Table 9 Transportation Standards

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| 9.1 Principle: |
| 9.1.1 It is the responsibility of the supplying wholesale dealer to protect medicinal products against breakage, adulteration, theft, and to ensure that temperature conditions are maintained within acceptable limits during transport. |
| 9.1.2 Regardless of the mode of transport, it should be possible to demonstrate that the medicines have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilised when planning transportation. |
| 9.2 Transportation: |
| 9.2.1 The required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the outer packaging and relevant packaging information. |
| 9.2.2 If a deviation such as temperature excursion or product damage has occurred during transportation, this should be reported to the wholesale dealers and recipient of the affected medicinal products. A procedure should also be in place for investigating and handling temperature excursions. |
| 9.2.3 Wholesale dealer should ensure that vehicles and equipment used to distribute, store or handle medicinal products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and packaging integrity. |
| 9.2.4 There should be written procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions. |
| 9.2.5 Risk assessment of delivery routes should be used to determine where temperature controls are required. Equipment used for temperature monitoring during transport within vehicles and containers, should be maintained and calibrated at regular intervals. |
| 9.2.6 Dedicated vehicles and equipment should be used, where possible, when handling medicinal products. Where non-dedicated vehicles and equipment are used procedures should be in place to ensure that the quality and integrity of the medicinal product will not be compromised. |
| 9.2.7 Deliveries should be made to the address stated on the delivery note and into the care or the premises of the consignee. Medicinal products should not be left on alternative premises. |
| 9.2.8 For emergency deliveries outside normal business hours, persons should be designated and written procedures should be available. |
| 9.2.9 Where transportation is performed by a third party, the contract in place |

should encompass the requirements of Table 7. Transportation providers should be made aware by the wholesale dealer of the relevant transport conditions applicable to the consignment. Where the transportation route includes unloading and reloading or transit storage at a transportation hub, particular attention should be paid to temperature monitoring, cleanliness and the security of any intermediate storage facilities.

9.2.10 Provision should be made to minimise the duration of temporary storage while awaiting the next stage of the transportation route.

9.3 Containers, packaging and labelling:

9.3.1 Medicinal products should be transported in containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.

9.3.2 Selection of a container and packaging should be based on the storage and transportation requirements of the medicinal products; the space required for the amount of medicines; the anticipated external temperature extremes; the estimated maximum time for transportation including transit storage at customs; the qualification status of the packaging and the validation status of the shipping containers.

9.3.3 Containers should 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 containers should enable identification of the contents of the containers and the source.

9.4 Products requiring controlled Conditions:

9.4.1 In relation to deliveries containing medicinal products requiring special conditions (e.g. controlled drugs), the wholesale dealer should maintain a safe and secure supply chain for these products in accordance with requirements laid down in national legislation. There should be additional control systems in place for delivery of these products. There should be a protocol to address the occurrence of any theft.

9.4.2 Medicinal products comprising highly active and radioactive materials should be transported in safe, dedicated and secure containers and vehicles. The relevant safety measures should be in accordance with international agreements and national legislation.

9.4.3 For temperature-sensitive medicinal products, qualified equipment (e.g. thermal packaging, temperature-controlled containers or temperature controlled vehicles) should be used to ensure correct transport conditions are maintained between the manufacturer, wholesale dealer and customer.

9.4.4 If temperature-controlled vehicles are used, the temperature monitoring

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| | equipment used during transport should be maintained and calibrated at regular intervals. Temperature mapping under representative conditions should be carried out and should take into account seasonal variations. |
| 9.4.5 | If requested, customers should be provided with information to demonstrate that medicinal products have complied with the temperature storage conditions. |
| 9.4.6 | If cool packs are used in insulated boxes, they need to be located such that the medicinal product does not come in direct contact with the cool pack. Staff must be trained on the procedures for assembly of the insulated boxes (seasonal configurations) and on the reuse of cool packs. |
| 9.4.7 | There should be a system in place to control the reuse of cool packs to ensure that incompletely cooled packs are not used in error. There should be adequate physical segregation between frozen and chilled ice packs. |
| 9.4.8 | The process for delivery of sensitive medicinal products and control of seasonal temperature variations should be described in a written procedure. |