Table 4 Documentation Standards

4.1	Principle: Written documentation should prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of medicinal products. Records should be made at the time each operation is undertaken.
4.2	General:
4.2.1	Documentation comprises all written procedures, instructions, contracts, records and data, in paper or in electronic form. Documentation should be readily available.
4.2.2	With regard to the processing of personal data of employees, complainants or any other natural person, national legislation on the protection of individuals applies to the processing of personal data and to the free movement of such data.
4.2.3	Documentation should be sufficiently comprehensive with respect to the scope of the wholesale dealer's distribution activities and in a language understood by personnel. It should be written in clear, unambiguous language and be free from errors.
4.2.4	Documentation should be approved, signed and dated by designated persons. It should not be handwritten; although, where it is necessary, sufficient space should be provided for such entries.
4.2.5	Any alteration made in the documentation should be signed and dated; the alteration should permit the reading of the original information. The reason for the alteration should be recorded.
4.2.6	Documents should be retained at least 5 years. Personal data should be deleted or anonymised as soon as their storage is no longer necessary for the purpose of distribution activities.
4.2.7	Each employee should have ready access to all necessary documentation for the tasks executed.
4.2.8	Valid and approved procedures should be used. Documents should have unambiguous content; title, nature and purpose should be clearly stated. Documents should be reviewed regularly and kept up to date. Version control should be applied to procedures. After revision of a document a system should exist to prevent inadvertent use of the superseded version. Superseded or obsolete procedures should be removed from workstations and archived.
4.2.9	Records must be kept either in the form of purchase/sales invoices, delivery slips, or on computer or any other form, for any transaction in medicinal products received or supplied. Records must include at least the following information: date; name of the medicinal product; quantity received,

supplied; name and address of the supplier, customer, or consignee; and batch number, expiry date, as required by national legislation.

Records are made contemporaneously and if handwritten, in clear, legible and indelible handwriting.