Table 6 Complaints, Returns and Recalls Standards

6.1 Principle: All complaints, returns, suspected falsified medicinal products and recalls must be recorded and handled carefully according to written procedures. Records should be made available to the competent authorities. An assessment of returned medicinal products should be performed by designated personnel before any approval for resale.

6.2 Complaints:

6.2.1 Complaints should be recorded with all the original details. A distinction should be made between complaints related to the quality of a medicinal product and those related to distribution. In the event of a complaint about the quality of a medicinal product and a potential product defect, the manufacturer and marketing authorisation holder should be informed without delay. Any product distribution complaint should be thoroughly investigated to identify the origin of or reason for the complaint.

6.2.2 If a defect relating to a medicinal product is discovered or suspected, consideration should be given to whether other batches of the product should also be investigated.

6.2.3 A person should be appointed to handle complaints.

6.2.4 If necessary, appropriate follow-up actions should be taken after investigation and evaluation of the complaint, including where required notification to the national competent authorities.

6.3 Returned Medicinal Products:

6.3.1 Returned products must be handled according to a written, risk based process taking into account the product concerned, any specific storage requirements and the time elapsed since the medicinal product was originally dispatched. Returns should be conducted in accordance with national legislation, and contractual arrangements between the parties. A record of returned goods must be maintained.

6.3.2 Medicinal products which have left the premises of the wholesale dealer should only be returned to saleable stock if all of the following are confirmed:

(1) The medicinal products are in their unopened and undamaged secondary packaging and are in good condition; have not expired and have not been recalled.

(2) Medicinal products returned from pharmacies authorised to supply medicinal products to the public should only be returned if they are returned within an acceptable time limit.

(3) It has been demonstrated by the customer that the medicinal products

have been transported, stored and handled in compliance with the specific storage requirements.

(4) They have been examined and assessed by a sufficiently trained and competent person authorised to do so; the wholesale dealer has reasonable evidence (via copies of the original delivery note or by referencing invoice numbers/batch numbers, expiry date etc.) that the product was supplied to that customer.

6.3.3 Moreover, for medicinal products requiring specific temperature storage conditions such as low temperature, returns to saleable stock can only be made if there is documented evidence that the product has been stored under the authorised storage conditions throughout the entire time. If any deviation has occurred a risk assessment has to be performed, on which basis the integrity of the medicinal product can be demonstrated.

The evidence should cover:

(1) Delivery to customer.

(2) Examination of the medicinal product.

(3) Opening of the transport packaging.

(4) Return of the medicinal product to the packaging.

(5) Collection and return to the wholesale dealer.

(6) Record of temperature readings during transportation.

(7) Return to the distribution site refrigerator.

6.3.4 Products returned to saleable stock should be placed such that the 'first expired first out' system operates effectively.

6.3.5 Stolen products that have been recovered cannot be returned to saleable stock and sold to customers.

6.4 Falsified Medicinal Products:

6.4.1 The sale and distribution of a suspected falsified medicinal product should be suspended immediately.

6.4.2 Wholesale dealers must immediately inform the competent authority and the marketing authorisation holder of any medicinal products they identify as falsified or suspect to be falsified and act on the instructions as specified by the competent authority. A procedure should be in place to this effect. It should be recorded with all the original details and investigated.

6.4.3 Any falsified medicinal products found in the supply chain should immediately be physically segregated and stored in a dedicated area away from all other medicinal products and be appropriately labelled. All relevant activities in relation to such products should be documented and records retained.

6.4.4 Upon confirmation as a falsified medicinal product, a formal decision should be taken on removal of such product from the market, ensuring that it does not re-enter the supply chain, including retention of any samples necessary for public health, regulatory, or legal needs and arrangements for its disposal. All related decisions should be appropriately documented.

6.5 Medicinal Product Recalls:

6.5.1 There should be documentation and procedures in place to ensure traceability of medicinal products received and distributed, to facilitate product recall.

6.5.2 In the event of a medicinal product recall, all customers to whom the product has been distributed shall be informed with the appropriate degree of urgency and clear actionable instructions.

6.5.3 The national regulatory authority should be informed of all product recalls. If the medicinal product is exported, the overseas related authorities must be informed of the recall as required by national legislation.

6.5.4 The effectiveness of the arrangements for product recall should be evaluated at least annually.

6.5.5 Recall operations should be capable of being initiated promptly and at any time.

6.5.6 The wholesale dealer must follow the instructions of a recall message, which should be approved, if required, by the competent authorities.

6.5.7 Any recall operation should be recorded at the time it is carried out. Records should be made readily available to the competent authorities.

6.5.8 The distribution records should be readily accessible to the person(s) responsible for the recall, and should contain sufficient information on wholesale dealers and directly supplied customers (with addresses, phone and fax numbers inside and outside working hours, batch numbers and quantities delivered), including those for exported products and medicinal product samples.

6.5.9 The progress of the recall process should be recorded for a final report including reconciliation of the recalled product.