

Table 5 Operation Procedures Standards

<p>5.1 Principle: All actions taken by wholesale dealers should ensure that the identity of the medicinal product is not lost and that the wholesale distribution of medicinal products is performed according to the information on the outer packaging. The wholesale dealer should use all means available to minimise the risk of falsified medicinal products entering the legal supply chain.</p> <p>All medicinal products distributed in the intended market by a wholesale dealer must be appropriately authorised by the national authorities.</p> <p>All key operations described below should be fully described in the quality system in appropriate documentation.</p>
<p>5.2 Qualification of Suppliers:</p>
<p>5.2.1 Wholesale dealers must obtain their supplies of medicinal products only from suppliers who comply with national legislation.</p>
<p>5.2.2 Where medicinal products are obtained from another wholesale dealer the receiving wholesale dealer must verify that the supplier complies with GDP regulations and that they hold a licence.</p>
<p>5.2.3 Appropriate qualification and approval of suppliers should be performed prior to procurement of any medicinal products. This should be controlled by a procedure and the results documented and periodically rechecked using a risk based approach.</p>
<p>5.2.4 When entering into a new contract with new suppliers the wholesale dealer should carry out 'due diligence' checks in order to assess the suitability, competence and reliability of the other party. Attention should be paid to:</p> <ul style="list-style-type: none">(1) The reputation or reliability of the supplier.(2) Offers of medicinal products more likely to be falsified.(3) Large offers of medicinal products which are generally only available in limited quantities.(4) Diversity of products handled by supplier.(5) And out-of-range prices.
<p>5.3 Qualification of Customers:</p>
<p>5.3.1 Wholesale dealers must ensure they supply medicinal products only to persons who comply with national legislation.</p>
<p>5.3.2 Checks and periodic rechecks may include: requesting copies of customer's authorisations, verifying status on an authority website, requesting evidence of qualifications and entitlement.</p>
<p>5.3.3 Wholesale dealers should monitor their transactions and investigate any irregularity in the sales patterns of medicinal products at risk of diversion (e.g. controlled drugs). Unusual sales patterns that may constitute diversion</p>

or misuse of medicinal product should be investigated and reported to competent authorities. Related measures should be taken to ensure fulfilment of any public service obligation imposed upon them.

5.4 Receipt of medicinal products:

5.4.1 The purpose of the receiving function is to ensure that the arriving consignment is correct, that the medicinal products originate from approved suppliers and that they have not been visibly damaged during transport.

5.4.2 Medicinal products requiring special handling, storage or security measures should be prioritised and once appropriate checks have been conducted they should be immediately transferred to appropriate storage facilities.

5.4.3 Batches of medicinal products should not be transferred to saleable stock before assurance has been obtained in accordance with written procedures, that they are authorised for sale.

5.4.4 If a falsified product is suspected, the batch should be segregated and reported to competent authorities as required by national legislation.

5.5 Storage:

5.5.1 Medicinal products should be stored separately from other products likely to alter them and should be protected from the harmful effects of light, temperature, moisture and other external factors. Particular attention should be paid to medicinal products requiring specific storage conditions.

5.5.2 Incoming containers of medicinal products should be cleaned, if necessary, before storage. Any activities performed on the incoming goods (e.g. fumigation) should not impact on the quality of the medicinal products.

5.5.3 Warehousing operations must ensure appropriate storage conditions are maintained and allow for appropriate security of stocks.

5.5.4 Stock should be rotated according to the first expiry, first out (FEFO) principle. Exceptions should be documented.

5.5.5 Medicinal products should be handled and stored in such a manner as to prevent spillage, breakage, contamination and mix-ups. Medicinal products should not be stored directly on the floor unless the package is designed to allow such storage (such as for some medicinal gas cylinders).

5.5.6 Medicinal products that are nearing their expiry date or shelf life should be withdrawn immediately from saleable stock.

5.5.7 Stock inventories should be performed regularly taking into account national legislation requirements. Stock irregularities should be investigated, documented and reported to the competent authorities when needed.

5.6 Destruction of obsolete Goods:

5.6.1 Medicinal products intended for destruction should be appropriately

identified, held separately and handled in accordance with a written procedure.

5.6.2 Destruction of medicinal products should be in accordance with national requirements for handling, transport and disposal of such products.

5.6.3 Records of all destroyed medicinal products should be retained for a defined period.

5.7 Picking: Controls should be in place to ensure the correct product is picked. The product should have an appropriate remaining shelf life when it is picked.

5.8 Supply: For all supplies, a document (e.g. delivery note, packing list) must be enclosed stating the date; name and pharmaceutical dosage form of the medicinal product, batch number, expiry date, as required by national legislation; quantity supplied; name and address of the supplier, name and delivery address of the consignee (actual physical storage premises, if different) and applicable transport and storage conditions. Records should be kept so that the actual location of the product can be known.

5.9 Import and export:

5.9.1 Import and export activities should be conducted in accordance with national legislation and with international guidelines or standards when appropriate. Wholesale dealers should take the appropriate measures in order to prevent medicinal products not authorised for the internal market and intended for export from reaching the internal market.

5.9.2 Where wholesale dealers obtain medicinal products from other countries, they must ensure that entities are authorised or entitled to supply/receive medicinal products in accordance with the applicable legal and administrative provisions of the countries concerned.