NATO STANDARD

AMedP-1.20

MILITARY GOOD DISTRIBUTION PRACTICE FOR MEDICAL MATERIEL

Edition A, version 1

FEBRUARY 2022

NORTH ATLANTIC TREATY ORGANIZATION

ALLIED MEDICAL PUBLICATION

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NATO STANDARDIZATION OFFICE (NSO)

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NORTH ATLANTIC TREATY ORGANIZATION (NATO)

NATO STANDARDIZATION OFFICE (NSO)

NATO LETTER OF PROMULGATION

25 February 2022

1. The enclosed Allied Medical Publication AMedP-1.20, Edition A, version 1, MILITARY GOOD DISTRIBUTION PRACTICE FOR MEDICAL MATERIEL, which has been approved by the nations in the MILITARY COMMITTEE MEDICAL STANDARDIZATION BOARD, is promulgated herewith. The agreement of nations to use this publication is recorded in STANAG 6534.

2. AMedP-1.20, Edition A, version 1, is effective upon receipt.

3. This NATO standardization document is issued by NATO. In case of reproduction, NATO is to be acknowledged. NATO does not charge any fee for its standardization documents at any stage, which are not intended to be sold. They can be retrieved from the NATO Standardization Document Database (https://nso.nato.int/nso/) or through your national standardization authorities.

4. This publication shall be handled in accordance with C-M(2002)60.

Dimitrios SIGOULAKIS
Major General, GRC (A)
Director, NATO Standardization Office

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RECORD OF RESERVATIONS

CHAPTER	RECORD OF RESERVATION BY NATIONS
Note: The reservations listed on this page include only those that were recorded at time of promulgation and may not be complete. Refer to the NATO Standardization Document Database for the complete list of existing reservations.	

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RECORD OF SPECIFIC RESERVATIONS

[nation]	[detail of reservation]
BEL	In Annexe A , paragraph A.1.3 d. on Fresh Frozen Plasma (FFP), BEL wil consider a temperature range ≤ -25°C (instead of ≤ -30°C).
DEU	1. Due to defined responsibilities in the organizational structure of the Bundeswehr, the tasks of the Responsible Person or the consignor cannot be completely performed by one person. In order to ensure a comparable result, the distribution of tasks along the supply chains is transparently presented, delineated or defined in directives, regulations and orders, and responsibilities are transferred/delimited as necessary within the framework of the nationally applicable regulations. 2. In addition to the requirements of this STANAG, the supply with unlicensed drugs, or drugs from local purchase is only permitted in individual cases after approval by the responsible authority in DEU. 3. Temperature specifications for the transport and storage of blood and blood products for German forces must comply with German medical guidelines. As a result, German medical guidelines slightly differ from the STANAG's temperature specifications.
FRA	Most of the requirements will be applied when allowed by the operational context and depending on the deployed health system. In France’s case, the responsible person is a pharmacist whose absence in a theatre is exceptional.
GBR	where the operational situation permits UK should be meeting the requirements of the STANAG. However, on operations, some of the more stringent requirements may not be possible.
Note: The reservations listed on this page include only those that were recorded at time of promulgation and may not be complete. Refer to the NATO Standardization Document Database for the complete list of existing reservations.	

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CHAPTER 1 INTRODUCTION

1.1. GENERAL

1.1.1 Good Distribution Practice (GDP).

1. Distribution is an important activity in the integrated supply-chain management of medical logistics. Those responsible for the handling, storage and distribution of pharmaceutical and medical products varies between Nations. In some cases, a person or entity is only involved in, and responsible for, certain elements of the distribution process. WHO defines GDP as "*That part* of quality assurance that ensures that the quality of pharmaceutical product is maintained by means of adequate control of *the numerous activities* which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded products"[1].

2. For the purpose of this publication, GDP means the processes that ensure that the quality and integrity of medical materiel is maintained throughout all stages of the military supply chain from the site of manufacture to the person authorised to supply the pharmaceutical to the patient. This includes preventing falsified medicines from entering the military supply chains.

3. Further guidance on the medical logistics system can be found in AJP-4.10(C) (Allied Joint Doctrine for Medical Support) Section 6[2].

1.1.2 Humanitarian or Peace Keeping Operations

Although the military are not categorized as humanitarian actors, they are often involved in large-scale humanitarian operations, usually in a logistics capacity. Usually the military logistics assets will support a logistics cluster. Coordination between civilian and military actors is essential during an emergency response. Therefore, it is important to identify who is coordinating the cluster in order to avoid duplication of effort or conflict of interests.

1.1.3 Storage Areas

1. Medical logistics will normally be accomplished by means of purpose-built storage areas, the formal appointment of a GDP Responsible Person (RP)[3] and the employment of specialised or trained staff. Within the JTF headquarters (HQ) and/or JLSG HQ, responsible staff will ensure that the correct supply procedures are

[1]WHO https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf January 2019
[2]AJP 4.10(C) Allied Joint Doctrine for Medical Support Section 6 Para 2.57
[3] Requirements of a Responsible Person is at Annex B

followed including: accounting of stocks; visibility of available assets to support operations; maintenance of safety; quality and efficacy of medical supplies, to ensure effective medical support.

2. This publication applies to pharmaceuticals but can be applied to all medical materiel used in support of medical care that requires environment control or specialist storage and handling. Examples include:

- medical consumables
- diagnostic agents
- Surgical and medical instruments; devices and appliances
- imaging and other diagnostic tools
- laboratory requirements
- rehabilitation equipment
- clinical training equipment

3. It lays down appropriate tools to assist all those involved in the supply, distribution and storage of pharmaceuticals in conducting their activities; to reduce unnecessary wastage; and to prevent falsified medicines from entering the military operational supply chain.

1.2. AIM

The aim of this publication is to:

a. Ensure GDP principles are applied in the military environment;

b. Establish a standardised approach to ensure interoperability on operations;

c. Reassure Commands that the adherence of GDP principles is applied throughout the military supply chain.

1.3. AGREEMENT

Participating nations agree:

a. To comply with the principles within this document;

b. To notify other member nations participating in mutual medical support when unable to meet the requirements prescribed herein.

1.4. SCOPE OF THE DOCUMENT

1. This document lays down guidelines for the distribution of medical materiel. Compliance with this publication will ensure control of the distribution chain and consequently maintain the quality and the integrity of products.

2. The core document will focus on the requirements for managing pharmaceutical products within the Joint Logistics Chain and will include procurement, storage, supply, movement, contractor support, disposal and donations.

3. The document does not specifically cover standard operating instructions which are to be developed, mission specific and within the guiding principles of this document.

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CHAPTER 2 GENERAL PRINCIPLES

2.1. RESPONSIBILITY

1. All parties involved in the distribution of medical materiel have a responsibility to ensure that the quality of pharmaceutical products and the integrity of the supply chain is maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient[4].

2. The principles of GDP should be included in national legislation and guidelines for the distribution of medical supplies, in a country or region as applicable, as a means of establishing minimum standards.

3. The principles of GDP are applicable both to pharmaceuticals moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing medical materiel to the patient and to products which are moving backwards in the chain, for example, as a result of a return or recall.

4. All entities involved in the distribution process should apply due diligence with adherence to the principles of GDP, for example, in procedures relating to traceability and in recognition of security risks. It is recommended that there is a nominated individual to assure GDP in line with the roles of an RP at Annex B.

2.2. QUALITY MANAGEMENT

2.2.1 Principles

Personnel involved in the storage and distribution of pharmaceuticals should maintain a quality management system that sets out roles and responsibilities, procedures and risk management principle to ensure that patients receive safe and effective medicines in a timely manner.

2.2.2 Documentation

Good quality documentation is the foundation of a quality system and provides the basis for detailed instructions and record keeping. Documents in paper and/or in electronic form should be readily available to improve recording and reducing error. All documentation should be version controlled and regularly reviewed and approved by an appropriate person and should be retained for a minimum of 5 years. As a minimum, the following should be maintained:

[4] WHO Good Distribution Practice- TRS957-Annex5

- Standard Operating Procedures (SOPs)
- Description of the interrelationships of all personnel involved in the distribution.
- Written job descriptions to define responsibilities under GDP
- Evidence of products meeting specifications
- Batch records
- Customs requirements and supporting licences
- Dangerous Goods Declarations.
- Import/Export Licences normally issued by Ministry of Health or National Drug Regulatory/Competent Authority.
- Temperature records to demonstrate that products have been stored appropriately.
- Controlled Drug licences. In addition to import and export, there may be specific requirements for controlled substances.

2.2.3 Deviations

A deviation reporting system should be established to evaluate the impact of any incidents or process that departs from defined process. Deviations should be documented in real time and investigated fully. A Corrective and Preventative Action (CAPA) plan should accompany any deviation.

2.2.4 Complaints

Complaints may relate to the quality of the pharmaceutical or the distribution system. A system to report complaints for both circumstances will ensure appropriate and prompt action is taken. Product related complaints should be referred to the Marketing Authorisation Holder. Complaints about the distribution will be investigated and corrective and preventative action taken by the responsible unit.

2.2.5 Self Inspection and Audit

1. A well-planned self inspection programme can identify areas of weakness and improve performance. Identifying areas for inspection should be risk based.

2. Audits from third parties (from allied countries or allied organizations) should be expected and encouraged to identify areas of weakness and improvement.

2.2.6 Risk Management

Quality Risk Management provides an opportunity to understand potential risks in the supply chain and put measures in to reduce those risks. The Risk SOP should cover the 4 ICH Q9 elements of Assessment, Reduction & Control, Communication and Review. All risks should be raised with the Chain of Command.

2.2.7 Suspected Falsified Medicines

Falsified medicines present a significant risk to the health of the deployed force. Ensuring that falsified medicines are let away from the legitimate supply chain is critical. All personnel should be vigilant, helping to identify any falsified medicines and preventing them from reaching patients. Therefore, there should be a system to risk assess procurement from legitimate sources, transportation routes, customer checks and training of personnel.

2.3. PERSONNEL

2.3.1 Personnel and Training

1. All personnel involved in distribution activities should be trained and qualified in the requirements of GDP, as applicable. Training should be based on the written standard operating procedures (SOPs) and appropriate job descriptions.

2. Key personnel involved in the distribution of medical supply, pharmaceutical products and Dangerous Goods, should have the ability and experience appropriate to their responsibility for ensuring that supplies are distributed properly. There should be an adequate number of competent personnel involved in all stages of the distribution of pharmaceutical products in order to ensure that the quality of the product is maintained. National regulations relating to the qualifications and experience of personnel should be adhered to.

2.3.2 Accountability

All parties involved in the management of medical supply have a responsibility to ensure that the quality of medical products and the integrity of the distribution chain are maintained throughout the distribution process. When deployed under the NATO construct, the NATO commander has overall responsibility for the strategic and operational management of deployed Healthcare, which complies with all legal and GDP requirements. However, it is the responsibility of the Chain of Command to ensure that appropriate SOPs, guidance and training are in place to cover all activities relating to medical logistics undertaken within their own Area of Responsibility (AOR). It is accepted that not all of the standards can be met on operations and exercises, but every effort must be made to manage medical supply as safely as possible, as far as is reasonably practicable, in line with this policy and WHO guidance[5].

[5] WHO Good Distribution Practice- TRS957-Annex5

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CHAPTER 3 PROCUREMENT

3.1. CENTRAL PROCUREMENT

3.1.1 Procurement

Procurement covers the activities through which pharmaceuticals are acquired for, or on behalf of, NATO. It is essential that there is an auditable trail for all materiel from their ordering and receipt to their distribution or disposal.

3.1.2 Licensing

All pharmaceuticals for use within NATO must be sourced from approved suppliers and be appropriate and legitimate for their intended use. Routinely these must have Marketing Authorisations from the appropriate national licensing bodies.

3.1.3 Unlicensed medicines

Where the supply of a medicine with Marketing Authorisation has been interrupted because of a manufacturing or supply problem, or there is not one available for a specific therapeutic use, NATO commanders must seek authority to use an unlicensed or specials manufactured product. The use of unlicensed medicines is not to be routine practice unless required for operational use and is only approved after a risk assessment by the National Authority which is to be formally documented.

3.1.4 Local Purchase (LP)

LP for medical supplies is only to be considered if a reputable source of the product is used, where the quality of the product can be assured, and bona fide checks can be undertaken. LP is only to be used when routine source of supply is unavailable or there is an unacceptable delay to patients' treatment. Advice should be sought from the designated RP or pharmacy professional. Package leaflet must be written or translated into an official NATO language. Potential local suppliers should be identified as soon as possible (ideally by Medical Intelligence during the operational planning process). Caution should be taken for not depleting the local resources when local purchases are made in order to supply the deployed forces.

3.2. CONTRACTED SUPPLIERS

3.2.1 Supplier Qualification

The same NATO publications must be applied by any third party contracted on behalf of member states. The contract should define the responsibility of each party including observance of the principles of GDP. There should be appropriate supplier checks undertaken supported by a written process and records of these checks.

CHAPTER 4 STORAGE

4.1. PREMISES AND LOGISTIC HUBS

4.1.1 Geneva Convention and Additional Protocols

Medical units (military or civilian) are protected by the Geneva Convention and the Protocols. This may include medical supply nodes, their building, or fixed and mobile units, as long as they are appropriately marked and comply with the provision of the Conventions and Protocol.

4.1.2 Security

Access to medical materiel must be restricted to authorised personnel only. The practitioner or logistic personnel in charge is responsible at all times for the safekeeping and secure storage of medical materiel in their service and ensuring that all medicines are stored according to national legislation and local policy. Particular attention is to be paid to the security of Controlled Substances and Dangerous Goods.

4.1.3 General Storage

Unless otherwise stated in product literature and labels, most medical products can be stored under conditions of controlled ambient temperature without compromise to their stability and recommended shelf-life. ‘Controlled’ ambient temperature implies a degree of control over the temperature of the storage environment, to avoid extremes of hot and cold temperature.

4.1.4 Medicine Storage and Management

1. Appropriate storage conditions are to be maintained at all times for pharmaceuticals, where possible, to reduce the risks associated with incorrect stock usage, adulteration, contamination, counterfeit and reduced efficacy. Contamination by other products is to be avoided. There should be:

   a. Appropriate turnover of stock
   b. Safe and secure storage areas.
   c. System(s) to enable faulty products to be rapidly found and recalled.

2. Good warehousing and distribution practices require that all pharmaceuticals are stored and transported under conditions which ensure that their efficacy and quality is maintained as described by the manufacturer or on the outer packaging. The control of environmental conditions is therefore critical and applies not only to products that need to be stored and distributed at low temperatures but also those that need to be stored at ambient temperature. Compliance with manufacturers’ recommendations concerning storage temperatures may require the use of specialised storage and

transportation. Breaches of temperature control may render the product unsafe; if there is any doubt about the integrity of the product, advice must be sought from the designated RP or pharmacy professional.

3. General cleanliness and pest control must also be undertaken to protect the integrity and efficacy of products.

4.1.5 Temperature Sensitivity

There is to be the ability to store at the various temperature ranges in accordance with the direction on the individual packaging. Further details on Temperature Controlled Storage and Assurance of medical materiel can be found at Annex A. A monitoring system is also to be employed to monitor the temperatures to ensure they stay in range and maintain the quality of the product.

4.1.6 Humidity Sensitivity

Some products will be affected by high humidity. Ideally, the storage area needs to be less than 60% humidity to protect the products from moisture. This can be achieved by adding ventilation and circulating fresh air, guaranteeing that packaging is appropriate and sealed, and preferably installing air conditioners and dehumidifiers if appropriate in temporary locations.

4.1.7 Light Sensitivity

Some products will be affected by light. Therefore, products should be stored in their original packaging and kept out of direct sunlight.

4.1.8 Deployed Operational Units

Where units are deployed into temporary accommodation or under canvas it may not be possible or economically feasible to meet the storage requirements detailed in National legislation. Fixed storage facilities that meet the requirements of regulations are to be obtained as soon as reasonably feasible following the occupation of any long-term accommodation. Where there is any doubt regarding the security of medical materiel, especially Controlled Substances, units are to approach the appropriate security advisor (e.g. military police) or the designated RP or pharmacy professional for advice on appropriate security measures.

CHAPTER 5 OPERATIONS

5.1. GENERAL

Medical supply must be properly managed throughout the supply chain in accordance with national regulations. The loss or damage of medicines or medical equipment carries inherent risk to both operational capability and those requiring medical care. For this reason, it is essential that risk-management measures related to these items, as advised by the designated RP or pharmacy professional are integrated into logistic sustainment planning.

5.2. SPECIAL CONDITIONS

5.2.1 Tracking

Additional measures for the tracking and accounting of Controlled Substances must be implemented in accordance with national regulations.

5.2.2 Customer Qualification

All potential customers should be authorised and checked that they are entitled to receive pharmaceuticals. This maintains a reliable chain of custody to the patient and reduces the risk of products being misdirected or used inappropriately.

5.2.3 Receipt

Accurate and diligent receipting of pharmaceuticals is important to provide assurance that the supplier is authorised, the product is the right product against an accurate demand, the product has not been damaged and has been stored correctly.

5.2.4 Picking

The picking and checking process determines what and how much product is sent to the receiving unit. This will prevent complaints and delays to medicines being supplied to patients.

5.2.5 Supply

This process is essential to ensure that the right product is delivered to the right location within a designated time period in the right condition. The mode of transportation has to be balanced with the need for maintaining quality.

5.2.6 Import and Export

Consideration has to be given to what international (including UN) and national restrictions and regulations are in place to import and also export the pharmaceuticals. This includes controlled substances and narcotics. These regulations cover:

a. Types of medical items allowed to be imported, restricted, or banned from being imported

b. Packaging requirements

c. Labeling requirements

d. Restrictions on quantities allowed to be imported

e. Documentation required (e.g. import licenses)

5.2.7 Handling

1. Safe and effective handling of pharmaceuticals improves efficiency but also protects the transporting unit. How this is managed depends on a number of factors:

a. Size, shape, and weight of the products/packaging

b. Value

c. Specific security requirements

d. Fragility

e. Dangerous Cargo

f. Speed of deterioration

2. Therefore, for pharmaceuticals, it is important to protect the product as best as possible by training staff to manually handle or use mechanical handling correctly and protect the packaging. Handling should be kept to a minimum.

5.2.8 Packaging

Outer packaging and transportation should be selected on the basis of their ability to maintain the required storage conditions for all the products.

5.2.9 Breaches of storage

There must be a system to report, assess and fix incidents where storage conditions are outside of the licensed parameters or where there has been damage or theft.

5.2.10 Hygiene and Pest Control

Appropriate procedures relating to personnel and environment hygiene, relevant to the activities being carried out, should be established and observed. Such procedures should cover health, hygiene and clothing. Rest, wash and refreshment rooms for personnel should be adequately separated from the storage and transportation areas. There should be active pest control in any storage areas where pharmaceuticals are held.

5.3. PRODUCT RECALL

1. All complaints, returns, suspected falsified medicinal products and recalls must be recorded and handled carefully according to written procedures. An assessment of returned medicinal products should be performed before any approval for redistribution. The effectiveness of the arrangements for product recall should be evaluated regularly (at least annually).

2. Recall operations should be capable of being initiated promptly and at any time. Any recall operation should be recorded at the time it is carried out. Records should be made readily available. The distribution records should be readily accessible to the person(s) responsible for the recall. The progress of the recall process should be recorded for a final report.

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CHAPTER 6 EQUIPMENT MAINTENANCE

6.1. GENERAL

There is equipment used to support the medical logistics function e.g. refrigerators and chillers. Equipment may be fragile and vulnerable to shock and environmental changes such as extremes in temperature and humidity. Certain equipment may require specialist storage and handling. This must be conducted in accordance with manufacturers' instructions to ensure the items are fit for purpose on receipt by the medical treatment facility

6.2. CALIBRATION AND REPAIR

All equipment that impacts on product quality is to be identified, listed with dates of servicing and calibration required to maintain accurate conditions. If there is a need for servicing repair and calibration facilities these must be of a suitable standard. This may require bespoke infrastructure and equipment; advice should be sought from equipment specialists.

6.3. QUALIFICATION AND VALIDATION

All equipment impacting on storage and distribution of pharmaceuticals should be designed, located and maintained to a standard which suits its intended purpose. Planned maintenance should be in place for key equipment vital to the operation. Suitable equipment and procedures should be in place to check the environment where pharmaceuticals are stored. An initial temperature mapping exercise should ideally be carried out on any storage area before use, under representative conditions.

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CHAPTER 7 TRANSPORTATION

7.1. MOVEMENT OF MEDICAL MATERIEL

The effective movement of medical supplies is dependent on maintaining the quality of the supplies during transportation by avoiding potential deterioration caused by temperature, humidity, light, moisture or contamination; or adulteration or theft from poor security. The control of the environmental conditions during both storage and distribution is therefore critical. Products must be consistently stored, transported and handled as required by the Marketing Authorisation or product specification.

7.2. RISK ASSESSMENT

7.2.1 Planning

It is a requirement that during operational planning (including during recce) the whole Supply Chain, and the proposed transport lanes (how are the products planned to be transported to the Medical Treatment Facility (MTF) in the theatre, including eventual risk mitigation measures), needs to be analysed and described as a risk assessment. This risk assessment must be available for the designated RP to identify high risk areas of the supply chain. If during the operation a new lane is required ("conduite de la bataile'), then this must be registered as a deviation in the Quality Management System (QMS) and risk assessed by the RP (or his/her representatives) using the available Transportation Modes guidance

7.2.2 Supply Chain

It is important to know the detail of the supply chain i.e. distances, routes, modes of transport, timelines, conditions, anticipated delays (eg customs) in order to risk assess properly and know when there are potential issues so they can be mitigated. A formal movement plan must be established that maintains the quality and integrity of medical materiel during transport; this may require suitable transit facilities or infrastructure.

7.3. SPECIAL CONSIDERATIONS

7.3.1 Mode Suitability

1. The consignor must understand the extent of the transport modes proposed to move the medical supplies. The length of journey and the climatic conditions likely to be experienced may make some modes of transport unsuitable for the transport of pharmaceuticals or may require the utilisation of specialist equipment to ensure that consignments reach the destination in a serviceable condition. Nevertheless, the most appropriate mode of transport commensurate with the supply priority is to be selected

in order to move pharmaceuticals economically. An assessment must be made to use one or more modes of transport – it might be possible to use the same one for all commodities or a decision may have to be made to separate pharmaceuticals from other commodities eg food and fuel. If the same transport is used then it is essential to ensure that pharmaceuticals are packaged separately, segregated and clearly marked as such to protect them.

2. The following should be used as a guide when deciding what mode of transport to use:

a. Assessment of speed of delivery against maintaining quality. This might also include an assessment of shelf life.

b. The best mode to reduce damage. Some medical products are susceptible to damage and must be protected; this includes packaging and sterile products.

c. The legal requirements for each product. A good example is dangerous goods.

d. Minimising impact to those products that are sensitive to temperature, humidity, light, mechanical shocks, and vibration

e. Valuable and attractive items: Ensuring that security is as important as maintaining quality.

3. For international transport lanes or for long supply chains, Air is often the best solution as this will reduce the time the product has to be stored in the correct environment. However, there are some restrictions eg filled oxygen cylinders. If the supply lane is shorter, the requirement is small and there is a regular turnaround then road or rail may be better. The speed, security condition, and frequency of the transport will determine what is used. Sea transport is not a favoured option unless temperature conditions can be maintained and assured.

7.3.2 Transport Regulations

All movement must be done in line with international and national regulations (e.g. International Air Transport Association (IATA) regulations and regulations for controlled drugs).

7.3.3 Vehicles

Dedicated vehicles should be used where possible and if not, procedures must be in place to guarantee the integrity of the product throughout transportation, to ensure that the quality of pharmaceutical product is maintained. It must be clear where responsibilities lie with the maintenance of vehicles and equipment. It is also important

to maintain the cleanliness of vehicles and equipment. Regular cleaning and maintenance are essential.

7.4. SPECIFIC REQUIREMENTS FOR PHARMACEUTICALS

7.4.1 Environmental Control

1. Transportation includes the delivery of medical materiel from a wholesaler but also the transfer of medicines between NATO military sites (e.g. between clinics, MTFs and an outside location). It is essential that the environmental control (as per licensed storage conditions) is maintained throughout all of the transportation of medical materiel, to retain their integrity. A temperature monitoring device should be included to provide assurance that temperatures during transportation have been in accordance with manufacturers' instructions. Items requiring refrigerated storage, such as vaccines, should be transported in separate containers (e.g. validated cool bags/boxes) to maintain environmental control. For Dangerous Goods (that potentially pose a hazard), reference must be made to legislation, relevant data sheets and a risk assessment undertaken. Where practicable, all medical materiel should be transported in a securely sealed or tamper evident container.

2. The best ways to maintain temperature and environmental conditions is to use one of the following:

a. Insulated containers that do not rely on power and can be reconditioned in between legs of the supply lane by trained personnel.

b. Refrigerated or heated vehicles, considering any power requirements that may be necessary to maintain the required temperature range.

c. Temperature monitoring systems. This can be vial monitors, cold chain monitor cards, freeze indicators, thermometers or data loggers. But a system that has been calibrated and maintained is required.

7.4.2 Receipt

1. Staff in receipt of pharmaceuticals must check that the temperature control requirements have been met during transit, and that the items are unpacked, checked and placed **immediately** in the dedicated medicines refrigerator/storage area. The integrity of the packaging should also be checked. Controlled Substances must be correctly documented and transferred to secure storage as soon as feasible. Any discrepancies must be reported to the supplier immediately and/or Chain of Command if necessary. Specialist advice must be sought from the designated RP if there have been any breaches of cold chain, security or packaging that might affect the integrity of the product.

2. Documented evidence should be kept – this can be achieved by temperature loggers in the shipments and vehicles and preferably by prior qualification of the supply lane. This has to account for seasonal variations ie in Summer and Winter. The storage conditions should be clearly stated on all documentation including shipping containers.

7.4.3 Transportation of Products That Require Controlled or Ambient Temperature

If transit times for bulk temperature-controlled goods are prolonged, ambient or refrigerated transport is to be considered. Small volume deliveries with short transit times should be adequately protected by specialist packaging. Specialised staff will be able to advise on appropriate packaging and packing; care should be taken that products, especially those denatured by freezing, are prevented from coming in to direct contact with ice packs at sub-zero temperatures. Where freight is used, each consignment should be monitored. It is key to note that the length of journey must be assessed along with any power requirements, and the ability to recondition/replace the storage media.

7.4.4 Security in Transit Between Units Outside the Military Supply Chain

1. All medical materiel must be kept secure during transit and have adequate security to prevent theft and minimise the risk of falsified medicines entering the supply chain. Additional measures may be required for the transport of Controlled Substances, expensive products or where there is a shortage. The consignor is responsible for determining the most cost-effective mechanism, based on the volume of the consignment and the potentials for the diversion of the contents. Measures that may be employed included personal carriage or the use of courier or other secure delivery services. Wherever possible, duplicate consignment notes must be forwarded separately to the receiving unit. Operational consignments are to be packaged and marked in accordance with any relevant STANAGs.

2. When planning transportation, the security of the vehicle, the driver and the route is critical. It is advised to:

a. Consider where the vehicles are parked and protecting entry to the vehicle (eg parking in secure car park and against a wall)

b. Using varied routes and on main well-lit and secure roads.

c. Having an escort or as part of a larger convoy

d. Tracking the vehicle eg GPS

e. Using alarms and immobilisers

f. Not leaving vehicles unattended

g. Rigid vehicles

h. Wrapping pallets and tight sheeting over open vehicles

i. Seals on doors to show tamper evidence

j. Careful selection and training of drivers with identification

k. Traceable tags on the products

l. Tracking of controlled substances in line with country regulations

7.4.5 Safety

Often roads are of lower standards and this contributes to a higher risk of accidents. Some products present a fire or hazardous risk. To reduce the impact of accidents then the following advice should be followed:

a. Reduce the risk of spillage/damage to dangerous cargo by securing and packing it appropriately.

b. Training personnel in safe handling and dangerous cargo

c. Minimise handling of products

d. Ensure that storage protects the product by ensuring handling of the product is safe and appropriate, the products are stored correctly on shelves or pallets and movement is kept to a minimum.

7.5. CONSIGNMENT TRACKING (CT)

1 All medical supplies consigned for transportation from one defence or defence-sponsored organization to another is to be tracked from as close to the point of origin to as close to the point of use. Measures should be in place to ensure that medical products have documentation that can be used to allow traceability of the products throughout distribution channels from the manufacturer/importer to the entity responsible for selling of supplying the product to the patient.

2. Regulations must foster a safe, transparent and secure distribution system which includes product traceability throughout the supply chain. This is a shared responsibility among the parties involved. There should be procedures in place to ensure document traceability of products received and distributed, to facilitate product recall.

7.6. PRODUCTS REQUIRING SPECIALIST CONSIDERATION

7.6.1 Dangerous Goods

Medical supplies may contain items meeting any of the criteria for Dangerous Goods (DG), particularly flammable liquids, flammable solids, oxidizers, organic peroxides, toxic or corrosive substances and must be handled accordingly.

7.6.2 Controlled Substances

All medical materiel requires appropriate handling to prevent misuse. Some pharmaceuticals, due to their potential for abuse, are subject to additional storage, record-keeping, prescribing controls and audit activities above those which may be imposed by their legal status. Controlled substances must be handled in accordance with national regulations

7.6.3 Blood and Blood Components

Specific storage and transport standards must be applied to blood and blood products. Blood components are only to be transported in a controlled manner in containers certified for that purpose; transport requirements are described in Annex A. Any delay to blood or blood products whilst in transit must be reported immediately to the nominated blood supply specialist.

7.6.4 Medical Gases

Physically medical gases are similar to other non-medical gases and should be stored and transported in accordance with national guidelines; however, they are prescribed for a patient by a doctor and have to meet the specification detailed in the appropriate US or European Pharmacopoeia. Only these approved medical gases are to be used for medical purposes. Where practicable, storage of all gases on operations / exercises shall be as for non-operational storage. Those elements that cannot be achieved without compromising operational effectiveness may instead be risk assessed.

CHAPTER 8 RETURNS AND DISPOSAL

8.1. GENERAL

Those responsible for the disposal of medicines and medical equipment should understand and must comply with the requirements of the relevant national and international regulations governing the disposal of products. Processes must be established to ensure that items are disposed of safely and securely; they must not re-enter military or civilian supply chains.

8.2. RETURNS

1. Management of returned products is as important as managing supply. A risk-based assessment will facilitate decision making regarding whether to return products back into the supply chain. If there is no evidence of appropriate storage conditions, then the manufacture should be consulted for advice on stability and shelf life. The origin of the returned product should be clearly identified (via copies of the original delivery documents, via the identification of the batch number, via the source of the returned products) and the integrity of the secondary packaging should be controlled (asking, “are the safety features still unaltered?”)

2. Returned products should be:

   a. Stored in separate, segregated areas at the labelled storage conditions until a clear assessment and decision has been made on disposition

   b. Returned within an agreed and acceptable time limit

   c. Returned to the supply chain only once the designated RP or pharmacy professional has agreed.

8.3. PHARMACEUTICAL WASTE

1. This includes expired, damaged, unused, spilt, and contaminated pharmaceutical products that are no longer required and need to be disposed of appropriately.

2. Basic standards for disposal ensure that the risk of harm to individuals and the environment is minimized. Certain products require more stringent disposal processes to meet health and safety or legislative requirements e.g. cytotoxic agents, medical gases and Controlled Substances. This may require specific infrastructure that meets minimum standards (e.g. incinerators). Specific advice can be found in the manufacturers’ product information leaflets and from medical specialist advisers.

8.4. DONATIONS

1. There are several scenarios where the donation of medicines may be considered in an operational environment. This may range from donations to individual healthcare workers up to supporting national healthcare systems. Regardless of the situation a few core principles must be applied:

2. Donations may only be made in accordance with the mission mandate. There must be a formal donation policy that meets national and international regulatory and administrative requirements of both donor and recipient.

3. Donations must be restricted to healthcare workers or recognised medical treatment facilities. They must be given with due respect for the wishes and authority of the recipient.

4. Only medicines that have been procured, stored, and transported in accordance with GDP principles may be donated. The recipient must provide explicit consent to receive medicines with less than twelve months expiry.

5. There must be an auditable record of all donations made and the ability to recall the product if necessary. Further guidance can be found in the WHO Publication “Guidelines for Medical Donations”.

6. Donations must not disturb the local supply chain. Caution should be taken in case donations of pharmaceuticals used in the treatment of chronical diseases for example: the local supply chain should be able to guarantee the treatment’s continuity afterwards

ANNEX A TEMPERATURE CONTROLLED STORAGE, TRANSPORT AND ASSURANCE

A.1. GENERAL

A significant proportion of medical products (mainly, but not exclusively medicines) require controlled storage and transit conditions. Whilst the risk varies, a number of products are at as great a risk from freezing as they are from excessive temperature and may be denatured or become physically unstable, even if stored for a brief period outside the required temperature.

A.1.1 Controlled Ambient Products (15-25°C) [6]

Ambient chain products are those that need to be stored below **25°C** or occasionally 30°C at a controlled room temperature. These products are usually labelled 'Do not store above 25°C' (or for some products 'Do not store above 30°C'). 'Room temperature' and 'temperate' are not acceptable terminologies for labelled storage recommendations.

A.1.2 Cold Chain Products

a. **Cool Storage (8°C to 15°C)[1].** A small number of pharmaceuticals are labelled 'Store in a cool place' or 'Store between 8°C and 15°C'. In the absence of a facility operating within this temperature range the goods should be stored between 2ºC and 8ºC, provided that storage below 8ºC does not affect their physical stability.

b. **Cold Storage (2ºC to 8ºC)[1].** Products that require cold storage are labelled 'Store between 2°C and 8°C' or 'Store in a refrigerator'. Where the volume of these products is low, a lockable pharmaceutical refrigerator should be used for pharmaceuticals requiring storage at this temperature. The use of a domestic refrigerator for this purpose should be the exception (Domestic refrigerators are not sufficient for high risk products; items placed next to the chiller plate / coil or products packed without adequate circulation are at risk of being exposed to temperatures that fall outside the recommended temperature range). Refrigerators should be sited in an environment where the ambient temperature does not affect the temperature control within the unit. Most refrigerators will function efficiently in an external environment of between 10°C to 32°C. Large volume operations will require a walk-in cold storage facility.

c. **Freeze (below -5ºC) and Deep Freeze (often below -20ºC but no lower limit) [1].** A small number of products must be stored frozen (eg some blood

[6] WHO definition: https://apps.who.int/medicinedocs/en/d/Js4885e/6.5.html#Js4885e.6.5

and biotechnology products). For example, these will be labelled ‘Store below -5ºC’ (freeze) or ‘Store below -20ºC’ (deep freeze) or they may show a range (eg 15ºC to -20ºC). Storage units must be capable of maintaining the required temperature in all parts of the load.

A.1.3 Blood and Blood Components

Specific storage and transport standards must be applied to blood and blood products. Blood components are only to be transported in a controlled manner in containers certified for that purpose; blood and blood products are listed below along with their transportation requirements:

a. **Red Cell Concentrate** (RCC). Temperature range 2°C – 6°C.

b. **Whole Blood Products.** Temperature range 2°C – 6°C.

c. **Human Platelets** (Plt). Temperature range 20°C – 24°C.

d. **Fresh Frozen Plasma** (FFP). Temperature range ≤ -30°C.

e. **Cryoprecipitate** (Cryo). Temperature range ≤ -30°C.

f. **Deep frozen Blood Products** (deep frozen erythrocytes (DEC), -80°C deep frozen thrombocytes (DTC) and -80°C deep frozen plasma (DFP)). Temperature range -65°C – -90°C.

A.2. ASSURANCE

Temperature monitoring devices are essential in demonstrating compliance with the required temperature ranges and in providing assurance that the quality and stability of medical supplies have not been adversely affected. These instructions should be read in conjunction with existing guidance produced by National regulatory bodies.

A.2.1 Temperature Checking On Receipt.

Temperature controlled items are to be removed to a controlled environment as soon as possible after receipt and always within two hours. Stores personnel are to ensure that the supplies have not been subjected to adverse conditions during transit by sight of a printout from a data logger or monitoring device placed in the load by the consignor.

A.2.2 Temperature Monitoring (Including Ambient Products)

a. **Temperate Chain Products.** Permanent or semi-permanent warehouses should be temperature mapped to determine the temperature distribution

under extremes of external temperature. Temperature mapping will highlight areas unsuitable for storage because of eg sun-facing windows. Mapping should be repeated based on risk or after any significant modification to the premises, stock layout, or heating system. The minimum requirement is for a max / min thermometer to be placed at a strategic location and read, recorded and reset daily. During periods of exceptionally hot or cold weather / climates the frequency of monitoring should be increased. Self-contained storage areas within warehouses, (Controlled Drugs Store / Flammables Store) should be included in temperature monitoring programmes.

b. **Cold Storage.** For low volume refrigerators, temperature monitoring should be by electronic max / min thermometer, with an accuracy of + 0.5°C, which should be readable from outside the refrigerator. The probe should be placed within the load (or within a suitable buffer) to record the load rather than the air temperature, and the max / min temperatures should be recorded daily (in hot climates, the temperature should be monitored more frequently). The device should be calibrated annually against a certificated thermometer. The unit should have an auto-defrost facility and the temperature within the unit should not be affected during the defrost cycle. A power failure alarm should be fitted.

c. **Large Refrigerators.** Large refrigerators (in excess of 6 m^3) and walk-in cold rooms should be fitted with a suitable electronic temperature-recording device which measures load temperature(s). The chart, print-out or direct reading should be checked daily and the examination recorded, either in a logbook, or by annotation of the chart / print-out if appropriate. The recording device should continue to function for 48 hours in the event of a power failure; the facility should be fitted with a power-failure alarm. Temperature mapping is to be repeated if significant changes take place, such as the repair or replacement of the refrigeration unit or changes to the internal storage layout. A calibrated max / min thermometer should be placed inside the unit for use as a back-up in case of failure of the electronic monitoring system and to confirm the temperature indicated on the recorder. Recording probes should preferably be independent of controlling probes. The low temperature alarm must trigger before the temperature drops below +1°C.

d. **Freezers.** Freezers are usually only required for blood or biological products which will often be the responsibility of the Pathology Laboratory. Storage units must be capable of maintaining the required temperature in all parts of the load and load temperatures are to be monitored and recorded daily.

A.2.3 Temperature Monitoring Records

Temperature monitoring records for each storage area are to be maintained and are to include the date / time, max and min temperatures, action taken if outside the range,

the initials of the individual who has recorded the temperature and confirmation that the recording device has been reset. Records are to be retained for 5 years.

A.2.4 Temperature Monitoring in Mobile Environments

The requirement to monitor and record temperatures extends beyond static storage facilities to personnel and vehicle-borne modules which contain temperature sensitive items; appropriate temperature monitoring devices should be made available to facilitate this. Temperature monitoring and recording not only provides confirmation that temperature sensitive items remain fit for use, but also provides the evidence to support requirements to enhance capability if temperature control is an issue.

A.2.5 Calibration of Measuring Devices

Manual and electronic measuring and recording devices which are used in critical areas (e.g. temperature monitoring of storage and transport facilities for high-risk cold-chain goods) are to be calibrated at least annually against a traceable reference device. Records are to include pre- and post-calibration readings and details of any adjustments made or corrections to be applied. Alarms should be checked for correct functioning at the designated set points.

A.2.6 Actions on temperature control failure

1. If Medical Materiel with a Shelf Life (MMSL) is not stored between the recommended temperatures of the drug's Marketing Authorisation, the manufacturer may disclaim responsibility for any apparent failure and render the medicine an unlicensed product. It is therefore recommended that any product knowingly stored outside of their recommended temperatures should not be used unless its stability, and any changes to subsequent storage requirements and shelf life has been verified by the manufacturer. Advice should be sought from the Responsible Person (RP) or pharmacist to verify future use[7].

2. On failure of a power unit, air conditioning unit or refrigerator, an investigation should take place, noting timeframes, temperatures and the reasons for exposure. A refrigerator is not to be opened, except for emergencies or to move stock into another refrigerator until this investigation has occurred. Affected stock is to be quarantined. Medicines are to be marked with the date of exposure and reduced expiry date where it shortens the manufacturers printed product expiry date.

3. The RP, or their representative, is to be informed and an assessment is to be made on the risk versus benefits of retaining the materiel.

[7] Definition of Responsible Person at Annex B

ANNEX B REQUIREMENTS FOR DESIGNATED RESPONSIBLE PERSON

B.1. GENERAL

1. The appointment of a “Responsible Person” (RP) is a legal requirement in many NATO countries for wholesale dealing, who has overall responsibility for the activities conducted under license and has the authority to bind the license holder. Licenses will not be required on NATO operations, but the principles of GDP should be applied in accordance with this STANAG. Therefore, each Nation that contributes to Medical Logistics must designate an individual to act as the Good Distribution Practice (GDP) Responsible Person (RP).

2. The designated RP must have sufficient knowledge of the provisions of the relevant legislation and regulations relating to GDP. The designated RP should meet the qualifications, and all conditions provided for by the legislation of that Nation. A degree in pharmacy is desirable. The designated RP must have appropriate competence and experience as well as knowledge of, and training in, GDP.

3. The designated RP must fulfil their responsibilities personally and should be contactable at all times. The RP may delegate duties to ‘qualified medical supply / medical logistical staff’ but not responsibilities. These delegated duties must be clearly stipulated in the written job description of the ‘qualified medical supply /medical logistical staff’. The written job description of the designated RP must define their authority to take decisions with regard to their responsibilities. The Nations should give them the defined authority, resources and responsibility needed to fulfil their duties. The designated RP must carry out their duties in such a way as to ensure that compliance with GDP is maintained at all times.

4. The responsibilities of the designated RP include:

   a. Ensuring that a quality management system is implemented and maintained;

   b. Focusing on the management of authorized activities and the accuracy and quality of records;

   c. Ensuring that initial and continuous training programmes are implemented and maintained;

   d. Co-ordinating and promptly performing any recall operations for medicinal products;

   e. Ensuring that relevant customer complaints are dealt with effectively;

f. Ensuring that suppliers and customers are approved;

g. Approving any subcontracted activities which may impact on GDP;

h. Ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place;

i. Keeping appropriate records of any delegated duties;

j. Deciding on the final disposition of returned, rejected, recalled or falsified products.

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