**Procurement and Distribution of medicines and Trust compliance with the RPS Standards**

**Scope:** This is a self checklist for the assessment of Trust compliance with the safe, secure and regulatory handling issues concerning medicines, as aligned to the RPS Standards.

This checklist has been produced by a sub-group of the NW Operational Group.

NB. There are additional requirements for the holders of wholesale dealer licences

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Domain 1 – Patient experience** | | | | |
| ***Audit point*** | | ***Primary reference*** | ***Audit finding*** | ***Best practice examples or links*** |
|  | Work systems are organised to facilitate efficiency of operation and ensure appropriate response times e.g. opening hours, liaison with customers, incidence of inability to supply, emergency drug cupboard use (appropriate access and stock held), responding to urgent requests, supply of critical medicines |  |  |  |
|  | There are robust communication systems in place between the clinical teams and procurement staff when patients require non-stock medicines |  |  |  |

| **Domain 2 – Safe and effective use of medicines** | | | | |
| --- | --- | --- | --- | --- |
| ***Audit point*** | | ***Primary reference*** | ***Audit finding*** | ***Best practice examples or links*** |
| 2.1 | **General** |  |  |  |
| *2.1.1* There is a designated senior member of staff who has overall responsibility for the procurement and storage of medicines within the pharmacy. This is stated in a policy document. e.g. Trust Medicines Policy, Purchasing Policy | Duthie |  |  |
| 2.2 | **Policy** |  |  |  |
| *2.2.1* There is a written policy statement or SOP for procurement. | Duthie |  |  |
| **2.2.2** The policy statement or SOP sets out the requirement for;   * Roles and responsibilities of staff involved in the procurement, receipt, storage and distribution of medicines. * Legal requirements for the procurement and storage of medicines, including: * licensed medicines * parallel imports * unlicensed medicines * clinical trial materials * Strict adherence to regulatory, professional and NHS requirements, e.g.: * Standing Financial Instructions * the Duthie Report * Good Distribution Practice * The Drug Contract (except in defined circumstances) * Policies for Disposal of Clinical and non-clinical Waste * An auditable trail of procurement processes * The purchasing on contract of licensed medicines and unlicensed medicines. The policy statement or SOP covers the process to be followed if products cannot be purchased on contract including off contract claims. * Regular review of workload, procedures, supplier performance and product ranges. * Dealing with suppliers and their representatives. * Contingency and business continuity planning in the event of major accidents, terrorism, reduced staffing, loss of facilities, power supply etc. * Record keeping requirements with recommended minimum retention periods | Duthie  Contracting Procedures document (produced by the Policy Group)  Records Management: NHS Code of Practice  An over-arching Trust document may be in place |  |  |
| 2.3 | **SOPs and work instructions** |  |  |  |
| **2.3.1** SOPs or work instructions are available to staff at the point of use |  |  |  |
| **2.3.2** SOPs or work instructions cover the scope of activity of the procurement, receipt, storage and distribution of medicines. These will include:   * Ordering procedures * The risk assessment, ordering and storage of unlicensed medicines (imported or UK “Specials”). * Receipt procedure including product acceptance, requiring special handling requirements and recording of batch numbers and expiry dates, e.g. CDs. * Management of late deliveries eg. Goods Ordered Not Received reports * Storage arrangements eg. on immediate receipt, storage until required for issue, dedicated quarantine areas, storage of medicines packed ready for transport/collection * Stock rotation including expiry date checking * Stock taking * The loading and use of a “robot” as appropriate * Assessment of the appropriateness of storing medicines in a “robot” before storing them in this way * Monitoring of storage conditions eg. fridge temperatures and room temperature * Issuing of stock * Picking of items * Packaging for transport * Stock returns * Handling breakages and expired stock * Product recalls/alerts * Invoice clearance and authorisation where appropriate * Invoicing customers where appropriate * Procurement of New Product procedure * Handling and release of bonded materials (including defects and rejects) * Reporting faults, defects and errors * Equipment maintenance and repairs (including schedules) * Reporting supplier problems * Managing waste * Retention of records * Dealing with complaints * Contingency planning for equipment failures * Maintaining disaster management files/Business Continuity plans | GDP  DoH Retention of Records |  |  |
|  | **2.3.3** There is a system in place for implementing changes to procedures including   * Training and briefing * Record keeping (e.g. staff sign to acknowledge that they have read and understood procedures) | GDP |  |  |
| **2.4** | **Purchasing for safety** |  |  |  |
| **2.4.1** There is active participation in local, regional and national medicines contract adjudications |  |  |  |
| **2.4.2** New products are introduced by a system that ensures   * purchasing decisions are consistent with formulary decisions. * adequate risk assessments are made * adherence to relevant contracts   e.g. via DTC or MMC |  |  |  |
| **2.4.3** There is a system to ensure continuing adherence to local and other medicines contracts. |  |  |  |
| **2.4.4** There is a process for approving and managing off-contract purchases, including risk assessments where appropriate |  |  |  |
| **2.4.5** There is a policy for the purchase and supply of unlicensed medicines. | Guidance Note 14; Human Medicines Regulations |  |  |
| **2.4.6** There is a system to manage change. This will include provision of information to pharmacy, nursing, medical and other relevant staff about   * Pack changes (where risks are identified and for critical products e.g. in Theatres) * Supply problems and discontinuations * New storage requirements * Unlicensed medicines |  |  |  |
| **2.4.7** There is a policy for the alerts/recall of medicines and medical devices that includes:   * the receipt, and action to take following receipt, of an MHRA Drug Alert, Company-led recall, QCNW Caution in Use, Medical Device Alert or Field Safety Notice * how to report a defective/potentially defective medicine or medical device | GDP |  | Guidance Documents available on the QCNW website |
| **2.5** | **Receipt of medicines** |  |  |  |
| **2.5.1 Receipt of medicines procedures cover confirming that what was ordered is what has been received, and that all documentation is matched. Procedures should include an awareness of counterfeit medicines and how to deal with discrepancies in general.** |  |  |  |
| **2.5.2** All returns are date checked and assessed by an authorised person according to procedure before returning to stock. A procedure is in place which details how such assessments are done, by whom, and what criteria apply. |  |  |  |
| **2.6** | **Storage of medicines** |  |  |  |
| **2.6.1** Medicines storage facilities, including robotic storage where applicable -   * are clean, dry and tidy * are adequately lit * have sufficient space and benching etc. to allow stores processes to be segregated * have labelled work areas * are organised to allow efficient stock rotation and selection of products. * are organised to ensure that stock is not stored directly on the floor * allow segregation of * Controlled drugs * Flammable materials * Products requiring refrigeration * Bonded products (quarantined, recalled etc.) * Products requiring frozen storage * Radiopharmaceuticals * Medical Gases * Unlicensed medicines * Cytotoxic agents * Damaged goods * Waste | GDP  Duthie  IR(MER)  HTM 02-01 |  |  |
| **2.6.2** Medicines are stored according to their labelled instructions e.g.   * at the correct temperature * protected from light | GDP  Duthie |  |  |
| 2.6.3 All storage facilities for medicines requiring temperature control are   * monitored to ensure that medicines are consistently stored at the correct temperature * mapped at suitable intervals (e.g. annually) to identify cool and warm areas | GDP  Duthie |  |  |
| **2.6.4** Refrigerators and freezers   * have external temperature displays * are continuously monitored by a system which allows for prompt intervention if out of limit temperatures are reached, and for the interrogation of real-time data * are connected to a remote monitoring system e.g. facility alarm system; automatic paging * are cleaned, maintained and stocked according to the manufacturer’s instructions | GDP  Duthie |  |  |
| **2.6.5** Monitoring devices are calibrated at intervals recommended by the manufacturer, and this is recorded. | GDP |  |  |
| **2.6.7** There is a formal process for assessing the impact of temperature excursions outside the manufacturers’ requirements and disposition of affected stock. |  |  |  |
| **2.6.8** There are pest control measures in place, and written records are kept. | GDP |  |  |
| 2.7 | **Issuing medicines** |  |  |  |
| **2.7.1** There is a system to ensure that urgently required items are obtained and issued as quickly and efficiently as possible. |  |  |  |
| **2.7.2** There is a system to ensure the accuracy of medicines issued (ie. picking and checking) |  |  |  |
|  | **2.7.3 Procedures cover how confirmation is obtained that an area requesting a stock or non-stock medicine is authorised to do so and has appropriate storage facilities** |  |  |  |
| 2.8 | **Transport of medicines** |  |  |  |
| **2.8.1** Transport containers for medicines are secure | Duthie |  |  |
| **2.8.2** Transport containers are clearly labelled to ensure delivery to the correct destination and correct handling conditions e.g. fridge items | Duthie |  |  |
| **2.8.3** Transport containers used for cold chain medicines are selected to ensure that the cold chain is maintained during delivery | Duthie |  |  |
| **2.8.4** Fragile or hazardous items are packed to minimise the risk of breakage. |  |  |  |
| **2.8.5** Records are kept of all medicines transferred out of the department. | Duthie |  |  |
| 2.9 | **Waste disposal** |  |  |  |
| 2.9.1 There are sufficient facilities for waste disposal: Waste materials are not allowed to accumulate in an uncontrolled way. |  |  |  |
| 2.9.2 The disposal of waste medicines complies with the Hazardous Waste Regulations 2005 | <http://www.legislation.gov.uk/uksi/2005/894/contents/made> |  |  |
| 2.10 | **Security and safety** |  |  |  |
| **2.10.1** Access to the pharmacy department is restricted to authorised personnel, and other hospital staff/contractors/delivery drivers/members of the public are accompanied by pharmacy staff when in the department. | Duthie |  |  |
| **2.10.2** There is a system for recording visitors’ entry to and exit from the department | Duthie  GDP | Duthie |  |
| **2.10.3** Medicines storage areas are subject to an appropriate security system controlling all access points and connected to an external, constantly manned, control facility. | Duthie | GDP |  |
| **2.10.4** Access to medicines available for wards/depts to obtain for out-of-hours use is   * restricted * recorded * appropriate | Duthie |  |  |
| **2.10.5** Medicines storage areas have a suitable system of fire detection connected to an external, constantly manned, control facility. |  |  |  |
| **2.10.6** Local Health and Safety risk assessments cover as a minimum:   * Fire safety * COSHH * Manual handling * Display screen equipment * Prevention of slips, trips and falls * General welfare e.g. adequate lighting, noise control, work space. * The personal safety of staff working in medicines storage and handling areas, including lone working where applicable | Refer to local Trust H&S policy |  |  |
|  | **2.10.7** There are adequate office facilities which allow for the efficient storage and retrieval of current purchasing documents.. This includes electronic and hard copies as applicable. The facilities support tthe principles of data integrity and information governance. |  |  |  |
| **2.11** | **Equipment** |  |  |  |
| **2.11.1** There is an inventory list or asset register for key equipment. |  |  |  |
| **2.11.2** There is a documented maintenance programme for specified equipment. |  |  |  |
| **2.11.3** There is a programme for the replacement of equipment |  |  |  |
| **2.11.4** There is a system of review that incorporates the introduction of new technologies. |  |  |  |

|  | **Domain 3 – Delivering the service** | | | |
| --- | --- | --- | --- | --- |
|  | ***Audit point*** | ***Primary reference*** | ***Audit finding*** | ***Best practice examples or links*** |
| **3.1** | **Leadership** |  |  |  |
| **3.1.1** There is a system to control the introduction of new products. |  |  |  |
| **3.1.2** There is a system in place to review the usage of and modify the stockholding of medicines at suitable intervals. |  |  |  |
| **3.1.3** The procurement manager contributes to the development and implementation of the Formulary and other medicines control policies |  |  |  |
| **3.1.4** There is a system to ensure the maintenance of in-date stocks of medicines required for   * medical emergencies * major incidents |  |  |  |
| **3.2** | **Financial governance** |  |  |  |
| **3.2.1** Pharmacy procurement strictly adheres to Trust Standing Financial Instructions. |  |  |  |
| **3.2.2** Items with an annual purchase value greater than Trust SFI or EU thresholds are tendered for unless there is good reason. |  |  |  |
| **3.2.3** There is adequate segregation of duties so that:   * No single individual can order, receive and certify an invoice. * The person authorizing payment is not involved in the actual payment process. |  |  |  |
| **3.2.4** There is an accountable system for processing and recording invoices and credit notes.   * The system for authorising invoices for payment ensures that duplicate payments are avoided. * Payments are made only for goods and services which have been officially ordered and received |  |  |  |
| **3.2.5** Medicines usage and expenditure data is made available for medicines use evaluations. |  |  |  |
| **3.2.6** There is a system to monitor slow moving/redundant lines |  |  |  |
| **3.2.7** Pharmacy Procurement Services have access to a suitably qualified person e.g. CIPS qualified. |  |  |  |
| **3.3.** | **IT** |  |  |  |
| **3.3.1** The IT system:   * has adequate computer equipment (software and hardware) to facilitate procurement * provides an appropriate audit trail. * has appropriate IT support and data backup to support the procurement function, and there are contingency arrangements for network loss. * The IT system has been validated , is fit for purpose and meets the requirements of the service,   eg. is able to reconcile computer transactions with actual stock movements and financial processes.  enables electronic data interchange for orders and invoices  supports the use of bar code technology in:   * Dispensing/picking functions * Ward stock ordering * Goods receipt   accounts for:   * prompt payment discounts * other invoiced discounts * carriage and packaging | GDP |  |  |
| **3.3.2** There is a policy which authorises access to the medicines and supplier data base and which defines circumstances for removal or deletion of records   * Members of staff use individual, secure passwords which define their access to specific computer programmes. * Staff do not have access to computer programmes which they are not required to use. * There is a system to ensure that personal passwords are protected and changed at regular intervals and for inactivation of passwords for staff who have left. * Any activities carried out electronically are password protected, and individual named staff can be identified at each stage of the transaction. | GDP |  |  |
| **3.4** | **Performance monitoring** |  |  |  |
| 3.4.1 Activity data is collated monthly, including:   * Issue transactions, value and number * Credit transactions, value and number * Number of items received * Value of stock adjustments (and number) * Number of failures to supply * Value of expired stock as a % of overall stock holding |  |  |  |
| **3.4.2** Key performance indicators (as per National KPIs) are set and monitored. These may include :   * Total stock value * Stock turn rate * Value of unmoved stock * Stocktaking, number of items or % * Number of invoices outstanding in the pharmacy department for over 1 month * Stock level of critical products is defined by local policy and a checklist completed at intervals confirming levels held Number of non- contract orders >£5000 or as given in KPIs * Number of order lines < £100 * Number of single line orders * Order frequency for stock lines as defined locally |  |  |  |
| **3.4.3** Levels of performance and customer satisfaction are monitored and the results made available to staff and customers. |  |  |  |
| **3.4.4** Action is taken to correct any deficiencies in service identified by the performance indicators. | GDP |  |  |
| **3.4.5** There is a system to regularly monitor   * prices being paid to ensure value for money. * Supplier performance |  |  |  |
| **3.4.6** Action is taken to deal with poor supplier performance. |  |  |  |
| **3.5** | **Managing quality incidents** |  |  |  |
| **3.5.1** There are systems for recording and reporting   * complaints * accidents * near misses * errors detected within pharmacy * errors detected after having left the pharmacy * breaches of security * incidents resulting in delay to patient treatment. * suspected theft or fraud | GDP |  |  |
| **3.5.2** There is a system in place to monitor quality incidents and to learn from events |  |  |  |
| **3.6** | **Audit** |  |  |  |
| **3.6.1** The procurement function has access to and contributes to the department/Trust responses to all external audit and benchmarking reports e.g.:   * Care Quality Commission reports * Benchmarking exercise * Internal Audit reports * MHRA/other regulatory inspections |  |  |  |
| **3.6.2** This audit checklist is completed and the findings are discussed as part of local management team/relevant Trust forum agendas. |  |  |  |
| **3.7** | **Documentation and record keeping** |  |  |  |
| **3.7.1** There is a documentation policy which states the frequency at which SOPs are reviewed, and there is evidence that the review has been undertaken. | GDP |  |  |
| **3.7.2** SOPs are authorised by senior staff. They are in a standard format, dated, version controlled with changes since the last issue identified in a suitable place. | GDP |  |  |
| **3.7.3** There is a policy for the retention, archiving and eventual disposal of records in line with current legislation. This covers both paper and electronic records, and includes (but is not limited to) .   * Requisitions * Picking tickets * Orders * Supplier delivery notes * Controlled drugs documentation * Invoices (see SFIs) and associated documents * Quality assurance documentation * Drug contract information | Records Management: NHS Code of Practice.  QCNW Guidance Document 140 Storage and retention of records. |  |  |
| **3.8** | **Workforce** |  |  |  |
| **3.8.1** There is a statement defining the overall staffing requirements for the procurement service. |  |  |  |
| **3.8.2** There is an organisational chart to demonstrate that pharmaceutical procurement takes place under the direction of a named person who is accountable to the Chief Pharmacist | GDP |  |  |
| **3.8.3** There are up to date, current job descriptions with defined responsibilities for each member of staff within an overall structure | GDP |  |  |
| **3.8.4** Staff appointed to work in procurement and distribution receive an appropriate induction. |  |  |  |
| **3.8.5** There are defined competencies for each post |  |  |  |
| **3.8.6** All staff involved in the procurement, receipt, storage or distribution of medicines have been trained according to the activities undertaken, and training records are available. These will include, according to job role:   * Standard operational procedures * Records * Pharmacy Computer System * Customer relations * Accounting for stock and finance * Trust policies that include   - SFIs  - Security awareness  - The role of pharmacy in the hospital quality systems in providing services to patients  - Health and safety | GDP |  |  |
| **3.8.7** All staff have appropriate objectives and personal development plans that are regularly monitored through regular appraisals with their line manager |  |  |  |
| **3.8.8** All staff are undertaking appropriate CPD/life-long learning in accordance with National/Trust/ Departmental policies. |  |  |  |
| **3.8.9** Staff are allocated duties appropriate to their grade and are not routinely and extensively working below or above grade |  |  |  |
| **3.8.10** Action is taken to deal with poor performance. |  |  |  |
| **3.8.11** Pharmacy procurement and distribution staff are aware of and adhere to relevant regulatory requirements and best practice guidance according to their job role. This includes, but is not limited to:-   * UK and EU public procurement law * Trust Standing Financial Instructions * the Data protection Act 1984, and updates * the Medicines Act 1968 and the Human Medicines Regulations 2012, and updates * the Misuse of Drugs Act 1971, and updates * Good Distribution Practice, latest version |  |  |  |