Section 20 – Medicines management

20.1 Procedures for drug selection

20.1.1 Medication selection
Medication selection should be a multidisciplinary process, overseen by the respective institution’s Pharmacy and Therapeutics Committee (P&T Committee) or other appropriate group. The process should involve medical staff (oncologist/haematologist), pharmacists, nursing and administrative staff.

20.1.2 Documentation – P&T committee
Written policies and procedures should be developed and implemented to define the functioning of the P&T committee or other appropriate group.

20.1.3 Documentation – medication selection
Written policies and procedures about the process of medication selection in an institution should be developed, approved and implemented, that include:
(a) How to request additions, changes or deletions to/from the formulary
(b) Evaluation process
(c) Dissemination of information about P&T Committee decisions
(d) Mechanism for updating the formulary or list (at least annually based on emerging information).

20.1.4 Criteria for medication selection
Medication selection should be based on safety, cost-effectiveness, and/or any pharmacotherapy innovation (for example, easier route of administration, reduced dosing frequency). Comparison should be made with alternatives already available at the institution.

20.1.5 Criteria for request(s)
Qualitative and/or quantitative criteria should be developed and implemented to evaluate the request, including:
(a) Clinical aspects (efficacy, safety)
(b) Availability of scientific evidence/documentation
(c) Pharmacotherapeutic criteria (dosages, administration route, premedication regimens, interactions)
(d) Pharmaceutical criteria (drug strength, stability and compatibility, convenience of drug presentation to usual doses, ease of manipulation, risk of breaking, potential for medication errors (sound alike, look-alike, labelling, packaging, etc.).
(e) Cost
(f) Specific criteria

20.1.6 Procuring non-formulary medication
A procedure for procuring non-formulary medication should be established.

20.1.7 Medication selection decisions
Medication selection decisions (additions/deletions/changes) and recommendations must be disseminated to health care professionals involved in patient care.

20.1.8 Updates
An updated hospital formulary or pharmacotherapeutic guide (printed or online) should be distributed to all the health-care staff (physicians, pharmacists and nurses). These documents summarise drugs available from the multidisciplinary process of medication selection, policies and guidelines of drug use at the institution and the minimum information needed to enhance drug rational use.

20.2 Procedures for drug purchasing
All drugs should enter the hospital through the hospital pharmacy, even those intended for clinical trial or compassionate use program and samples.

20.2.1 Purchasing decisions
Purchasing decisions are based on the medication selection process.

20.2.2 Criteria to evaluate purchasing process
Criteria are developed and implemented to evaluate the purchasing process, including: usage, generic policies, economic offers (industry promotions, flexible pricing and public tenders), pharmaceutical criteria (unit-dose packaging, strength of doses available, bar-coding), laboratory facilities (logistics, laboratory information), and labelling and patient safety considerations.
20.2.3 High cost/use medications review
High cost or/and high use medications should be reviewed regularly to ensure appropriate use of resources and compliance with formulary guidelines. Contracts for drug purchase, if entered into by the institution or group purchasing organisation of which the institution is a member, must be honoured.

20.2.4 Purchase approvals
Purchase of medication from wholesalers or manufacturers should be approved by a pharmacist or designate (such as a pharmacy technician) and must follow all applicable local regulatory laws and regulations. Products with very similar packaging should be avoided wherever possible.

20.2.5 Purchase history
There should be a computerised system that provides information on purchase history and use for all medications managed by the pharmacy department.

20.2.6 Purchasing updates
Periodic updates on purchasing and use of medication should be made available to the hospital administration, directors of clinical units and the P&T Committee (to be used in their review process).

20.3 Procedures for stock control

20.3.1 Medication security
Medication must be secured in all storage areas in accordance with all local laws, regulations, and organisational policies.

20.3.2 Discrepancies
Drugs received are checked against the manufacturer’s/wholesaler’s delivery note/invoice and the pharmacy order form. Discrepancies should be reconciled by the responsible pharmacist or designate.

20.3.3 Update drug inventory
An updated (computerised or manual) drug inventory should be available that includes information about drug batch and expiry dates.

20.3.4 Drug inventory documentation
Written policies and procedures should be developed and implemented to regularly review drug inventory information with actual drug stock. Discrepancies should be analysed and corrective action(s) taken.

20.3.5 Discrepancies documentation
Written policies and procedures should be developed and implemented for handling drug shortages, outages and recalls including proper processes for communicating this information with other health care professionals.

20.3.6 Expiry dates
There should be a strict procedure for the checking of expiry dates (manual/automated) throughout the institution and for the removal of expired stock.

20.3.7 Disposal
Policies and procedures should be established for the disposal of expired or damaged stock and must comply with all applicable local regulatory laws and regulations.

20.3.8 Documentation – medication storage
Written policies and procedures about medication storage system/organisation (alphabetical order, pharmaceutical forms) and labelling (generic, brand names, expiry, appropriate warnings) should be developed and maintained.

20.3.9 Error prevention
To prevent errors from occurring, medication that can be easily mistaken for another (sounds alike, looks alike, similar labelling) must be separated in all areas of the health care organisation. This must include the modification of the medication storage system/organisation.

20.3.10 Storage guidelines
Drugs are stored in accordance with the manufacturer’s recommendations and storage conditions are monitored periodically following organisational policy to ensure their effectiveness and safety (temperature, moisture, light protection).

20.3.11 Documentation – high manipulation risk drugs
Policies and procedures about drugs with high manipulation risk (cytotoxic or hazardous drugs) are developed and implemented that include: identification of special handling requirements, separate storage areas with measures to prevent/minimise breakage and personnel protection equipment should be available. Ideally this storage area should have an extraction fan which can be activated in an emergency. Cytotoxic spill kits should be available where appropriate.
20.4 Procedure for re-use of drugs

20.4.1 Responsible parties
The pharmacy department is responsible for the management of all unused medications returned that were compounded and/or dispensed for oncology patients.

20.4.2 Documentation – medication return(s)
Written policies and procedures about the process/method of medication return to the pharmacy should be developed and implemented.

20.4.3 Quality control
A quality control policy on returned medications should be developed and implemented to address patient safety, including technical (integrity/packaging, labelling, defective devices, expiry dates) and physicochemical aspects (colour/precipitation).

20.4.4 Documentation – disposal
Written policies and procedures for the safe reuse or disposal of returned medication based on efficacy and safety criteria should be developed and implemented. This is mandatory for pharmacy-prepared sterile products. These criteria should consider stability and compatibility under actual handling conditions including storage or transportation when outside the pharmacy (temperature, humidity and light exposure) and microbial risk level according to potential for microbial growth. Only drugs which have remained within formal system controls may be reused. Drugs that have released to a patient, or into the community, should not be reused for other patients.

20.4.5 Causes for medication return
Causes/reasons of medication return are documented and recorded (manual/computerised) and the pharmacotherapy history is updated if needed.

20.4.6 References for accepted expiration dates
There is an updated table or chart of accepted expiration dates for commonly pharmacy-prepared sterile products according to stability and compatibility at the usual/standardised concentration range, vehicle and environmental conditions.

20.4.7 Documentation – medication re-use
Written policies and procedures for safely re-dispensing or recycling returned medication should be developed and implemented that include but are not limited to: process of new expiry date assignment, identification and labelling as recycled, re-dispensing process, dose banding, and optimum storage conditions to its immediate re-use. Health-care professionals involved in all these medication re-use processes are recorded.

20.4.8 Disposal
Policies and procedures for the disposal of expired or other unusable returned medication must follow all applicable local regulatory laws and regulations.

20.4.9 Bibliographies
Bibliographic sources (product approved labelling and reliable published stability data) used to establish criteria are referenced and available and basic information (tables/charts) is periodically updated.

20.5 Procedure for partial vials

20.5.1 Final concentrations
Irrespective of different dosage strengths of a drug which may be available, the final concentration should be the same to avoid medication preparation errors and facilitate stability concentration limits.

20.5.2 Maximal accepted expiration dates
There should be a table or chart available within the preparation area listing the maximal accepted expiration dates for drugs reconstituted in the sterile area using validated aseptic technique. This data should be based on the stability and compatibility at the final concentration, type and volume of reconstituent, microbial risk level, and optimal storage conditions (light protected, refrigerated).

20.5.3 Drugs in solution
Drugs provided in solution (not requiring reconstitution) which are manipulated using validated aseptic technique, should have a maximal expiry based on when they are first used. The institution should base this expiry on the microbial risk level and optimal storage conditions.

20.5.4 Labelling
Residual volume in multidose vials generated during antineoplastic compounding should be labelled with the reconstitution/first used date and time and the expiry according to recommended storage conditions.
20.5.5 Storage
Residual volumes in vials should be stored appropriately (strictly adhering to temperature, light, etc. criteria) and should be used before a new vial is opened.

20.5.6 Disposal
Policies and procedures for the disposal of expired or other unusable vials must follow all local applicable regulatory laws and regulations.

20.5.7 Bibliographies
Bibliographic sources (product approved labelling and reliable published stability data) used to establish criteria are referenced and available and basic information (tables/charts) should be regularly updated.

20.6 Procedures for use of unlicensed drugs
20.6.1 Documentation – unlicensed drugs
There should be written policies and procedures in place regarding the rational and safe use of unlicensed drugs in accordance with regulatory laws, patients’ rights and ethics. Unlicensed drugs include: drugs not approved or licensed in a country but available in a foreign country used for a labelled indication (foreign drugs), off-label use of licensed drugs, and investigational drugs in the setting of clinical trials.

20.6.2 Foreign drug procedures
A procedure for purchasing, storage and stock control of foreign and compassionate use drugs should be developed and implemented.

20.6.3 Documentation – off label use drugs
Written policies and procedures should be developed and implemented for the effective and safe use of approved drugs for off-label use. This should include selection, prescription, preparation, dispensing, administration, and monitoring.

20.6.4 Documentation – foreign drugs
Written policies and procedures for the effective and safe use of foreign drugs should include selection, prescription, preparation, dispensing, administration, and monitoring.

20.6.5 Procedures – investigational drugs
A procedure for approving, receiving, storage and stock control of investigational drugs is developed and implemented.

REFERENCES