Table 1 Quality Management Standards

1.1 Principle: Wholesale dealers should maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities.

All distribution activities should be clearly defined in procedures and systematically reviewed. All critical steps of distribution processes and significant changes should be justified and where relevant validated.

The quality system is the responsibility of the organization's management and requires their leadership and active participation and should be supported by staff commitment.

1.2 Quality System:

1.2.1 The system for managing quality should encompass the organizational structure, procedures, processes and resources, as well as activities necessary to ensure confidence that the medicinal products delivered maintains its quality and integrity and remains within the legal supply chain during storage and transportation.

1.2.2 The quality system should be fully documented and its effectiveness monitored. All quality system related activities should be defined and documented. A quality manual or equivalent documentation approach should be established.

1.2.3 Designated responsible person(s) should be appointed by the management, who should have clearly specified authority and responsibility for ensuring that a quality system is implemented and maintained.

1.2.4 The management of the wholesale dealer should ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

1.2.5 The size, structure and complexity of wholesale dealer's activities should be taken into consideration when developing or modifying the quality system.

1.2.6 A change control system should be in place. This system should incorporate quality risk management principles, and be proportionate and effective.

1.2.7 The quality system should ensure that:

(1) Medicinal products are procured, held, supplied, imported or exported in a way that is compliant with the requirements of the regulations.

(2) Management responsibilities are clearly specified.

(3) Medicinal products are delivered to the right recipients within a satisfactory time period.

(4) Records are made contemporaneously.

(5) Deviations from established procedures are documented and investigated.

(6) Appropriate corrective and preventive actions are taken to correct deviations and prevent them in line with the principles of quality risk management.

1.3 The quality system should extend to the control and review of any outsourced activities related to the procurement, holding, supply, import or export of medicinal products. These processes should incorporate quality risk management and include:

(1) Assessing the suitability and competence of the Contract Acceptor to carry out the activity, preserving the integrity and security of the medicinal products, and requesting, preserving documentation, and checking authorisation and marketing status, if required.

(2) Defining the responsibilities and communication processes for the quality-related activities of the parties involved

(3) Monitoring and review of the performance of the Contract Acceptor, and the identification and implementation of any required improvements on a regular basis.

1.4 Management Review and Monitoring

1.4.1 The management should have a formal process for reviewing the quality system on a periodic basis. The review should include:

(1) measurement of the achievement of quality system objectives;

(2) assessment of performance indicators that can be used to monitor the effectiveness of processes within the quality system, such as complaints, recalls, returns, deviations, CAPA, changes to processes; feedback on outsourced activities; self-assessment processes including risk assessments and audits; and external assessments such as inspections, findings and customer audits.

(3) Emerging regulations, guidance and quality issues that can impact the quality management system;

(4) innovations that might enhance the quality system;

(5) changes in business environment and objectives.

1.4.2 The outcome of each management review of the quality system should be documented in a timely manner and effectively communicated internally.

1.5 Quality Risk Management

1.5.1 Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of medicinal products. It can be applied both proactively and retrospectively.

1.5.2	Quality risk management should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. The level of effort, formality and documentation of the process should be commensurate with the level of risk.