Annex 4

Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection

1. Introduction

The Expert Committee on Specifications for Pharmaceutical Preparations of the World Health Organization (WHO) adopted a model quality assurance system for procurement agencies (MQAS) during a meeting in Geneva, Switzerland in 2005. This was subsequently published as Annex 6 in the Technical Report Series, No. 937 in 2006.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) Secretariat coordinated this project with the aim of preparing a harmonized assessment tool based on the WHO documents: *Model quality assurance system for procurement agencies (MQAS)*; WHO *guidelines on good storage practices (GSP)* and WHO *guidelines on good distribution practices (GDP)* (for current versions, see www.who.int/medicines).

This harmonized tool was developed by a working group consisting of representatives from the following organizations: Committee for Medicinal Products for Human Use (CHMP), Crown Agents, global drug facility (GDF), Global Fund to Fight AIDS, Tuberculosis and Malaria, International Committee of the Red Cross (ICRC), International Development Association (IDA), Médecins Sans Frontières (MSF), Management Sciences for Health (MSH), Partnership for Supply Chain Management (PFSCM), Quality Medicines for All (QUAMED), United Nations Children's Fund (UNICEF), United Nations Office for Project Services (UNOPS) and United States Agency for International Development (USAID).

2. Purpose

This harmonized tool was developed by the working group with the objective that it could result in better use of resources by coordinating procurement agency (PA) assessments; and working towards mutual recognition of the findings of PA assessments.

3. Scope

The assessment tool is based on the six modules in the MQAS:

Module I	General requirements for procurement agencies
Module II	Prequalification
Module III	Purchasing
Module IV	Receiving and storage
Module V	Distribution
Module VI	Reassessment

The tool covers the topics each of the above-listed Modules below. The logical flow considered is the quality system and infrastructure of the PA under assessment, how the PA performed prequalification, then purchasing of the products followed by the receiving and storage thereof. The last two modules then focus on the receiving of orders and dispatch of products followed by the reevaluation concept.

4. Assessment tool

The tool should be used by qualified, experienced persons when assessing a PA (including wholesalers and distributors) for compliance with recommended international standards. It can also be useful for a PA when doing a self-assessment.

The tool is not a checklist, but serves as a document to help and remind inspectors as to what should be assessed during inspections of PAs.

Module I: General requirements for procurement agencies

This Module covers general requirements for PAs including premises, equipment, transport and documentation (such as standard operating procedures (SOPs), confidentiality, code of conduct and complaint handling). Module I should be used in all cases of assessment of a procurement agency. (Modules II to VI may be used depending on the activities performed by the PA.)

Area of operation	Note	Critical aspects
Premises, equipment, furniture, transport	*General* • Licensed to operate • Sufficient space (offices for personnel, products, documents, samples, etc.) • Suitable conditions • Necessary furniture • Working office equipment • Stationery and consumables • Telephone and email access • Appropriate transport available	Compliance with legislation (licence) There must be a sufficient and functional infrastructure to enable the PA to perform its activities

Table *continued*

Area of operation	Note	Critical aspects
Human resources	*Personnel* • Compliance with national legislation (e.g. responsible person) • Sufficient number of people • Key personnel – quality assurance, prequalification, purchasing, storage and distribution • Quality assurance/ prequalification and purchasing independent of one another • Support staff • Contracted personnel and agreements • Training, education and experience	Compliance with legislation Quality assurance/ prequalification and purchasing independent of one another (personnel and reporting structure)
Organization	*Organization chart* • Authorized and current • In line with the job descriptions *Job descriptions* • Written job descriptions • Signed and dated	
Ethical considerations	*Conflict of interest* • Policy on conflict of interest is observed • Signed declaration of interest No vested interests *Code of conduct* • Written, authorized and implemented • Covers conduct of personnel • All personnel to comply with a code of conduct *Confidentiality* • Relevant product information kept confidential • Confidentiality agreements exist	Declaration and management of conflict of interest

Table *continued*

Area of operation	Note	Critical aspects
Computers	*Appropriate hardware and software* • Sufficient capacity and memory • Access control • Data transfer procedures • Reliable and accurate quality and management of data and information • Data storage (e.g. hard copies) • Back-up at defined intervals, storage, access, readable • Virus protection program and firewall • Technical support • Maintenance • Trained personnel	If used, reliable data management (including access control)
Financial systems	• Adequate banking facilities • Signatories of bank accounts appointed • Accounting system in place • National and international financial transactions • Financial transactions performed without delay • Funds available • Regular financial audits are performed	
Documentation	*Comprehensive documented system* • Covers policies, guidelines, norms, standards, manuals, procedures, records and related documents • SOPs for activities *Quality manual (QM)* • Contains a quality policy • Evidence of QM implementation, QM maintained, reviewed and amended as necessary	Activities and responsibilities described in SOPs which are implemented and followed Records reflecting activities

Table *continued*

Area of operation	Note	Critical aspects
	Standard operating procedures • SOP for writing an SOP followed • Written, clear, detailed SOPs for activities • Controlled, distributed and retrieved when required • Available for use • SOPs are reviewed periodically • Quality risk management (QRM) principles applied *Style and layout* • SOPs in defined format • Signed and dated	
Activities to be covered by SOPs	All activities should be covered by SOPs and include: • prequalification • purchasing • receiving and storage • distribution • training • handling of complaints • handling of recalls • document/record control including distribution and retrieval of SOPs • self-inspection • monitoring of environmental conditions (e.g. temperature) • monitoring of supplier performance • identifying and reporting SSFFC medical products • evaluating offers received • ordering product(s) from supplier or manufacturer • change control • variations • corrective and preventive action (CAPA)	Written SOPs followed for prequalification, purchasing, storage, distribution, complaints, recalls, identifying and reporting substandard/ spurious/falsely-labelled/ falsified/counterfeit (SSFFC) medical products Change control

Table *continued*

Area of operation	Note	Critical aspects
List of prequalified products, manufacturers and suppliers	• Current, authorized, access-controlled list • Based on the outcome of evaluation • Contains required information • Product-, manufacturing site- and supplier-specific (where relevant) • A key person responsible	A controlled list is maintained
Maintenance of records	• Records of all operations kept • Sufficient space for archiving • Access controlled • Retention period appropriate	Records are available for review
Contract arrangements	• Written contracts for delegated activities	Written, valid agreements in place

Module II: Prequalification

Prequalification is one of the key elements in ensuring purchase and supply of pharmaceutical products of acceptable quality. The prequalification process can be subdivided into two major parts, i.e. product-related assessment and manufacturer-related inspection.

Area of operation	Note	Critical aspects
Principles	• Documented policy and procedures for prequalification • Include assessment of product and manufacturers/suppliers • If delegated – written agreement in place	

Table *continued*

Area of operation	Note	Critical aspects
Key persons and responsibilities	• Responsible personnel identified • Independent from the purchasing personnel • Job descriptions • Communication between personnel involved in evaluation and inspections *Evaluation of product information (evaluators)* • List of evaluators • Suitable qualifications and experience • Job descriptions • Contracted external evaluators used (confidentiality, conflicts of interest and financial resources, references) *Inspection of manufacturing sites (inspectors)* • List of inspectors • Job descriptions • Qualified, trained, experienced • Contracted inspectors – confidentiality and no conflict of interest	Qualified, trained personnel perform prequalification activities (including assessment and inspections) Quality assurance/ prequalification and purchasing independent of one another (personnel and reporting)
Key steps in prequalification defined	*Step 1: Soliciting information* • Procedures for preparation of detailed, clear specifications; soliciting information; receiving and processing of the information • Policy and procedure for handling late submissions • Recording of data received • Procedure for submitting product information publicly available and accessible • Product information to be submitted defined (as a minimum, see product questionnaire)	Evaluation of product data and information as well as the criteria used to approve or reject a product Ensuring compliance with good manufacturing practices (GMP)

Table *continued*

Area of operation	Note	Critical aspects
	Step 2: Receive product information • Written procedures for receiving, identification, marking files, containers and samples; and sufficient space for unpacking and storage • Procedure to ensure traceability of the product information • Personnel available *Step 3: Screen product information* • SOP: screen for completeness • A screening form used • Record of screening kept • Outcome communicated to manufacturer/supplier *Step 4: Evaluate product information* • Follow SOP for evaluation to check that the product meets requirements • Time frames • Evaluation report for each product exists • Outcome communicated to the manufacturer/supplier • Response invited where needed • Outcome accepted or rejected • Evaluation report kept as record • Samples analysed if needed (see also monitoring below) *Step 5: Plan, prepare and perform inspections* *General points* • Evidence of GMP compliance • Site of manufacture known • Site inspection policy • Contract manufacturing sites known • Control over active pharmaceutical ingredients (APIs) (inspection risk-based)	

Table *continued*

Area of operation	Note	Critical aspects
	Plan • SOP and recording system for inspection planning • Procedure and data reviewed as part of preparation for inspection (e.g. site master file) *Conduct* • SOP: how to perform an inspection • Scope: data and information verified and WHO GMP compliance assessed • If not done – conditions for waiving on-site inspections *Inspection report* • Inspection report for each site inspected • Outcome communicated • CAPA requested, received and reviewed • Conclusion or outcome • Copy of report kept *Step 6: Finalize assessment process* • Written procedure followed • Covers product evaluation plus laboratory results and inspection outcome • Responsible persons (decision-taking) and reasons for decision • Outcome communicated • List of prequalified products, manufacturers and suppliers • Agreement between PA and supplier/manufacturer • List reviewed and updated at regular intervals	
Cost recovery	• If used, transparent procedure • Fee-for-services structure	

Module III: Purchasing

Procurement should be done with the aim of purchasing effective, quality assured products, and not focused on price alone. The term "procurement" in this Module relates specifically to the purchase of health sector goods from manufacturers or suppliers. The module goes on to describe the key activities in purchasing pharmaceutical products, as well as the recommended organizational structure of the procurement agencies which carry out these key activities.

Area of operation	Note	Critical aspects
Procurement strategies	• Policy: suppliers are selected and monitored through a process that takes into account product quality, service reliability and performance, delivery time, ethics, legal status, financial viability and minimum order quantities *Purchase prequalified products (from manufacturers/suppliers)* • Efficient and transparent management • Financial management procedures • Competitive procurement methods • Procedure to calculate lowest possible total cost • Procurement and purchasing procedures are transparent • Independent contract review • Purchasing and tender documents list all pharmaceutical products by their international nonproprietary name (INN) or national generic names • Intellectual property rights are respected in accordance with best practice and national law	Purchasing prequalified products

Table *continued*

Area of operation	Note	Critical aspects
Procurement methods	• If they are responsive to the defined terms and conditions, responses are examined from invited suppliers • Adjudication procedure • Explicit criteria for awarding contracts • Informed of the outcome • Restricted tender • Prequalified products and suppliers • Competitive negotiation • Direct procurement	Adjudication procedure and related records Use a defined, transparent procurement method
Key activities	• Develop a list or catalogue of products (INN) • Develop specifications for the products *Quantification* • Methods of product quantification • Quantities purchased based on reliable estimate *Procurement method* • According to the policy and procedures of the procurement agency	
Organization and responsibilities	• Personnel with appropriate qualifications and training • Job descriptions • Independent from those responsible for prequalification and quality assurance • Procurement planned	

Table *continued*

Area of operation	Note	Critical aspects
Monitoring of the performance of prequalified products, manufacturers and suppliers	• Procedure for continuous monitoring of the performance of products, manufacturers and suppliers *Monitoring may include:* • review of quality control results • verification that the product batches supplied have been manufactured in compliance with standards and specifications accepted in the product information through inspection • adverse events • random samples of batches supplied analysed (risk-based approach) • independent testing – reliable quality control laboratory (see selection criteria for quality control laboratory) • certificates of analysis available where appropriate • status of the laboratory (e.g. authorized, accredited) • handling of out-of-specification results • monitoring of complaints • outcome of inspection of manufacturing sites • outcome of reassessment of product information • monitoring of direct and indirect product costs • monitoring of adherence to delivery schedules • contract terms and conditions • tracking system (values of contracts awarded, total purchases, performance)	Handling out-of-specification results Monitoring performance of products, manufacturers and suppliers and action taken by the PA in case of non-compliance
Donations	• Written procedure	

Module IV: Receiving and storage

The PA should ensure that the pharmaceutical products purchased are received and stored correctly and in compliance with applicable legislation and regulations. Products should be received and stored in such a way that their quality and integrity is preserved, batch traceability is maintained and stock can be rotated.

Area of operation	Note	Critical aspects
General arrangements	• Received and stored correctly • Quality and integrity is maintained • Batch traceability • Stock rotation • Unidirectional flow • Security of materials and products • Subcontracting	Procedures followed for receiving and storage Batch traceability
Pre-shipment quality control	• Batches released by the manufacturer (certificate of analysis (CoA)) • Batches additionally tested (risk-based approach) prior to shipment to PA • Selection criteria for quality control laboratory	Batch release with CoA (meeting specifications)
Receiving of stock	• Receiving and dispatch bays • Incoming containers cleaned, quarantined • Review of CoAs • Released for use or distribution (responsible person involved) *Checks on receipt:* • order, delivery note, labels and transport conditions, integrity of packages and seals and for uniformity of the containers	Goods received and checked according to an appropriate SOP – supported by records Products released by responsible person

Table *continued*

Area of operation	Note	Critical aspects
	Visual inspection for: • contamination, tampering and damage, expiry date, compliance with labelling and packaging instructions • suspect containers and damaged containers – recorded and investigated	
Post-procurement control	• Random sampling for independent laboratory analysis • Selection criteria for quality control laboratory • SOP and national legislation • Representative samples – sampling plans and instructions (risk assessment) • Appropriately trained and qualified personnel	Action taken in case of non-conforming product
Rejected materials	• SOP for rejected products • Separate storage or validated computerized system • Action approved by authorized personnel and recorded	Rejected materials kept separately, access controlled and handled appropriately
Storage of materials/ products	*Personnel* • Trained • Personal hygiene and sanitation • Appropriate garments *Storage areas* • No unauthorized access • Sufficient space • Adequate ventilation, temperature and relative humidity • Conditions checked, monitored and recorded • Segregation of rejected, expired, recalled or returned stock • Toilet and washing facilities separated from storage areas	Access controlled and sufficient space Appropriate conditions for storage

Table *continued*

Area of operation	Note	Critical aspects
	• Narcotics/psychotropic medicines as per national legislation • SOP for fire control • No smoking or eating • SOP and records for cleaning • Waste management • Pest control • SOP for handling spillages *Storage conditions* • As established by the manufacturer • Orderly, batch segregation, stock rotation, first expired-first out (FEFO) • Stored off the floor • Space to permit cleaning and inspection • Pallets in a good state of cleanliness and repair • Stacking of products without damage • Freeze-sensitive products – use monitoring devices • Cold rooms (qualification, temperature mapping, alarm, monitoring, records, back-up system in case of failure) *Monitoring of storage conditions* • Temperature mapping protocol and report • Calibrated sensors/devices • Ongoing monitoring with records • Out-of-limit and out-of-trend results investigated, action taken *Miscellaneous and hazardous materials* • Rodenticides, insecticides, fumigating agents and sanitizing materials • Toxic substances and flammable materials	

Table *continued*

Area of operation	Note	Critical aspects
Re-packaging and re-labelling	• If performed – in compliance with national legislation and WHO GMP	Compliance with national legislation and WHO GMP
Stock control	• Validated stock control system • Batch number control and expiry dating • Periodic stock reconciliation • Significant stock discrepancies investigated • Records maintained • Damaged containers handled *Control of obsolete and outdated materials and products* • SOP • Regular checks *Recalled materials and products* • SOP • Written records of actions with signatures • Products identified, recorded, reconciled and stored separately • Decision by appropriately qualified and experienced member of staff *Returned goods* • SOP • Quarantined and assessed • Resale conditions • Destruction in compliance with national requirements • Records *Waste materials* • SOP • Safe storage while awaiting disposal • Toxic substances and flammable materials • No accumulation • Safe disposal, national regulations	Stock control in place (e.g. reconciliation, obsolete materials, recalled products, returned goods, FEFO and waste)

Table *continued*

Area of operation	Note	Critical aspects
Documentation: written instructions and records:	• SOPs for activities • Handling of expired stock • Ensuring batch traceability • Records for storage conditions, precautions • National regulations concerning labels and containers • Comprehensive records of all activities • Retention of records	Record-keeping ensuring traceability (e.g. receiving, issuing, expired goods)

Module V: Distribution

The PA (or contracted party) should have a well-managed distribution system meeting the objectives of ensuring constant supply of quality medicines. Distribution should be done in accordance with general principles of GMP.

Area of operation	Note	Critical aspects
General	• Constant supply of medicines • Minimize medicines losses (spoilage and expiry) • Accurate inventory records • Prevent theft and fraud	
Transport conditions	• Transport process has no negative impact on product • Required storage conditions maintained • Temperature excursions – risk assessment	Appropriate transport conditions

Table *continued*

Area of operation	Note	Critical aspects
Cold chain	• Validated process • Applied where needed • Appropriate containers • Packaging procedure • Cooling agents used • Calibrated monitoring devices • Monitoring records reviewed, maintained	Cold chain validated, maintained and monitored
Dispatch procedures	• Compliance with legislation • Authorized recipients • Procedures in place • Special packaging requirements observed where needed • Dispatch and transport after receipt of a delivery order	Compliance with legislation Authorized recipients
Dispatch containers	• Provide protection • Appropriately labelled • Prevent theft (e.g. locked/ wrapped)	
Dispatch records	• Detailed records kept (e.g. date, customer name and address; product name and batch number and quantity) • Products and batches traceable • Discrepancies investigated	Records ensure traceability of goods
Port of entry	• Storage conditions met • Temperature-sensitive products handled appropriately • Security measures in place (e.g. prevent theft, fraud and bribery)	

Module VI: Reassessment

Quality of products and services should be continuously monitored. This process includes reassessment.

Area of operation	Note	Critical aspects
Reevaluation of manufacturers	• Reinspection frequency based on risk assessment • Within five-year cycle • Change control • Mechanism for suspension and withdrawal	Reinspection policy and procedure followed
Reevaluation of products	• Reevaluation procedure • Within five-year cycle • Variations procedure	Reevaluation of product policy and procedure followed
Monitoring performance of contractors	• Written procedure • Covers continuous monitoring, periodic review and renewal of contracts • System for documenting service problems	Procedure followed for monitoring performance