u> to this Annex. The BMed 12 / 13 is to be used as follows:
  - a. In each location where a BMed 12 / 13 is required to be maintained, a separate register is to be opened for CDs and ADs. On operations, a single register may be maintained where a very small range (2 or 3 items) is maintained of either product group, but measures must be taken to segregate the ranges within that register.
  - b. On opening a register, the full unit address and the date on which the register is opened are to be inserted in the relevant section of the front cover. The name, rank and service / staff number of the account holder and dates account held are to be annotated on the inside back cover.
  - c. Registers which form part of a continuous account are to be serially numbered.
  - d. A running index of current pages is to be maintained on the relevant page(s) at the front of the book.
  - e. All drug presentations, including those with different strengths, are to be afforded a separate page and all details are to be completed on the page header.
    - (1) **Nomenclature.** The nomenclature area in the page header is to show details of the drug, form, strength and, where known, the NSN.
    - (2) Unit of Issue (UoI)/Denomination of Quantity (DofQ). In wards, dispensaries and clinical areas, where the original container may be broken on issue or return, all CDs/ADs are to be accounted for by dosage form irrespective of package quantities ie a pack of 10 tablets is to be issued and accounted for as individual tablets. For stores accounts, where the original pack size will never be broken, presentations are to be accounted for by unit of issue (ie 1 X pack of 10 tablets) is to be accounted for as 1 pack. This box in the BMed must be completed to provide clarity of quantities being accounted for.
  - f. All entries, less stock checks, are to be made in permanent blue or black ink.
  - g. Stock checks and handover / takeover entries are to be made in permanent red ink.
  - h. Transactions are to be recorded on the date on which they occur (or, exceptionally, on the following day).
  - i. All entries are to show the date on which the entry was made and are to be signed by the person making the entry. All entries are to be individually dated and signed; bracketing of multiple entries is not permitted.
  - j. No entry is to be obscured or struck through and the use of pencil or correcting fluid is forbidden. Where corrections or cancellations of entries are necessary, these should be

inserted as a footnote.

k. Unused boxes in the stock balance columns are to be struck through with a single horizontal line, thus:



- I. All entries are to be sequential. Blank rows are not to be left between any entries on a page.
- m. On completion of a page, stock balances are to be carried forward to a new page or new register and the corresponding donor and recipient pages or registers cross-referred and signed by an authorised signatory.
- n. Individuals who may be required to make entries in the register are to complete the specimen signature record prior to first use of the register.
- o. Sealed containers do not need to be opened to check the physical contents if the seal is intact. Unless there is reason to suspect tampering, the label may be taken to show the relevant contents.
- 32. **Voucher management.** Within medical stores, continuous and separate records of issue and receipt vouchers are to be maintained against which all vouchers relating to the demand, receipt, issue or disposal of CDs and ADs are to be recorded. Entries in the register are to be cross-referred to the relevant voucher series number, which is to be annotated on each voucher prior to filing. In medical centres, dispensaries, wards and other clinical areas voucher series are recommended, but are not required as all entries in the register are supported by a prescription or entries in the patient's drug administration record, the latter being retained with the patient's records and retrieved from Medical Records storage in the event of any subsequent investigation or audit.
- 33. **Temporary loans**. In certain cases CDs or ADs may be placed in the charge of an individual so that they are immediately to hand when required. Loans may be made to individuals for their personal use (see para 34) or as a means of making elements of CD and AD stock readily available in order to facilitate response to emergency situations, either as part of an approved module or locally produced kit. Such 'temporary loans' differ from 'issues' as they are not struck from the main account. Instead, a certificate of loan (AFG1033, DMED 579, RAF Form 668 or equivalent) is to be retained with the BMed 12 to support the absence of the physical stock. The stock must be returned to the issuing account in the event that it is not consumed. If the stock has been used, then it is to be struck from the account, with supporting paperwork eg prescription, statement or incident report.
- 34. **Loans to individuals.** CDs and ADs may only be loaned to individuals (as opposed to a secondary account) who will then become personally responsible for the security of the CD and AD whilst it is in their charge. If the stock has been used, then it is to be struck from the account, with supporting paperwork eg prescription, statement or incident report. Morphine auto-injectors and fentanyl lozenges issued on loan to individuals are not to be re-issued to another individual; they are to be issued for the duration of the tour or exercise or for 6 months, whichever is the shorter period.
- 35. **Returns.** Loan vouchers are valid for a maximum period of 6 months from the date of signature or until the date of departure from theatre, whichever is the sooner. At the end of the loan period the signatory in whose care the CD or AD have been placed, must either return the CD or AD or provide documentary evidence to support their consumption. Loan vouchers outstanding after 6 months are to be the subject of formal investigation, issued from the account and written off in order to reconcile the account. CDs and ADs held on loan are not to be transferred between individuals but must be returned to the unit from which they were obtained and signed for by the

new custodian. Units are to ensure that all individuals leaving a theatre of operations or exercise area are required to make a formal declaration that they have no loaned CDs or ADs in their possession.

36. **Disposals.** CDs and ADs returned from loan should be viewed as doubtful stock and disposed of in accordance with <a href="Paragraph 54-58">Paragraph 54-58</a> below.

#### **Dispensing**

- 37. **Dispensing individual patient supplies.** CDs and ADs are to be dispensed for named individual patients only on receipt of a prescription completed in accordance with the instructions in <a href="Paragraph 22">Paragraph 22</a>. Second checking and countersignatures are required when dispensing all CD prescriptions.
- 38. **CD** and **AD** supplies. For both CD and AD supplies, the dispenser is to endorse the completed prescription form with details of the items supplied and date of dispensing. For all CDs and ADs, on delivery of the completed prescription to the patient or their representative, a signature is to be obtained on the FMed 296 to verify collection. Details of all CD and AD transactions are to be recorded in the relevant register, as detailed in <a href="Paragraph 31">Paragraph 31</a>. Individuals dispensing Schedule 2 CD in DMS medical facilities are to make a record in the BMed 12<sup>64</sup> at the time of supply of the following <sup>65</sup>:
  - a. Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional acting on behalf of the patient.
  - b. If the person who collected the drug was a health care professional acting on behalf of the patient, that person's name and address.
  - c. If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (Yes / No).
  - d. Whether evidence of identity was provided by the person collecting the drug (Yes / No).
- 39. **Retention of dispensing records.** When all other actions have been completed, the prescription is to be filed in date order and retained to support the entries in the register. Prescriptions and registers are to be retained as detailed in Paragraphs 43 46.

#### Checking of CDs and ADs

- 40. **Types of stock check.** There are 3 types of stock check<sup>66</sup>:
  - a. Commanding Officers' checks All units. The Chain of Command is responsible for ensuring that a 100% stock check of all CDs and ADs held within their area of responsibility is completed at least 4 times a year at intervals not exceeding 3 calendar months. Additional stock checks are to be completed on change of account holder<sup>67</sup> as part of the formal handover / takeover process. COs of deployed units are to ensure that a 100% stock check of all sub-unit CD and AD holdings within their area of responsibility is completed

<sup>&</sup>lt;sup>64</sup> The current version of the BMed 12 does not easily facilitate recording of this additional information. As an interim measure, this should be recorded in the FMed 296 or FMed1063, whilst the format of the BMed 12 is updated.

<sup>&</sup>lt;sup>65.</sup> The current version of the BMed 12 does not facilitate the recording of the additional information required in 38 a-d. Therefore, as an interim measure, all the information should be recorded on the FMed 296 or 14.

<sup>&</sup>lt;sup>66</sup> When conducting any type of Stock Check, cross-reference to the Fundamentals of Materiel Accounting and Defence Stocktaking Policy sections of the <u>DLF</u> is to be made to ensure conformity.

<sup>67</sup> The account holder should be someone in an appropriate position - In medical centres this could be the pharm tech, or if not a

<sup>&</sup>lt;sup>b'</sup> The account holder should be someone in an appropriate position - In medical centres this could be the pharm tech, or if not a dispensing med centre, the SMO, SNO or if necessary the Practice Manager- is it the person <u>directly</u> responsible for the management of the CDs.

at intervals not exceeding one calendar month. These checks are to be recorded on the page relating to each drug and strength held.

- b. **Account holder checks.** Each department of a deployed MTF or subunit commander is to certify to the CoC , on a weekly basis, that all CDs and ADs held within their area of responsibility have been checked and accounted for appropriately. These and any more frequent checks are to be recorded in a log separate to the BMed 12/13. Checks are to be conducted by 2 staff within that department nominated by the account holder, and signed by both staff. In peacetime primary care facilities, Tactical Medical Wing (TMW), Royal Navy (RN) /Royal Fleet Auxiliary (RFA) platforms, checks are to be undertaken monthly applying the same checking principles. Additional stock checks are to be completed on change of account holder as part of the formal handover / takeover process.
- c. Managerial checks. Any additional managerial checks such as random spot checks by COs are known as Managerial Checks. These will be dictated by single-Service regulations or local policy. These are to be recorded at the back of the BMed 12/13 in a section reserved solely for that purpose as opposed to under each drug.
- 41. **Checking procedures.** The checks referred to in Paragraphs 40a and 40c above are to be undertaken by the account holder and the CO or an officer nominated to complete the check on the CO's behalf who must not be connected with the medical materiel account or the BMed 12 / 13. Patient identifiable data must be obscured during the checking process to maintain patient confidentiality. All stocktaking entries are to be made in red ink and are to be signed and dated by the checking officers. Items showing a NIL balance are to be included in the total number of items checked unless they have been annotated during the previous stocktake as a NIL balance and there have been no transactions between checks. There is no requirement to open packaging with a tamper-evident seal but checks must be made to ensure that the seal is intact. It is essential to just not check the physical balance but also the transactions to identify any unusual entries or anomalies.
- 42. **Temporary loan certificates.** The checking officer is expected to confirm the validity of any loan certificates produced to support the absence of physical stock from an account. Provided the certificate is an original copy, not a photocopy or other reproduction, has been fully completed, showing Service number rank, name and parent unit address of the recipient, and the date of signature is no older than 6 months, the certificate may be accepted in lieu of physical stock. Where the checking officer is in any doubt as to the validity of the certificate, this must be highlighted to the chain of command as an observation against the check.

#### Retention of records

- 43. The time period for archiving CD and AD documentation, which includes requisitions, Issue Voucher (IV), Receipt Voucher (RV), voucher schedules, BMed 12/13, external orders, delivery notes, prescriptions (inpatients and outpatients), clinical trials and destruction certificates, is 7 years<sup>68</sup> unless the type of patient it refers to dictates a longer retention period eg a child. Records are to be retained in an easily accessible location for at least 2 years (from the date of closure of the register to which they refer) prior to archiving at Central Health Records Library (CHRL) for a further 5 years. Further detail on retention and archiving can be found in JSP 950 Leaflet 1-2-11 Defence Healthcare Record Annex A.
- 44. All CD demand books, registers and supporting vouchers are to be held securely when not required for immediate use. Registers from dispensaries or other clinical areas contain patient details and are subject to the same patient confidentiality constraints as any other document with the government security classification of 'Official Sensitive Personal Medical in Confidence'.

 $<sup>^{68}</sup>$  This accommodates an anticipated change to require the retention of all CD records for up to 7 yrs.

- 45. Supporting records, which includes all prescriptions, Issue Vouchers (IV) / Receipt Vouchers (RV), voucher schedules etc, are to be retained with the register to which they relate. On closure of a register any remaining stock balances are to be transferred to a new register. Prior to local archiving, a check of the register is to be made to ensure that the date of closure is recorded on the cover, all stock balances are reduced to NIL and all active and blank pages are closed with a diagonal line after the last entry to prevent further entries.
- 46. For operational theatres, in order to ensure ease of access for local audit, PJHQ is to nominate a theatre repository for all CD and AD registers and vouchers for the duration of the operation. On drawdown of individual unit locations, or on cessation of the operation, documentation is to be archived in accordance with Paragraph 43 above.

#### Management of CDs / ADs in modules and kits

- 47. Modules released from the central Warehouse in Donnington will be supplied deficient of CDs and ADs. The CD / AD component will then be held as an authorised deficiency by the demanding unit. The CoC must authorise any demand to make up deficiencies of CDs / ADs when they are required. On receipt, they are to be stored and managed in accordance with the direction in the preceding paragraphs. Sealed first aid kits containing CDs or ADs are to be stored in lockable cupboards suitable for the purpose.
- 48. If a local risk assessment shows that CDs or ADs cannot be retrieved from storage in sufficient time to respond to an incident, then they may be held in the module. In these cases, the numbers of kits containing CDs and ADs are to be kept to a minimum. The kits are to be secured with a lock or tamper-evident seal, checks of which are to be made and recorded daily in accordance with local SOPs. Where practicable, the kits themselves are to be locked away. Local risk assessments will need to encompass issues relating to the temperature of the environment in which the kits are to be stored.

#### **Discrepancies**

- 49. **Loss.** If the balance in the BMed 12 / 13 does not tally with the quantity being stored then the discrepancy must be reported to the account holder, investigated and resolved. Immediate checks are as follows:
  - a. All receipts / issues have been entered into the correct page.
  - b. All drugs administered / issued have been entered into the BMed.
  - c. Items have not been stored elsewhere.
  - d. There are no arithmetical errors.
  - e. No entries have been omitted.
  - f. No duplicate entries have been made.

If the error is traced and requires an amendment to the BMed 12 / 13, the amendment entry must clearly state the reason for the entry as a footnote and corrected balance. Anything more than a simple arithmetical error must be referenced to a statement signed by both the account holder and witness (eg nurse, operating department practitioner, pharmacist, pharmacy technician, doctor or other authorised signatory). The statement should provide a detailed explanation and be inserted into the voucher series or retained with other supporting documentation relating to the register. A copy of this statement is to be forwarded to the relevant CO if further investigation is required.

- 50. **Unresolved discrepancies.** If the discrepancy cannot be resolved, the Register is to be annotated 'Stock checked and discrepancy found actual stock is XXX', and signed / dated by the account holder and a witness. The discrepancy is then to be reported to the relevant CO, irrespective of volume, for further investigation. Where no satisfactory explanation for the discrepancy is found then the stock quantity is to be adjusted by Certificate Issue Voucher (CIV) on an AF G1033 (FMed 587 or other equivalent) initiated and forwarded through the Chain of Command to Comd Med (or equivalent) and the military police for consideration for further investigation. A copy of the CIV (or single-Service equivalent) is to be retained in the voucher series or with other documentation to support the stock adjustment action and referenced to the register entry. Correspondence relating to the discrepancy should be cross referenced with the documentation supporting the write-off. All losses of CD and AD, irrespective of quantity, are to be the subject of formal Unit investigation if there is any suspicion of misappropriation or general mismanagement.
- 51. Additional reporting requirements. Medical Units are also to raise an SE or Occurrence report to the Command's Subordinate Accountable Officer if there is a risk to patient safety and ensure that the words 'CD' or 'Controlled Drug' are used in the free text so that they can be easily identified.
- 52. **Other losses.** Where it is apparent to the account holder that an individual issued with CD or AD against an AF G1033 (or other single-Service equivalent) has lost them, the account holder or individual concerned must report the loss immediately to the relevant CO. The loss is to be dealt with through the Chain of Command. A register entry signed by both the account holder and individual concerned is to be made explaining the loss, the balance adjusted, and a full written statement detailing the loss is be referenced to the register entry, filed, and a copy submitted to the relevant CO.

#### **Breakages**

53. For any breakage or explained loss, an incident report must be submitted through the Chain of Command to support subsequent write-off action. If available, the broken ampoules, vials or bottles, with any remaining contents, are to be retained for inspection by an officer independent of the account. Once this procedure has been carried out and the inspector is content, the articles are to be disposed of as detailed in Paragraphs 54 to 58.

#### Disposal of controlled and accountable drugs

- 54. A CD or AD is regarded as having been destroyed when it has been dissipated or denatured such that it is incapable of being retrieved, reconstituted or used. Following destruction, the waste may be disposed of in a similar manner to any other pharmaceutical waste. Particulars of the date of destruction and the quantities destroyed must be entered in the relevant register (BMed 12 or 13) and be signed and dated by the person in whose presence the drug was destroyed and by the account holder.
- 55. All CDs and ADs generated within peacetime primary care are to be destroyed locally using commercially available CD denaturing kits (eg DOOP); see below at para 58. Local SOPs will specify who may witness destruction but they must not be directly involved with the operation of the MTF. This can include Service Police or the local civilian police Controlled Drug Liaison Officer (CDLO).
- 56. Within peacetime secondary care assets eg DMRC Headley Court, destruction may be witnessed by the CO, the Senior Administrative Officer or other officers who have responsibility for health and safety, security, clinical governance or risk management and report directly to the CO, so long as they are not directly involved with the running of the dispensary. Local SOPs may extend the groups of individuals who may witness destruction.

- 57. Operational units are to dispose of their CDs and ADs (including morphine auto-injectors and OTFC) locally in accordance with current policy on the disposal of pharmaceutical waste. Destruction should be witnessed by the account holder and the CO of the unit or a designated officer, so long as that officer is not directly involved in the operation of the account in the MTF. In small units where all members may be involved in the operation of the CD or AD account, such as operational dog units, destruction may be witnessed by a member of the military provost. There is no need to retain separate destruction certificates and destruction certificate schedules; however, the CIV (or equivalent) used to support issue off of the account is to be annotated with full details of the CD or AD being destroyed (full name, strength, form, quantity), details of witnesses (name, signature, position) and a declaration to the effect that the CD or AD have been destroyed, see above.
- 58. Detail on the methods of destruction can be found in the Royal Pharmaceutical Society of Great Britain document 'Guidance for Pharmacists on the Safe Destruction of Controlled Drugs England, Scotland Wales'. All expired CD and AD are to be segregated to ensure they cannot be supplied or administered in error.

#### **Carriage of Controlled Drugs overseas**

- 59. On occasions, deployments, exercises and other tasking will require individuals to carry CD as part of the mission. Serving members of HM Armed Forces acting in their official capacity, and travelling on either civil or Service transport may import and export CD without the requirement to be licensed by the Home Office<sup>69</sup>. In these circumstances, the individual should carry with them a letter of authority: an example is at Appendix 3 to this Annex. The sole purpose of the letter of authorisation<sup>70</sup> is to allow the passage of personnel through UK customs with the minimum of delay and provide assistance with other countries' customs processes.
- 60. As part of the planning process for operations and exercises, appropriate points of contact in the country to be visited should be contacted to determine whether there are any specific import requirements that must be met and whether there are any national regulations which supersede those of the UK.<sup>71</sup> Where carriage of CD through the customs of a particular country is an issue, an alternative medication should be sought.

#### **Standard Operating Procedures**

- 61. Commands, formations and units are to ensure that SOPs are in place to cover the following areas as a minimum:
  - a. Ordering and receipting.
  - b. Assigning responsibilities.
  - c. Storage of CDs and ADs.
  - d. Access to and safe custody of CD and AD cupboard keys.
  - e. Record-keeping and confidentiality.

<sup>&</sup>lt;sup>69</sup> Section 2(3) of the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 exempts Crown servants from Home Office licence requirements for the purposes of importing and exporting CD.

<sup>&</sup>lt;sup>70</sup> The letter is to be signed by the issuing officer or, in the case of authority required by a medical officer, the CO of the unit or another MO.

<sup>&</sup>lt;sup>71</sup> Further guidance is available from Foreign and Commonwealth Office website. https://www.gov.uk/travelling-controlled-drugs

- f. Action to be taken when anomalies arise.
- g. Destruction.
- h. Security, in relation to storage and transportation.

#### Logistic Support Inspections (LSI) and other governance visits

- 62. LSIs, and other governance visits are to ensure that the following are incorporated:
  - a. All CDs and ADs are correctly maintained in a BMed 12/13.
  - b. All demands for CDs and ADs have been authorised at the appropriate level (electronic demands for Type 1 customers are to be supported by an AF G8620).
  - c. A complete audit trail is in place which links all supplies (from Team Leidos), demands, receipts and issues to the entries in the BMed 12 and associated IT systems<sup>72</sup>.

#### Further guidance

- 63. These instructions are not exhaustive. Local SOPs should determine the detail, particularly in operational theatres, and additional input will be required to place the principles into the context of the different healthcare delivery environments within the DMS. For clinical areas, these instructions should be read in conjunction with the following documents which provide further guidance in specific areas:
  - a. <u>Safer Management of Controlled Drugs</u> Care Quality Commission. 2013.
  - b. A Guide to Good Practice in the Management of Controlled Drugs in Primary Care (England). National Prescribing Centre. Liverpool, February 2007.

<sup>&</sup>lt;sup>72</sup> A record of the supply of CD / AD from the Team Leidos may be made available if there are particular issues causing concern but will not be made available on a routine basis.

## CONTROLLED AND ACCOUNTABLE DRUGS<sup>73, 74</sup>

#### **CONTROLLED DRUGS**

Substance / Product	Classification	Comment
ALFENTANIL	CD Sch 2	
COCAINE	CD Sch 2	
CODEINE	CD Sch 2	Injection only
DEXAMFETAMINE	CD Sch 2	
DEXTROMORAMIDE	CD Sch 2	Special Order 5mg tablets only
DIAMORPHINE	CD Sch 2	
DIHYDROCODEINE	CD Sch 2	Injection only
DIPIPANONE	CD Sch 2	Combination preparation with Cyclizine
FENTANYL	CD Sch 2	
HYDROMORPHONE	CD Sch 2	
KETAMINE	CD Sch 2	
LISDEXAMPHETAMINE	CD Sch 2	
METHADONE	CD Sch 2	
METHYLPHENIDATE	CD Sch 2	
MORPHINE	CD Sch 2	Morphine sulphate solution 10mg / 5ml (Oramorph) is an accountable drug
NABILONE	CD Sch 2	
OXYCODONE	CD Sch 2	
PAPAVERETUM	CD Sch 2	
PETHIDINE	CD Sch 2	
SECOBARBITAL (QUINALBARBITONE)	CD Sch 2	Immediate acting Barbiturate preparations containing amobarbital sodium, butobarbital and secobarbital sodium are available as Individual Patient Supply.
SODIUM OXYBATE	CD Sch 2	Reclassified from Sch 4 in Oct 2013
REMIFENTANIL	CD Sch 2	
TAPENTADOL	CD Sch 2	

#### **ACCOUNTABLE DRUGS**

Substance / Product	Classification	Comment					
ALPRAZOLAM	CD Sch 4 Part 1	NHS Black Listed – Private Prescription Only					
AMYL NITRATE	MOD Specific						
ANABOLIC STEROIDS	CD Sch 4 Part 2						
BARBITURATES	CD Sch 3	Immediate acting Barbiturate preparations containing amobarbital sodium, butobarbital and secobarbital sodium are available as Individual Patient Supply.					
BUPRENORPHINE	CD Sch 3						
BROMAZEPAM	CD Sch 3	NHS Black Listed – Private Prescription Only					
CHLORAL HYDRATE /	POM						
BETAINE	MOD Specific						
CHLORDIAZEPOXIDE	CD Sch 4 Part 1						
CHLOMETHIAZOLE	POM MOD Specific						
CHORIONIC GONADOTROPHIN	CD Sch 4 Part 2	Red Drug – Hospital Only					
CLOBAZAM	CD Sch 4 Part 1						
CLONAZEPAM	CD Sch 4 Part 1						
CODEINE PHOSPHATE	POM	Applies to all strengths unless incorporated into a first aid					
TABLETS	CD Sch 5	kit or outfit which is an individually accountable					

<sup>73</sup> Classification applies to all products containing the listed substances unless otherwise annotated.
74 This list is not exhaustive but contains drugs that have been or are used in the MOD.

## Appendix 1 to Annex B

Substance / Product	Classification	Comment
		Oral compound codeine preparations are excluded.
CYCLIZINE	POM	
CYCLIZINE	MOD Specific	
DANAZOL	CD Sch 4 Part 2	
DIAZEPAM	CD Sch 4 Part 1	
DIHYDROCODEINE	CD Sch 5	DF118 NHS Blacklisted, prescribe generically. Oral compound Dihydrocodeine preparations are excluded.
FLUNITRAZEPAM	CD Sch 3	NHS Black Listed – Private Prescription Only
FLURAZEPAM	CD Sch 4 Part 1	NHS Black Listed – Private Prescription Only
LOPRAZOLAM	CD Sch 4 Part 1	
LORAZEPAM	CD Sch 4 Part 1	
LORMETAZEPAM	CD Sch 4 Part 1	
MEPROBAMATE	CD Sch 3	
MEPTAZINOL	POM MOD Specific	
MESTEROLONE	CD Sch 4 Part 2	
MIDAZOLAM	CD Sch 3	
MORPHINE SULPHATE	POM	All other merchine preparations are CD Cab 2
SOLUTION 10MG / 5ML	MOD Specific	All other morphine preparations are CD Sch 2
NALBUPHINE	MOD Specific	'Special Order'
NANDROLONE	CD Sch 4 Part 2	
NITRAZEPAM	CD Sch 4 Part 1	
OXANDROLONE	CD Sch 4 Part 2	'Special Order' BNF for children
OXAZEPAM	CD Sch 4 Part 1	
OXYMETHOLONE	CD Sch 4 Part 2	'Special Order'
PENTAZOCINE	CD Sch 3	
PHENOBARBITAL	CD Sch 3	Previously known as Phenobarbitone
PHENTERMINE	CD Sch 3	
POTASSIUM CHLORIDE	РОМ	Excludes preformulated potassium chloride infusions.
CONCENTRATE	MOD Specific	Incorporated in response to NPSA Alert
INTRAVENOUS SOLUTION	·	·
SOMATROPIN	CD Sch 4 Part 2	Red Drug – Hospital Only
TEMAZEPAM	CD Sch 3	
TESTOSTERONE	CD Sch 4 Part 2	
TRAMADOL	CD Sch 3	
ZALEPLON	CD Sch 4 Part 1	
ZOLPIDEM	CD Sch 4 Part 2	
ZOPICLONE	CD Sch 4 Part 1	

#### **VETERINARY CONTROLLED DRUGS**

Substance / Product	Classification	Comment
ETORPHINE	CD Sch 2	Immobilon
FENTANYL	CD Sch 2	Hypnorm
KETAMINE	CD Sch 2	
METHADONE	CD Sch 2	comfortan
MORPHINE	CD Sch 2	
PETHIDINE	CD Sch 2	
SECOBARBITAL (Quinalbarbitone)	CD Sch 2	Somulose

#### **VETERINARY ACCOUNTABLE DRUGS**

Substance / Product	Classification	Comment
BUPRENORPHINE	CD Sch 3	Temgesic, Vetergesic
CLENBUTEROL	CD Sch 4 Part 2	Ventipulmin
CODEINE PHOSPHATE TABLETS	Cd Sch 5	
DIAZEPAM	CD Sch 4 Part 1	
ETHYLESTRENOL	CD Sch 4 Part 2	
MIDAZOLAM	CD Sch 3	
NANDROLONE	CD Sch 4 Part 2	Laurabolin, Nandrolin, Retarbolin
PENTAZOCINE	CD Sch 3	
PENTOBARBITAL (PENTOBARBITONE)	CD Sch 3	Dolethal, Pentoject, Euthatal
PHENOBARBITAL (PHENOBARBITONE)	CD Sch 3	Epiphen
TEMAZEPAM	CD Sch 3	
TRAMADOL	CD Sch 3	

#### **Correct Completion of a Controlled Drugs Register**

**BMED 12 – Controlled Drugs Register** 

	STOCK	NO 6505-99-	512-1226		No	mer	clatu	ure	Alfentanil	<b>HCL Injection</b>	5mg / ml 1ml A	mpoules	Denomination of Quantity					Quantity	Box of 10
			RECEIPT	S	ISSUES							Balance	By Whom						
Note	Date	Received From	Receipt Voucher No			antity eive	,		FMed 296 or Reqn SN	Name of Patient	Ward, Department or Address	Prescribed by		Qua Iss	ntity ued	•		in Stock	Checked and Date
(a)	20/06/07	Brought forward	From page XX	1	-	1	2		-	-	-	-	-	-	-	-		1 1 / 1	D Young 20/06/07
(b)	21/06/07	-	-	-	-	-	-		IV 146/07	RAP, 4 Blankshires	Camp Caruso, BFPO 564	Capt J Taylor RMO 4 Blanks	-	-	-	1			D Young 21/06/07
(c)	28/06/07	From 84 MSS Det	RV 54 / 07	-	-	-	5		Dmd No 63	-	-	-	-	-	-	-		ı ın ı	D Young 22/06/07
(d)	30/06/07	From 84 MSS Det	RV 63 / 07	-	-	-	5	1 1	Dmd No 66	-	-	-	-	-	-	-		<i>       </i>	D Young 23/06/07
(e)	1/07/07	-	-	-	-	-	-		Stock Check	Found Correct	A Davies Capt	Duty Officer	-	-	-	-		21	D Young A Davies 24/06/07
(f)	02/07/07	-	-	-	-	-	-		IV 150/07	Certified Destroyed 2 (two) boxes Timex	D Young OIC Med Stores	H Wood Adj	-	-	-	2		19	D Young H Wood 2/7/07
(g)											C	Carried forward	-	-	-	-		19	To page XX

\* entered in error. Should Read 21 DY 30 / 06 / 07

#### Notes:

- (a) Balance brought forward entry from previous page.
- (b) Issue to Unit from Med Stores. The IV number is annotated on the demand enabling cross checking. There is no need to insert the Medical Stores IV number in the register for dispensaries.
- (c) Example of a receipt entry.
- (d) Example of incorrect entry.
- (e) Example of stock check (in RED).
- (f) Destruction of Timex Drugs.
- (g) Example of an entry to carry forward to next page.

All entries must be made in blue / black ink, except entries for stocktakes / handovers, which should be in RED ink.

Nothing in the BMed 12 is to be obliterated or altered in any way. Zero balances are always entered as 'NIL'.

Note. This is essentially an example of a BMed 12 Register held in a Medical Store.

#### **BMED 13 – Controlled Drugs Register**

							<b>DRUG</b> : Alfentani NSN: 6505-99-5			Ampoules						Denominatio n of Quantity	Ampoul e
		REC	CEIF	PTS				ISSUE	ES							PERIODIC C	HECKS
		FMed 296					Name of	Dose	Time		Checked					Checked By	
	Date	or Reqn			ntity					Given By	Ву	В		nce	in		Date
		SN	ŀ	₹ece	eive	<u>d</u>	Patient	Given	Given		, ,		W	ard		SIGNATURE	
(a)	20/06/07		-	-	0	1	From Page 09			Brought	Forward	-	-	0	1	A Jones	20/06/07
(b)	21/06/07	Req no 004	-	-	1	0	Received From	Medical Stores	UK Med Gp	A Jones	A Smith	-	-	1	1		
(c	22/06/07		-	-	1	-	PTE JAMES HALL 25118979	5mg	1700	A Jones	A Smith	-	-	1	0		
) (d)	23/06/07		-	-	-	-	PTE JAMES HALL 25118979	7.5mg given and 2.5mg discarded	1300	A Jones	A Smith	-	-	0	8		
(e)	24/06/07		-	-	-	-	PTE JONES* 25118979	5mg	1700	A Jones	A Smith	-	-	0	7		
(f	25/06/07		-	-	ı	-	PTE JAMES HALL 25118979	2.5mg given and 2.5mg discarded	1400	A Jones	A Smith	-	-	0	6		
)	26/06/07			_			Mbetkly Stock	Found	Correct	D Young	Pharmacis		_	0	6	A Jones	26/06/07
(g) (h)	30/06/07		_	_		_	(Second Second S	Out of date	A Julies Ward NOIC	D Young Pharmacist	T .	-	N	I	L(i)		

Carried forward

\* Should Read Pte JAMES HALL. AJ 24 / 06 / 07

Page 10

#### Notes:

- (a) First Entries will always have the initial stock balance as NIL. Otherwise the balance is carried forward from previous page (as in this case).
- (b) Receipt, requisition serial number and quantity received from the Medical Stores UK Med Gp.
- (c) Correctly completed administration record.
- (d) Correctly completed administration record where part dose is given and remainder discarded.
- (e) Example of an incorrect entry.
- (f) Correctly completed administration record where part dose is given and remainder discarded.
- (g) Example of correct entry for stock check always in RED.
- (h) Example of destroyed out of date drugs.
- (i) Zero balances are always written in words ie NIL, rather than figures, to avoid fraudulent entries.

All entries are to be made in b or altered in any way.	lue or black ink, except entries for stoo	ck checks / handovers, wh	nich should be in RED ink.	Nothing in the BMed 1	3 is to be obliterated

# **Authority to Possess and Carry Controlled Drugs for the Purpose of Administering Medical Care**

Standard Unit Header  1. THIS IS TO CERTIFY that:  No Rank.  Passport No Rank.  Passport No official duty. In the course of the purpose of administering medic specified.  Valid from	neir duties, this individual is recal care, the controlled drugs l	I is telled to, or signed on, a valid NHS Tax Cordet Exe  B	scy use Sound Sugn
NATO Stock No Item	Name and Description	CD Schedule	Qty
of the drugs listed above,  The state of the drugs listed above,  White of	In patient Medicine Prescription and Administration Record  PMED 122 one to the Impact of the Impact	their possession.  The control of th	A sea to a sea of a s
Official Unit Stamp	Name (block letters)  Rank & Appointment  Date  Tel No		

### **Examples of Prescription Forms used in the DMS**

FMED 296 - DMICP

FMED 296 – Standard

**FMED 296 - REAR** 

**FMED 152** 

FP10 (PCD)