# WHOLESALE DISTRIBUTION AUTHORISATION AUDIT

**EDITION 1**

August 2014

# Wholesale Distribution Authorisation (Human) Audit against current EU Good Distribution Practice[1, 2]

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on behalf of the
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## Section No: 1 Quality Management

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **1.1** | An internal audit programme is in place with a system to close out audit actions. | **Y/N/NA** | |
| **1.2** | An appropriate system is in place for documenting deviations from standard procedures. | **Y/N/NA** | |
| **1.3** | An appropriate system is in place for managing changes. | **Y/N/NA** | |
| **1.4** | There is a written complaints procedure. | **Y/N/NA** | |
| **1.5** | There is evidence that complaints are recorded and acted on appropriately. | **Y/N/NA** | |
| **1.6** | There is a written policy specifying the range of medicinal products covered by the licence which can be supplied by wholesale dealing. | **Y/N/NA** | |
| **1.7** | Unlicensed medicines are purchased in accordance with local policy or guidance. | **Y/N/NA** | |
| **1.8** | Corrective and preventative actions taken following deviations or errors are documented | **Y/N/NA** | |
| **1.9** | There is a quality manual which defines the quality management system. | **Y/N/NA** | |
| **1.10** | Management has a formal process for reviewing the quality system on a periodic basis. The review includes:<br>(i) measurement of the achievement of quality system objectives or assessments of key performance Indicators (e.g. review of workload, procedures, supplier performance and product range at regular intervals. Levels of performance and customer satisfaction are monitored).<br>(ii) assessment of performance indicators that can be used to monitor the effectiveness of processes within the quality system (e.g. complaints, deviations, CAPA, change control, feedback on outsourced activities, self-assessment processes including risk assessments and audits, external assessments such as inspections, findings and customer audits). | **Y/N/NA**<br>**Y/N/NA** | |
| **1.11** | There is evidence that action is taken to deal with poor performance. | **Y/N/NA** | |

## Section No: 2 Personnel

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **2.1** | There is a designated Responsible Person who ensures compliance with EU Good Distribution Practice (GDP). | **Y/N/NA** | |
| **2.2** | The Responsible Person has appropriate competence and experience as well as knowledge of and training in GDP (i.e. MHRA RP Gold Standard Role Profile[3]) | **Y/N/NA** | |
| **2.3** | The written job description of the Responsible Person defines their authority to take decisions with regard to their responsibilities. | **Y/N/NA** | |
| **2.4** | The Responsible Person has defined responsibility and authority for ensuring that a quality system is in place and is maintained. | **Y/N/NA** | |
| **2.5** | Suitable arrangements are in place for the duties of the Responsible Person to be delegated in his/her absence | **Y/N/NA** | |
| **2.6** | There is a clear management structure setting out the responsibility and accountability of each member of staff involved in wholesale distribution. | **Y/N/NA** | |
| **2.7** | Staff members are allocated duties appropriate to their grade and are not routinely and extensively working above or below their grade. | **Y/N/NA** | |
| **2.8** | A training policy with details of training required for all designations of staff is available. | **Y/N/NA** | |
| **2.9** | Staff members are suitably trained and training records are complete. | **Y/N/NA** | |
| **2.10** | All personnel involved in wholesale distribution activities are trained on the requirements of GDP. | **Y/N/NA** | |
| **2.11** | Personnel dealing with any products which require more stringent handling conditions receive specific training (e.g. handling hazardous products, radioactive materials, controlled drugs, and temperature-sensitive products). | **Y/N/NA** | |
| **2.12** | The effectiveness of training is periodically assessed and documented (e.g. knowledge of procedures, competency assessment to perform duties and attendance on training courses). | **Y/N/NA** | |

## Section No: 2 Personnel contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **2.13** | The training programme includes:<br>• Health and Safety, including COSHH.<br>• Safe handling and lifting.<br>• Dealing with spillage and contamination.<br>• Dealing with accidents and injuries.<br>• Security.<br>• Procedures.<br>• Records.<br>• Customer relations.<br>• Quality services.<br>• Recalls/Drug alerts/Counterfeits. | **Y/N/NA** | |
| **2.14** | Designated porters or drivers used to distribute medicines are appropriately trained. | **Y/N/NA** | |

## Section No: 3 Premises and Equipment

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **3.1** | The premises are structurally soundto allow safe storage and handling of the medicinal products. | **Y/N/NA** | |
| **3.2** | The premises are of sufficient capacity to allow safe storage and handling of the medicinal products. | **Y/N/NA** | |
| **3.3** | There is sufficient space and benching to allow segregation of stores processes. | **Y/N/NA** | |
| **3.4** | Storage areas are provided with adequate lighting to enable all operations to be carried out accurately and safely. | **Y/N/NA** | |
| **3.5** | Medicinal products are stored in segregated areas from other materials (which are clearly marked). | **Y/N/NA** | |
| **3.6** | Medicines are stored appropriately and are not stored directly on the floor unless the package is designed to allow such storage (e.g. medicinal gas cylinders, stock on pallets). | **Y/N/NA** | |

## Section No: 3 Premises and Equipment contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **3.7** | Products pending a decision as to their disposition (e.g. expired, damaged or contaminated stock)or products that have been removed from saleable stock should be segregated either physically in a quarantine area or through an equivalent electronic system. This includes, for example, any product suspected of falsification and returned products. | **Y/N/NA** | |
| **3.8** | Controlled drugs are stored in accordance with Home Office guidance. | **Y/N/NA** | |
| **3.9** | Radioactive materials and other hazardous products, as well as products presenting special safety risks of fire or explosion (e.g. medicinal gases, combustibles, flammable liquids and solids), are safely and securely stored in one or more dedicated areas | **Y/N/NA** | |
| **3.10** | Receiving and dispatch bays protect medicines from prevailing weather conditions. | **Y/N/NA** | |
| **3.11** | There is adequate separation between the receipt and dispatch and storage areas and procedures are in place to maintain control of inbound/ outbound goods. | **Y/N/NA** | |
| **3.12** | Reception areas where deliveries are examined following receipt are designated and suitably equipped. | **Y/N/NA** | |
| **3.13** | Premises and storage facilities are clean and free from litter and dust. | **Y/N/NA** | |
| **3.14** | Cleaning programmes, cleaning instructions and records are in place. | **Y/N/NA** | |
| **3.15** | Premises are designed and equipped to prevent, as far as is possible, the entry of insects, rodents or other animals. | **Y/N/NA** | |
| **3.16** | A preventive pest control programme is in place. | **Y/N/NA** | |
| **3.17** | Cold temperature storage is subject to at least daily recording of actual, minimum and maximum temperatures. | **Y/N/NA** | |
| **3.18** | The maximum ambient store temperature is recorded daily and should not exceed 25°C at any time (this may also include any robotic storage equipment). | **Y/N/NA** | |

## Section No: 3 Premises and Equipment contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **3.19** | There are systems to detect the failure of cold storage facilities. | **Y/N/NA** | |
| **3.20** | There is a written action plan or procedure for dealing with out of limits temperatures. | **Y/N/NA** | |
| **3.21** | Storage areas, including cold stores, refrigerators and freezers, are temperature mapped initially and remapped based upon risk assessment or following any major change. | **Y/N/NA** | |
| **3.22** | Temperature monitoring equipment is located according to the results of a temperature mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations. | **Y/N/NA** | |
| **3.23** | Temperature monitoring devices are calibrated to a traceable national standard annually. | **Y/N/NA** | |
| **3.24** | If a dispensary robot is used to hold stock which might be supplied by wholesale, there is no evidence of contaminated, dislodged or fallen material around the hopper and conveyor belts or inside the robot. | **Y/N/NA** | |
| **3.25** | If a walk in refrigerator or cold room is used;<br>• The location is not overfull and the internal air circulation fans are unobstructed.<br>• Excessive amounts of cardboard, plastic and other packaging material is not present within the storage area.<br>• No medicine is stored directly on the floor.<br>• There is adequate segregation of active (“live”) stock, returns and quarantined material with clear signage. | **Y/N/NA** | |
| **3.26** | Unlicensed medicines are stored separately from other medicines or can be identified as unlicensed medicines through computerised systems, documentation or similar means. | **Y/N/NA** | |
| **3.27** | Stock is rotated to ensure ‘first expiry - first out’ | **Y/N/NA** | |

## Section No: 3 Premises and Equipment contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **3.28** | There are adequate office facilities that allow for the efficient storage and retrieval of current documentation, procedures and records. | **Y/N/NA** | |
| **3.29** | Records of all repair, maintenance or calibration of any equipment are kept. There is a programme of preventative maintenance for critical equipment. | **Y/N/NA** | |
| **3.30** | Computerised systems must be demonstrated to be capable of achieving the desired results accurately, consistently and reproducibly through appropriate validation or verification studies (e.g. the computer system has been validated to reconcile computer transactions with actual stock movements and financial processes. There are facilities to enable electronic data interchange for orders and invoices). | **Y/N/NA** | |
| **3.31** | A written, detailed description of any computerised system is available (including diagrams where appropriate) which is kept up- to-date. The document should describe principles, objectives, security measures, system scope and main features, how the computerised system is used and the way it interacts with other systems. | **Y/N/NA** | |
| **3.32** | Data is only be entered into the computerised system or amended by persons authorised to do so. | **Y/N/NA** | |
| **3.33** | Data is secured and protected against accidental or unauthorised modifications. | **Y/N/NA** | |
| **3.34** | Stored data is checked periodically for accessibility. | **Y/N/NA** | |
| **3.35** | Data is protected by backing up at regular intervals. | **Y/N/NA** | |
| **3.36** | Back up data is retained for a period of at least five years at a separate and secure location. | **Y/N/NA** | |
| **3.37** | Rest, wash and refreshment rooms are physically separated from the storage area | **Y/N/NA** | |
| **3.38** | Food and drink is not consumed in the distribution areas. | **Y/N/NA** | |

## Section No: 4 Security of Premises and Equipment

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **4.1** | The premises are suitably secure to allow safe storage and handling of the medicinal products. | **Y/N/NA** | |
| **4.2** | A monitored intruder alarm system is in place which is regularly tested, serviced and maintained and records of testing and maintenance are kept. | **Y/N/NA** | |
| **4.3** | Access is restricted only to authorised personnel. | **Y/N/NA** | |
| **4.4** | There are systems to detect the presence of smoke and/or fire. | **Y/N/NA** | |
| **4.5** | Staff members appointed to work in procurement, storage and distribution are subject to appropriate criminal record checks. | **Y/N/NA** | |
| **4.6** | Members of staff use individual, secure passwords that define their access to specific computer programmes. | **Y/N/NA** | |
| **4.7** | Staff members do not have access to computer programmes that they do not require to use. | **Y/N/NA** | |
| **4.8** | There is a system to ensure that personal passwords are protected and changed at regular intervals. | **Y/N/NA** | |
| **4.9** | There is adequate segregation of duties so that no individual can order, receive and certify an invoice. | **Y/N/NA** | |
| **4.10** | There is a system for identifying and dealing with suspected theft and fraud. | **Y/N/NA** | |

## Section No: 5 Documentation

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **5.1** | Procedures are approved signed and dated by the Responsible Person. | **Y/N/NA** | |

## Section No: 5 Documentation contd...

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **5.2** | Standard Operating procedures exist for at least the following:<br>• Receipt and checking of deliveries<br>• Putting stock away (including robotic storage)<br>• New product procedure<br>• Purchase of unlicensed materials including named patient products<br>• Stock location and rotation<br>• Stock checks / stock balancing<br>• Handling of Controlled Drugs<br>• Ordering system<br>• Storage and recording of storage conditions<br>• Invoices and credits for goods received<br>• Invoicing customers<br>• Delivery to customers<br>• Security of stocks on site and in transit<br>• Packaging of materials for dispatch to customers (refrigerated items/cytotoxics)<br>• Maintenance of cold chain for refrigerated/frozen deliveries<br>• Returns from customers<br>• Returns to suppliers<br>• Breakages/spillages/disposal of medicines<br>• Recall system and defect reporting<br>• Complaints, deviations and errors<br>• Dealing with suspected counterfeits<br>• Cleaning and maintenance of premises (including pest control)<br>• Stock control system (including what to do if a computerised system fails)<br>• Records<br>• Health and Safety and manual handling | **Y/N/NA** | |

## Section No: 5 Documentation contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **5.3** | Any alteration made in records or documentation is signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration is recorded. | **Y/N/NA** | |
| **5.4** | Documents and records are retained for at least five years. This includes but is not limited to:<br>• Requisitions<br>• Picking notes<br>• Orders<br>• Supplier Delivery Notes<br>• Controlled Drug records<br>• Invoices (see Standing Financial Instructions) and Associated Documents<br>• Quality Management documentation | **Y/N/NA** | |
| **5.5** | Documents are unambiguous; the title, nature and purpose of the document is clearly stated. | **Y/N/NA** | |
| **5.6** | Documents are reviewed regularly and kept up-to-date. | **Y/N/NA** | |
| **5.7** | Version control is applied to procedures and other documents. | **Y/N/NA** | |
| **5.8** | After revision of a document, systems exist to prevent inadvertent use of the superseded version. | **Y/N/NA** | |
| **5.9** | Superseded or obsolete procedures are removed from use and archived. | **Y/N/NA** | |
| **5.10** | Records are kept either in the form of purchase/sales invoices, delivery slips, or on computer for any transaction in medicinal products received or supplied. | **Y/N/NA** | |
| **5.11** | Records must include at least the following information: date; name of the medicinal product; quantity received, supplied or brokered; name and address of the supplier, customer, broker or consignee, as appropriate; and batch number. | **Y/N/NA** | |
| **5.12** | Records are made at the time each operation is undertaken. | **Y/N/NA** | |

## Section No: 5 Documentation contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **5.13** | There is a system in place to inform all staff of updates in procedures and working practices. | **Y/N/NA** | |
| **5.14** | Service level agreements / specifications / contracts are in place with providers of support services external to Pharmacy:<br>• IT<br>• Estates<br>• Quality Assurance<br>• Cleaners<br>• Pest control<br>• Portering<br>• Transport<br>• Refrigeration companies | **Y/N/NA** | |
| **5.15** | Service level agreements / specifications / contracts are reviewed at least every 3 years. | **Y/N/NA** | |

## Section No: 6 Operations

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **6.1** | Supplies of medicinal products are obtained only from companies that are themselves in possession of a wholesale distribution authorisation, or that are in possession of a manufacturing authorisation which covers the product in question. | **Y/N/NA** | |
| **6.2** | Qualification and approval of suppliers is performed prior to any procurement of medicinal products. This is controlled by a procedure and the results documented and periodically rechecked (e.g. annual recheck of licence status). | **Y/N/NA** | |

## Section No: 6 Operations contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **6.3** | When entering into a new contract with new suppliers, the wholesale distributor must carry out 'due diligence' checks in order to assess the suitability, competence and reliability of the other party. Attention should be paid to:<br>• the reputation and reliability of the supplier<br>• offers of medicinal products more likely to be falsified<br>• large offers of medicinal products which are generally only available in limited quantities<br>• out-of-range prices | **Y/N/NA** | |
| **6.4** | Medicinal products are only supplied to persons who are themselves in possession of a wholesale distribution authorisation or who are authorised or entitled to supply medicinal products to the public. | **Y/N/NA** | |
| **6.6** | Mechanisms are in place to report irregularity in the sales patterns of controlled drugs or the suspected diversion or misuse of other medicinal products. | **Y/N/NA** | |
| **6.7** | Deliveries are examined on receipt to check for damage and to ensure that they correspond to the order. | **Y/N/NA** | |
| **6.8** | Products requiring specific storage measures are identified promptly and stored appropriately. Products for wholesale distribution requiring specific storage may include:<br>• Controlled Drugs<br>• Flammable products<br>• Medicines requiring refrigeration<br>• Medicines requiring frozen storage<br>• Medical gases in cylinders | **Y/N/NA** | |
| **6.9** | Medicinal products are handled and stored in such a manner as to prevent spillage, breakage, contamination and mix-ups. | **Y/N/NA** | |
| **6.10** | Medicinal products intended for destruction are appropriately identified, held separately and handled in accordance with a written procedure. | **Y/N/NA** | |

## Section No: 6 Operations contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **6.11** | Destruction of medicinal products is in accordance with waste medicines policies. | **Y/N/NA** | |
| **6.12** | Records of all destroyed medicinal products are retained for 5 years. | **Y/N/NA** | |
| **6.13** | Controls are in place to ensure the correct product is picked. | **Y/N/NA** | |
| **6.14** | For all supplies, a document (e.g. delivery note) is enclosed stating the date; name and pharmaceutical form of the medicinal product, batch number; 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. | **Y/N/NA** | |
| **6.15** | Records of all supplied medicines are kept so that the actual distribution of a given medicine can be known. | **Y/N/NA** | |
| **6.16** | Medicines are delivered in a manner that ensures that:<br>• Their identification is not lost<br>• They do not contaminate, and are not contaminated by other medicines or materials<br>• Adequate precautions are taken against spillage, breakage and theft<br>• They are not subject to adverse conditions (heat, cold, light or moisture) nor attack by micro-organisms or pests | **Y/N/NA** | |
| **6.17** | Products requiring cold temperature storage are transported by appropriate means to maintain the cold chain | **Y/N/NA** | |

## Section No: 7 Complaints, Returns, suspected Falsified Medicinal Products & Recalls

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **7.1** | All complaints, returns, suspected falsified medicinal products and recalls are recorded and handled carefully according towritten procedures. | **Y/N/NA** | |

## Section No: 7 Complaints, Returns, suspected Falsified Medicinal Products & Recalls contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **7.2** | Records of all complaints, returns, suspected falsified medicinal products and recalls are kept and can be made available to the MHRA on request. | **Y/N/NA** | |
| **7.3** | Complaints are recorded with all the original details and are acted on appropriatelyand thoroughly investigated to identify the origin of or reason for the complaint. | **Y/N/NA** | |
| **7.4** | A person is appointed to handle complaints and allocated sufficient support to achieve the task. | **Y/N/NA** | |
| **7.5** | If necessary, appropriate follow-up actions (including CAPA) are taken after the investigation and evaluation of the complaint, including where required notification to the MHRA. This is covered by the complaints procedure. | **Y/N/NA** | |
| **7.6** | Non-defective returns (including from wards) are separated from saleable stock in a designated quarantine area until disposal / assessment for reuse is made. | **Y/N/NA** | |
| **7.7** | Medicinal products which have left the premises of the distributor are returned to saleable stock only if all of the following are confirmed:<br>• the medicinal products are in their unopened and undamaged secondary packaging and are in good condition; have not expired and have not been recalled;<br>• medicinal products returned from a customer not holding a wholesale distribution authorisation or from pharmacies authorised to supply medicinal products to the public are only returned to saleable stock if they are returned within an acceptable time limit, for example 10 days;<br>• it has been demonstrated by the customer that the medicinal products have been transported, stored and handled in compliance with their specific storage requirements; | **Y/N/NA** | |

## Section No: 7 Complaints, Returns, suspected Falsified Medicinal Products & Recalls contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| | • they have been examined and assessed by a sufficiently trained and competent person authorised to do so;<br>• the distributor has reasonable evidence that the product was supplied to that customer (via copies of the original delivery note or by referencing invoice numbers, etc.) and the batch number for products is known, and that there is no reason to believe that the product has been falsified. | | |
| **7.8** | 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. Evidence should cover:<br>• delivery to customer;<br>• examination of the product;<br>• opening of the transport packaging;<br>• return of the product to the packaging;<br>• collection and return to the distributor;<br>• return to the distribution site refrigerator. | **Y/N/NA** | |
| **7.9** | Products returned to saleable stock are placed such that the 'first expired first out' system operates effectively. | **Y/N/NA** | |
| **7.10** | Medicines that have been returned by patients are never returned to saleable stock. | **Y/N/NA** | |
| **7.11** | Counterfeit medicines found in the distribution network are clearly segregated and labelled. | **Y/N/NA** | |
| **7.12** | The procedure for counterfeit medicines states that the holder of the Product Licence for the genuine product and the MHRA are informed immediately. | **Y/N/NA** | |
| **7.13** | Comprehensive records pertaining to any counterfeit medicines found are kept. | **Y/N/NA** | |

## Section No: 7 Complaints, Returns, suspected Falsified Medicinal Products & Recalls contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **7.14** | There is a valid SOP in place to cover recalls and the quarantine of recalled products | **Y/N/NA** | |
| **7.15** | Recall operations are capable of being initiated promptly and at any time. | **Y/N/NA** | |
| **7.16** | The distributor always follows the instructions of a recall message, which has been approved by the MHRA. Records of recalls are readily available if requested by the MHRA | **Y/N/NA** | |
| **7.17** | Records (including reconciliation of recalled stock) are made at the time any recall operation is carried out. | **Y/N/NA** | |
| **7.18** | The distribution records are readily accessible to the person(s) responsible for the recall and contain sufficient information on distributors and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batch numbers at least for medicinal products bearing safety features as required by legislation and quantities delivered) to allow the effective recall of a given batch of medicine. | **Y/N/NA** | |
| **7.19** | The effectiveness of the arrangements for product recall are evaluated regularly (at least annually). | **Y/N/NA** | |

## Section No: 8 Outsourced Activities

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **8.1** | Any activity covered by the GDP guide that is outsourced is clearly defined, agreed and controlled in order to avoid actions or oversights which could affect the integrity of the product. | **Y/N/NA** | |
| **8.2** | There is a written contract or service level agreement between the contract giver and the contract acceptor which clearly establishes the duties of each party. | **Y/N/NA** | |

## Section No: 9 Self Inspection

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **9.1** | There is an internal audit programme and reports are available for all audits/self-inspections, showing agreed corrective actions and timetable for completion. | **Y/N/NA** | |
| **9.2** | Internal self-inspection has taken place within the last 2 years. | **Y/N/NA** | |
| **9.3** | Corrective actions are undertaken in a timely manner, or reasons for non-compliance are stated. | **Y/N/NA** | |
| **9.4** | Reports of audits/self- inspections are issued to the Pharmacy Manager and Responsible Person. | **Y/N/NA** | |
| **9.5** | There is planned external audit of any third party undertaking outsourced activities and audit reports are available. | **Y/N/NA** | |

## Section No: 10 Transportation

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **10.1** | A procedure is in place for investigating and handling temperature excursions during transportation. | **Y/N/NA** | |
| **10.2** | There are written procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions. | **Y/N/NA** | |
| **10.3** | Documented risk assessment of delivery routes are used to determine whether temperature controls are required. | **Y/N/NA** | |
| **10.4** | Equipment used for temperature monitoring during transport within vehicles and/or containers is maintained and calibrated at regular intervals at least once a year. | **Y/N/NA** | |
| **10.5** | Dedicated vehicles and equipment are used, where possible, when handling medicinal products | **Y/N/NA** | |
| **10.6** | Where non- dedicated vehicles and equipment are used, procedures are in place to ensure that the quality of the medicinal product will not be compromised. | **Y/N/NA** | |

## Section No: 10 Transportation contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **10.7** | Deliveries are made to the address stated on the delivery note and into the care or the premises of the consignee. Medicinal products are never left on alternative premises. | **Y/N/NA** | |
| **10.8** | For emergency deliveries outside normal business hours, specific persons are designated and written procedures are available. | **Y/N/NA** | |
| **10.9** | Containers bear labels providing sufficient information on handling and storage requirements and precautions to ensure that the products are properly handled and secured at all times. The container labels enable identification of the contents of the containers and the source | **Y/N/NA** | |
| **10.10** | In relation to deliveries containing controlled drugs the wholesale distributor maintains a safe and secure supply chain for these products in accordance with requirements laid down by the Home Office. | **Y/N/NA** | |
| **10.11** | There is a procedure to address the occurrence of any theft during delivery. | **Y/N/NA** | |
| **10.12** | Medicinal products comprising highly active and radioactive materials are transported in safe, dedicated and secure containers and vehicles. The relevant safety measures are in accordance with the requirements of the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations SI 2009 No.1348 (CDG2009) as they affect the transport of radioactive materials by road. | **Y/N/NA** | |
| **10.13** | For temperature-sensitive products, qualified equipment (e.g. thermal packaging, temperature-controlled containers or temperature-controlled vehicles) is used to ensure correct transport conditions are maintained between the wholesale distributor and customer. | **Y/N/NA** | |

## Section No: 10 Transportation contd…

| No | Acceptance Criteria | Audit Result | Comments/Actions to be Taken |
|---|---|---|---|
| **10.14** | If temperature-controlled vehicles are used, the temperature monitoring equipment used during transport is maintained and calibrated at regular intervals and temperature mapping under representative conditions is carried out and takes into account seasonal variations | **Y/N/NA** | |
| **10.15** | If requested, customers can be provided with information to demonstrate that products have complied with the temperature storage conditions. | **Y/N/NA** | |
| **10.16** | If cool-packs are used in insulated boxes, they are located such that the product does not come in direct contact with the cool-pack. | **Y/N/NA** | |
| **10.17** | Staff members are trained on the procedures for assembly of the insulated boxes and on the reuse of cool-packs. | **Y/N/NA** | |
| **10.18** | There is a system in place to control the re-use of cool- packs to ensure that incompletely cooled packs are not used in error. | **Y/N/NA** | |
| **10.19** | There is adequate physical segregation between frozen and chilled cool packs if both types are used. | **Y/N/NA** | |
| **10.20** | The process for packing and delivery of temperature sensitive products is described in a written procedure. | **Y/N/NA** | |
| **10.21** | If an external courier is used, medicines are stored at any transport hubs for less than 24 hours. Any sites where medicines are cross-shipped from one vehicle to another are audited. | **Y/N/NA** | |

## References

1: Guidelines on Good Distribution Practice of medicinal products for human use. 5 November 2013
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF

2: UK Guidance on Wholesale Distribution Practice. Rules and guidance for Pharmaceutical Manufacturers and Distributors 2014. Pharmaceutical Press, London. 2014. Pages 513 – 538.

3: Responsible Person – Gold Standard role profile (MHRA)
http://www.thegold-standard.co.uk/job-details/?jobid=297

| Document History | Issue date and reason for change |
|---|---|
| Version 1 | Issued August 2014 |
| Version 2 | |
| Version 3 | |
| Version 4 | |