



# Carefully to Carry

## Pharmaceuticals in temperature controlled containers

### Introduction

The world of pharmaceuticals continues to develop with new and improved products launched after expensive research and clinical trials.

Many different pharmaceuticals are supplied worldwide, and some require temperature controlled storage and distribution to maintain their efficacy and other properties.

Until fairly recently, long distance distribution of products needed without delay has been undertaken by air. In recent years, however, there has been a trend to move some of these products by sea in refrigerated containers. Clearly, products must have sufficient storage lives for the complete chain, and the carrier needs the required expertise and level of diligence to ensure successful outcomes.

The carriage of pharmaceuticals and intermediaries is already established on many trade routes with different transit times. Two examples are the increasing use of Ventolin (an aid to breathing) carried at chilled temperatures, and blood products moved as frozen cargoes.

Some cargoes can give significant cold chain challenges if they are temperature sensitive or have a very high value. When both the sensitivity and high values of a pharmaceutical shipment combine, a careful and systematic approach to the planning and carriage must be undertaken.

### Dangerous cargoes

Some materials are hazardous and must be declared as dangerous under the International Maritime Organization (IMO) rules. These cargoes require a trained person to assess documents including Material Safety Data Sheets (MSDS). European Union regulations require the services of a qualified dangerous goods safety adviser (DGSA) to be used by relevant distribution companies outside the shipping industry. Shippers are required to declare and label classified products correctly as they know the properties of the materials and packaging.

International and national regulations change frequently, so continuous monitoring is needed on amendments to requirements. The UN Globally Harmonised System of Classification and Labelling of Chemicals, (GHS), will become the standard in the future.

### Product attributes and challenges

Pharmaceutical product attributes have to be preserved, through the cold chain, to give the consignee the outturn expected after loading good quality product into the container. It is extremely helpful if shippers can explain the physical,



“The carrier shall properly and carefully load, handle, stow, carry, keep, care for and discharge the goods carried.”

Hague Rules,  
Articles iii, Rule 2

### Carefully to Carry Advisory Committee

This report was produced by the Carefully to Carry Committee – the UK P&I Club’s advisory committee on cargo matters. The aim of the Carefully to Carry Committee is to reduce claims through contemporaneous advice to the Club’s Members through the most efficient means available.

The committee was established in 1961 and has produced many articles on cargoes that cause claims and other cargo related issues such as hold washing, cargo securing, and ventilation.

The quality of advice given has established Carefully to Carry as a key source of guidance for shipowners and ships’ officers. In addition, the articles have frequently been the source of expertise in negotiations over the settlement of claims and have also been relied on in court hearings.

In 2002 all articles were revised and published in book form as well as on disk. All articles are also available to Members on the Club website. Visit the Carefully to Carry section in the Loss Prevention area of the Club website [www.ukpandi.com](http://www.ukpandi.com) for more information, or contact the Loss Prevention Department.

chemical and biological attributes of sensitive products being carried. Products must have adequate storage lives for the transit and the next distribution chain to the patient or user.

Carriers want to transport pharmaceuticals to maintain the quality factors that meet the customers' expectations. Temperature control and times 'off refrigeration' should be clearly specified and well controlled.

In the event of problems or claims of loss concerning products whose characteristics are unknown, or not fully known, carriers/shipping lines should contact their P&I club who is able to identify experts to provide assistance.

## Carriage challenges

For the successful carriage of pharmaceutical materials on long sea routes carriers should ensure that:

- Cold chain requirements are met using equipment that operates correctly.
- Procedures, information flows, and operations are compatible and co-ordinated.
- Due diligence actions for quality systems and security requirements are defined.
- Careful work by trained personnel provides good quality control and assurance.

Most people employed in reefer container shipping will only see, or be prescribed, a relatively small number of pharmaceuticals in their lifetimes. There is less knowledge of their needs than when moving large amounts of food on well-established routes. It may be helpful to consider the features of an equivalent class of food product in transit.

A big difference is that many pharmaceuticals have a very much higher value than the equivalent volume of food products. They are also regulated by national or state medicines agencies that have several similar roles to foods standards agencies.

The United States has a joint organisation called the Food and Drug Administration (FDA). The FDA announced a 'strategic action plan' in August 2003 entitled *Protecting and Advancing America's Health - Responding to new challenges and opportunities*. This includes the objective of seeking "continuous improvements in patient safety by reducing risks associated with FDA-regulated products." The result is that distributing pharmaceuticals presents management, commercial and operational issues that may need to be reviewed and updated on a continuous basis.

## Management issues

Carriers should define the extent to which they are prepared to carry cargoes of certain materials on different routes, as they can differ significantly in sensitivity, monetary values and the levels of control that are possible.

It is suggested that risk analyses should be carried out before new/high value materials, shippers, and routes are routinely accepted. Pre-transit assessments of the requirements should be made including discussions with

the shippers (and consignees if necessary). Accepted cargoes should initially transit as trial shipments, with reviews after outturns. One approach, is to limit risks by only accepting 20ft container loads of particular products until the transits have been established.

Corrective actions can be taken, if necessary, for further shipments and in extreme circumstances bookings possibly be refused.

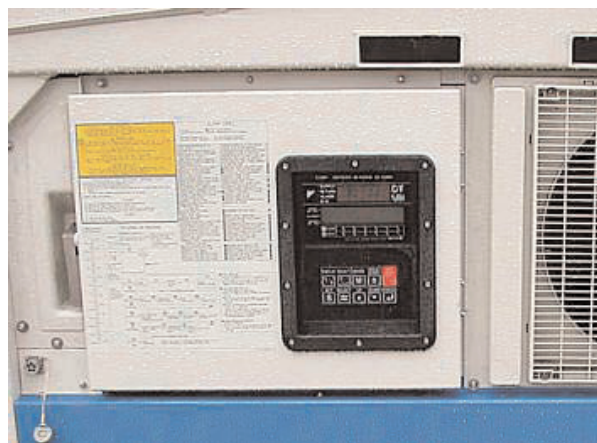
## Commercial issues

Additional insurance premiums may be payable, depending on the risk limits and previous experience in carrying similar products. Special rates may be necessary to cover the additional work in carrying the cargoes successfully and the extra precautions taken against the risks of loss. Careful wording on bills of lading is also required.

## Operational issues

Shippers define the 'set point temperatures' the cargoes require. Other carriage requirements must also be agreed with the carriers when the containers are booked. There may be a need for additional instructions and checks in transit, depending on product sensitivities and the routes. Clearance by the appropriate authorities in importing countries may be specified, as well as meeting consignees due diligence standards.

Shippers may include their own independent data-loggers in the cargo space to measure product or air temperatures. A few logger types are able to calculate 'mean kinetic temperatures' (a defined form of weighted average), whilst others have been developed to record shocks and vibrations. Relative humidity is measurable, but the accuracy of the data must be considered carefully and large variations allowed.



Temperature/data recorder

Security of cargoes has always been important, but the global terrorism threat has increased the precautions as many countries have imposed more requirements. The United States, the largest pharmaceutical market, has imposed significant regulations.

Shippers have to be aware that shipping lines must submit cargo manifests for all ships destined for the United States 24 hours before cargo loading begins at each origin port.

This is linked to the US Container Safety Initiative, Customs - Trade Partnership Against Terrorism (C-TPAT) requirements. The aim is to monitor and inspect any high-risk cargo before it is loaded at the port of origin to prevent undesirable cargo reaching a US port.

Secure sealing of containers is important, with bolt seals becoming more refined. Although nearly anonymous, except for their owners names and identification numbers, reefers may follow the trend set for some road haulage trailers to have tamper alarms.



*Types of container seals*

The technology for remote monitoring of land transits by satellite is available in some countries. (Mobile telephone technology is another possible approach to allow information to be transmitted.) There is not yet an international agreement of radio frequencies for monitoring reefer containers world-wide. Practical issues (especially with containers located underdeck) are evident at sea. Controlled experiments in remote real time monitoring of several transits of very sensitive fruit cargoes on deck have been successful.

## Processes, procedures and risk analysis

### Processes

Manufacturers of pharmaceuticals have standard operating procedures (SOPs) for the production, packaging, storage and distribution of products. There are also specified retention times for records. Individual producers may decide to establish that their quality control requirements are achieved throughout the cold chain as part of the delivery process to patients.

### Procedures

There is a need for diligence as "the carrier shall properly and carefully load, handle, stow, carry, keep, care for, and discharge the goods carried".

An increasing duty of care is placed upon carriers by developing legislation in product and human safety, with cargo security gaining in importance. Better distribution control supports due diligence, which needs the efficient management of all functions. It also allows for continuous improvement as an evolving process. None of this is possible without clear procedures and communications. It is helpful to consider planned transits of pharmaceuticals to ensure that procedures and instructions include:

- Definitions of the responsibilities of all parties.
- Checks that communication links are established and working.

- Shippers and consignees requirements confirmed and communicated.
- Carriage requirements and standards agreed.
- Container availability and suitability determined.
- Land and sea movements defined.
- Container monitoring and times off-power rules established.
- Repair protocols agreed including availability of spare parts, oils and refrigerants.
- Staff trained for the appropriate functions.
- Feedback to shippers if problems reported en-route.
- Nominated person to co-ordinate, resolve issues and inform all concerned.

The above are common to many types of reefer container shipments but the requirements of particular pharmaceuticals and cold chains differ.

### Risk analysis

It is suggested that the previous points are considered when carrying out a risk analysis. The following is an outline that could be adapted and extended to include relevant details:

- Flowchart the transit from container booking until the return of the empty container after tipping.
- Look at each step to identify possible temperature control issues and security hazards. Evaluate the risk factors based on previous knowledge, local information obtained from enquiries, or earlier transits of other products.
- If possible, consider the causes of past reefer claims and incidents, affecting comparable products or routes, as they can be valuable sources of information.
- Identify the risks that are key (or critical) to the temperature management and security of the cargo.
- Define and introduce control measures to reduce the risks or eliminate the issues and hazards. They could involve a variety of actions such as training people, issuing special instructions, changes in timings or additional monitoring checks that also include container sealing.
- Define limits such as acceptable maximum times off-power during the transit.
- Ensure that a practical monitoring plan is in place, including any need to download container memory units to provide additional due diligence records.
- Check instructions available to staff and contractors on managing equipment faults.
- Identify responsibilities for supplying spare parts, oils and refrigerants for containers on the designated vessels, which can vary in accordance with the customs of the trade.
- Determine times when repairs cannot be effected, such as during road transport or at inland locations. Issue instructions that minimise the risks of cargo damage.
- Review staff knowledge to plan and offer additional training.
- Verify that insurance cover is in force, or obtainable, and any restrictions imposed.

If time permits, check data from containers that have transited the route, preferably onboard the vessels expected to carry pharmaceuticals. Advanced knowledge of the routes is an advantage so that points of control may be identified.

As a post delivery audit verify the initial analysis by:

- Reviewing records from data-loggers until routes or new products established.
- Following up with occasional checks that may include feedback from shippers and consignees.

Consider the use of carrier-supplied independent temperature recording data-loggers, or USDA probes in the cargo spaces of sample containers to measure the carriage conditions.

## Container challenges

Pharmaceuticals should be carried in integral containers with good refrigeration capacity, high internal airflow rates and an ability to provide the required temperature control. Following the stuffing of the cargoes into containers, they require the capability to deal with the heat loads to which they may be subjected.

Both ashore and afloat containers are supplied with temperature-controlled air, driven around the containers by the equipment's evaporator fans operating on the vessels' electrical system. This has a frequency of 50Hz ashore and 60Hz aboard vessels. Fans run 20% faster thereby increasing the potential air flow rate. Warm cargo must never be shipped for cooling onboard. All cargo must be pre-cooled to its temperature for carriage prior to stowing in a container.



Typical sockets that connect reefer containers to the ship's power supply

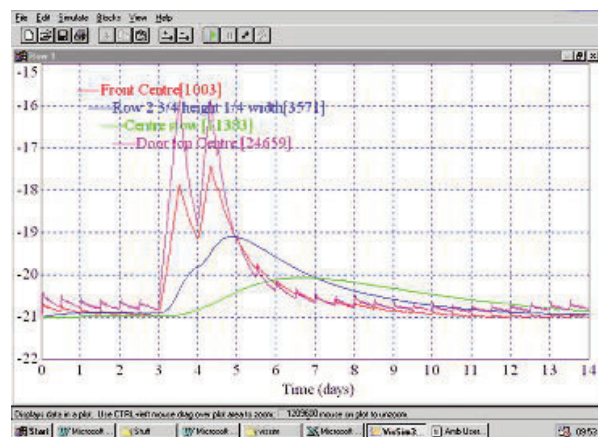
## Transit temperature simulation and off-power times

Shippers and consignees should know that cargoes are not carried at a single product temperature. They should be aware of the temperature gradients that can be expected through the cargoes within the containers. These depend on ambient temperatures, airflows inside the containers, air temperatures and flows outside the containers plus

their thermal efficiencies. Temperature gradients inside the cargo volume vary in different sizes of containers operating at different set points. They are also greatly influenced by the way the cargo is stowed.

Temperature gradients in normal operation and the effects of problems of temperature control can be modelled in advance. The bulk density of pharmaceutical materials vary, as do their thermal masses. It is helpful to know in advance if cargoes have low densities and are relatively more susceptible to air temperature fluctuations and times off-power.

The software CRT Censor (ref 1) has been developed so that it can be used to estimate cargo temperature changes during normal operations. It is useful to be able to simulate the effects of times off-power on cargo temperatures, and the times required to recover stability.



Typical sockets that connect reefer containers to the ship's power supply

The effects on products' mean kinetic temperatures (a form of weighted average temperature that can be linked to product storage life) can be calculated. An experienced party who knows the acceptable limits for the cargo will be able to express an opinion.

Shippers and consignees, who check temperature records, must be aware that containers set at temperatures causing evaporators to operate at 0°C or colder normally defrost automatically. This is to remove any build up of ice formed from condensed water vapour carried in the air returning from the containers. The evaporator fans stop until defrosts are complete.

## Temperature set points

Pharmaceuticals are often transported in reefer containers, in nominated temperature zones. The shipper should understand that, in the chilled mode, the control point is the supply air sensor. The return air temperature at the return air sensor is the control point in the frozen mode. It is important that customers understand that cargo temperatures are not controlled directly by the refrigeration system.

Carriers are contracted to supply temperature controlled air to containers to meet shippers' (bill of lading) requirements and do not directly control product temperatures. The following are not exclusive but are given as a guide:

- **Chilled** - many require an environment in the +2°C to +8°C range. These products must not freeze or become too warm in transit so that their potency, release potential, colloidal suspension or other properties are affected. They vary in their sensitivity, but the most sensitive could be considered somewhat similar to chilled meat for carriage. The container set point is normally in the above range and +4°C or +5°C are often used.
- **Frozen** - temperatures colder than minus 18°C are specified for some products. They are often sensitive to temperature fluctuations as well as needing a cold base temperature. A temperature set point of minus 25°C for containers is often requested. Serious thawing can often be observed by eye, but changes in protein structure, or other changes, through invisible temperature fluctuations require laboratory assessment.

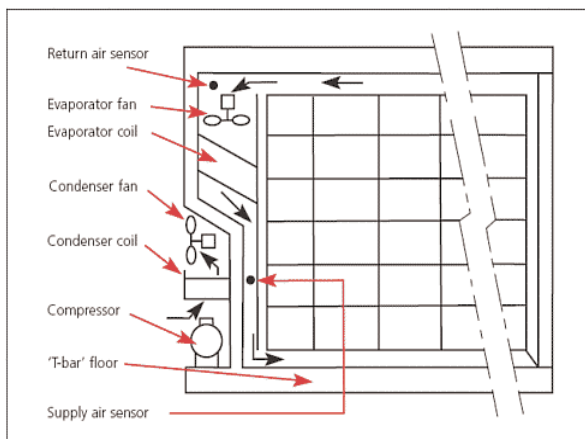
For example, frozen blood products could be compared to carrying a product with the combined properties of ice cream and individually quick frozen (IQF) prawns. Temperature fluctuations in ice cream can cause texture changes whilst prawns can incur protein denaturation and weld together. Both can generate ice crystals. Similarly blood products can suffer protein damage and separation if not stored correctly.

- **Cool** - temperatures colder than +15°C or even +25°C. They are relatively 'shelf stable' provided they do not become too warm. Examples are powders, liquids and tablets. An equivalent food product is chocolate confectionery (usually carried with a set point of +10°C).

Shippers' set points - The shipper may specify individual container set points outside the above general ranges to meet a product requirement. If the carrier is uncertain as to shipper's requests, independent expert advice should be sought.

## Containers in the chilled mode

It is important that the supply air sensor is accurately calibrated, to control the temperature of the air entering the container at the set point. If the set point is sufficiently cold to require the evaporator to be at a temperature of 0°C or colder then automatic defrosting occurs at intervals (see next section below). Evaporator fans run at high speed whilst containers are on power, except when they are defrosting.



Container airflow

Under ambient conditions, warmer than the set point, the air circulating around the container absorbs heat conducted through the insulation. The return air temperature will be slightly warmer at the return air sensor.

## Containers in the frozen mode

The return air sensor, in the centre of the air stream returning to the refrigeration system, controls the temperature of the air. This is the set point temperature and the sensor requires accurate calibration. The set point temperature is usually applied at the return air sensor for temperatures colder than minus 10°C.

Air entering the container will normally be slightly colder than the air returning to the refrigeration system as it absorbs heat entering the cargo space through the insulation. This allows the product to be maintained in the required frozen state.

Controller software usually regulates the speed of the fans, between high/low/and off depending upon the heat load on the container, and the instructions in the controller's software.

## Data logger temperature probes

If the container has secondary probes for recording supply and return air temperatures then they must also be correctly calibrated, as the data they supply is important as discussed earlier. (Some container manufacturers can also use these probes as backups for control should the primary sensors fail.)

## Relative humidity (RH)

The shipper may request relatively dry air circulated in the containers. Many modern containers are fitted with a dehumidifier, so can offer a value-added service to reduce the relative humidity (RH). The RH is measured and controlled by a probe in the refrigeration unit. It does not represent the actual RH throughout the cargo space, which is difficult to measure accurately, and a tolerance of at least +/-5% over the available range should be expected.

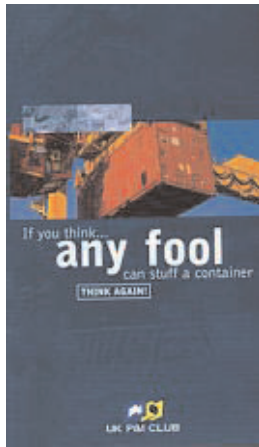
## Fresh air ventilation

Fresh air ventilation is not expected for chilled pharmaceutical cargoes, but the need should be checked before bookings are accepted. Ventilation volumes should be kept as low as is essential. This is to ensure that better temperature control is maintained (with evaporator coil defrosting kept to a minimum).

## Outer packaging

Good quality packaging is necessary to protect products from damage and possible contamination. It must be capable of being stacked to the maximum height allowed (approximately 2.5 metres) in a hi-cube integral container, which is generally taller than in land-based palletised operations.

Carton designs are key factors to protect products, allow uniform stacking in the containers without crushing, and maximise the cube that can be occupied. The cost of outer packaging can be significant and environmental concerns are increasing, as are the costs of the disposal of waste packaging.



Shippers need to ensure that their packaging has been tested to ensure it is suitable for transit by sea in a refrigerated container. A containership can roll heavily during a voyage and shifting of cargo is a cause of damage, which can also obstruct the container airflow and affect temperature control. The UK P&I Club video entitled Any fool can stuff a container illustrates what can happen at sea (ref 2). It emphasises the responsibilities and importance of correct container vanning to avoid personal injury and damage to goods on loading, door opening, and outturns.

Several countries apply restrictions on the use of untreated wood in pallets, packaging and dunnage. Shippers should check the current situation with the carrier, so that wood and other restricted materials can be treated or fumigated in advance of the shipment.

## Load-outs and container stows

Carriers should supply units that are internally clean and maintained, with the refrigeration systems pre-tripped. This does not absolve the shippers from inspecting and accepting the empty containers before they van cargoes, including test running of the refrigeration units if generators are supplied.



Load-out area with port doors

Most modern temperature-controlled final product stores have load-out areas, with port doors or temperature controlled bays (see picture above), so that the containers can back onto rubberised seals when its doors are open.

This allows the container to be pre-cooled to minimise the ingress of warm moist air during the loading operation. If delays occur when vanning containers in the open air, then the rear doors should be closed. A decision to refrigerate the container may be necessary if a long delay is expected or experienced.

Unless the load-out stores are near to the export terminals, the trailers or containers require electrical generators which can be switched on when the container doors are closed and temperature stabilisation starts.

Stowage of the product is the absolute responsibility of the shippers. Each carrier has his own rules for load-out inspections and is aware of the customs of the Trade. Carriers can advise but some caution is needed not to incur liability.

The aim is to maximise the occupancy of the internal container cube below the load limit line, and between the end of the T-section floor and the doors. This is to enable an uninterrupted flow of air around the cargo.

Good air circulation is achieved by stowing along the complete floor length of the container without extending beyond the end of the T-section floor.

Palletised cargo is to be loaded to minimise the airflow between the pallets and, if necessary, using suitable dunnage placed in any void spaces. The rear pallets may be braced to prevent them falling onto the doors. If only a few pallets are carried in the containers then they should be braced to prevent movement that could damage the inside of the units.

## Initial temperatures

The export stores must maintain records of product temperatures, measured just before vanning the containers. Product and packaging temperatures must have been allowed to stabilise before load-out starts. Modern containers are not designed to freeze or chill cargoes but to maintain temperatures. Shippers are responsible to ensure control of the final freezing or chilling processes.

The need is to present products, in good quality dry packaging (on dry pallets if used) at the required carriage temperature, to the containers. (Uncoated fibreboard can absorb moisture vapour.) Some shippers may request containers that are pre-cooled so it is relevant to know the likely loadout conditions before agreeing. Cooling below the dew point can allow condensation to occur on the inside surfaces of the container and on packaging.

Water in a container, and on packaging, will evaporate during the transit and condense on the evaporator coils of the refrigeration systems. Taken to extremes, the effective refrigeration times can be noticeably reduced during the early part of a transit.

The supply and return air temperature records from container dataloggers can be checked before they leave the export terminals. Warmer than expected return air temperatures are a warning of a possible problem that should be investigated.

If containers have been working properly for sufficient time, then inadequate precooling of the cargoes should be considered. Prudent carriers should agree actions with the shippers at this point. Containers can be shipped, delayed, or returned depending on the seriousness of the problems and the risks involved



Internal cargo stowage

## Defrosting

The following points are made assuming that cargoes have been properly pre-cooled, packaging is dry and the contents of containers stowed correctly. It is not possible to define each situation.

Depending on the design of the control systems, and the algorithms in the software, defrost intervals may be adjustable (some containers may also have systems to terminate defrosts at a cooler temperature). Other containers have a 'defrost on demand' setting that may be useful for some cargoes.

It is desirable that refrigeration systems can restart and cool the evaporators to the required temperatures before the fans switch on again. This is sometimes called 'snap freezing'. Warm air in the machinery sections, following defrosts, will be minimised from being blown around the containers after defrosts. Cooled air will enter the containers, and an overall improvement in the level of temperature stability in the cargo spaces can result.

## Equivalent product comparisons and test shipments

The carriage of low, medium or high risk pharmaceuticals on established routes may present only a small number of practical questions that require solutions before bookings are accepted. Staff may be proficient in handling containers of temperature sensitive products, have a good knowledge of risks, and can take corrective actions if a problem occurs.

New products, and new or low reefer volume routes, require more careful consideration. Container requirements can be estimated by reference to the products being carried, and by comparing them with products having similar characteristics in distribution.

Products may also require container off-power times to be carefully controlled. Their efficacy may be affected, or made unusable, if they become warmer in hot ambient or overcooled in cold ambient conditions.

These reports are a useful tool for identifying any improvement needs. Examples are:

- Delays in loading and discharge of vessels or road vehicles.
- Road transport drivers switching generators off when stationary.
- Actual availability of road vehicle generators and their efficiency.
- Need for protected stows ashore and aboard vessels (see picture below).
- Monitoring reports that are at variance with logged data.
- Vessels reducing container power supplies to operate bow propellers or unavailability of propeller shaft generators.
- Terminals relocating reefers to create space, or remove lower rows of containers.



Protected stows

## Bookings

Recommendations regarding carriage instructions for refrigerated cargoes (ref 3, below) were published by the International Cold Chain Technology Group (ICCT).

They commented that the responsibility for specifying the carriage instructions for individual reefer containers is that of the shipper; the owner of the goods. Only the shipper knows the full nature of the goods and their properties. Frequently this responsibility is passed to the shipping line, but in this case the shipper should accept the specified conditions.

Items such as relative humidity and maximum time without refrigeration should not be over specified, but should meet the necessary properties of the products. This tends to lead to more, and sometimes spurious, claims involving technicalities that have not actually affected cargo quality.

## Checklist of operational cargo care requirements for pharmaceuticals

A simple cold chain is expected to contain the following eleven steps. Cold chains can often be more complicated with, for example, transshipments using feeder vessels to the export terminal or from the import terminal.

- Accepted bookings plus discussion with shippers and consignees.
- Container selections and pre-trip inspections.
- Transport to packing points carrier or merchant haulage.
- Container stowing.
- Transport to export terminals.
- Export terminals - store, monitor and load vessels.
- Store and monitor aboard vessels.
- Transfer to import terminals.
- Store and monitor at import terminals.
- Transport to outturn points.
- Outturn.

The Appendix contains checklists of points added to assist the analysis of cold chains. They include some of the ICCT advice with additional points added for pharmaceuticals. They are of necessity incomplete, as each cold chain is different.

## Putting it all together

It is the good performance of people that makes the difference in ensuring that containers of pharmaceuticals are selected, prepared, controlled, and delivered on time with cargoes at the right temperatures. Open information flows play an important role ensuring that containers move smoothly along the routes. None of this is possible without clear procedures and good communications.

Some issues and challenges have been considered for carrying pharmaceuticals. They include customers' expectations, product properties, plus quality control standards of the performance of equipment and the need to manage operations.

Meeting the requirements is necessary to ensure that cargo outturns enthuse clients. The products will then be of the quality demanded and become available for distribution to users and patients.

## References

- Software *CRT Censor* - Further information from CRT, 140 Newmarket Road, Cambridge CB5 8HE. [www.crttech.co.uk](http://www.crttech.co.uk)
- Video *Any fool can stuff a container* UK P&I Club c/o Thomas Miller & Co Ltd, London.
- International Cold Chain Technology Group (ICCT) - Recommendations regarding carriage instructions for refrigerated cargoes - Further information from ICCT, 140 Newmarket Road, Cambridge CB5 8 HE. [www.icct.org.co.uk](http://www.icct.org.co.uk)

## Appendix

Checklists for the carriage of pharmaceuticals in refrigerated container

The following points provide a guide for developing procedures and instructions. In practice each cold chain needs to be reviewed so that its variations are identified.

### Accepted bookings plus discussion with shippers and consignees

- Cargo description weight and stowage (full or part-loaded container).
- Cargo value - (also to allow a discussion of insurance if necessary).
- Cargo density and potential heat sink (high, medium or low) can be estimated.
- Sensitivity of products in the cargoes.
- Hazardous classification if designated as dangerous.
- Request for protected stow if on deck.
- Schedule times and vessels (including feeder vessels if required).
- Cut-off times for delivery of loaded containers to export terminal.
- Dehumidifier probe set point if required (%RH).
- Maximum times without refrigeration.
- Electrical generators availability if refrigeration required during land transits.
- Pre-cooling of containers if port door loading being used and generators supplied.
- Protected stows ashore, if available, in very hot or cold weather.
- To be informed if known out of specification in-transit situations occur.
- Reporting requirements - downloading container data logger to provide information of the transits for due diligence reporting.
- Availability of an audit trail to meet the cargo owners due diligence requirements.

### Container selections and pre-trip inspections

- Select containers:
  - Required sizes, in good condition suitable for foodstuffs.
  - Inbuilt data loggers to record supply and return air temperatures plus events.
  - Modems fitted for data transmission on relevant terminals and vessels.
- Inspect, repair, CSC validate and clean to food grade standards.
- Pre-trip refrigeration systems to carrier's requirements.
- Ensure thermometers used for probe calibration checks have small resolutions and are accurate with valid calibration certificates from a competent agency.
- Check vents and floor drains are closed.

- Apply customs seal to inspection plates if necessary.
- Ensure that container temperature probes are correctly calibrated and positioned.
- Test run in chilled and frozen modes to verify running correctly.
- Apply required settings to controllers including set point temperatures in °C.
- Set defrosting requirements (possible default 12hr intervals).
- Dehumidifier in percent relative humidity (%RH) if required.
- Input any additional information required into containers' controllers.
- Ensure door seals in good condition and doors/locking bars working properly.
- Store equipment until required to be sent to packing point.
- Pre-trip plus inspection reports completed and signed.

### **Transport to packing points**

- If required, drivers qualified to move relevant classes of dangerous cargoes.
- Drivers trained to carry sensitive cargoes and the operation of equipment.
- Ensure that equipment is fit for carriage and operational if generators fitted.
- Verify sufficient fuel for the generator if fitted.
- Moving collected equipment to packing points at the times specified.
- Check before loading cargoes for export.
- Pre-cool containers before vanning if instructed.
- Collect and later fit security seals with customer's staff if required.

### **Transport to export terminals and later in the chain to outturn points**

- Loaded containers kept under running refrigeration unless otherwise instructed.
- If requested, observe and record air temperatures at regular intervals.
- Drivers given instructions on actions in case of equipment problem or accident.

### **Export terminals - store, monitor and load vessels**

- Log receipt of export containers of pharmaceuticals and verify details.
- Disconnect from generators' electrical supplies.
- Demount from transport.
- Move containers to stows (protected if requested or available).
- Connect to terminal power.
- Ensure times off-power are less than the maximum limits agreed.

- Check the start up of the refrigeration equipment and that set points are correct.
- Minimise containers of sensitive pharmaceutical cargoes relocation.
- Monitor containers regularly (include power-line data transmission if available).
- Verify containers operating correctly.
- Report if air temperatures deviate.
- Disconnect from terminal's power supply.
- Load vessels with off-power times less than maximums agreed.
- Connect to vessel's electrical supplies.
- Check the start up of the refrigeration equipment and that set points are correct.

### **Stow and monitor aboard vessels**

- Availability of relevant spare parts to maintain/repair each type of container.
- Ensure that containers are checked manually at specified frequency to determine that they are operating correctly.
- If data transmission is not available, monitor manually at specified frequency. Maintain monitoring reports showing the cumulative readings for each container.
- Maintain or repair refrigeration units as required.
- After arrival at the import terminal, ensure that containers remain on power until shoreside operations ready to discharge them.

### **Import terminals - discharge, store, monitor and load transport**

- As for import terminals in reverse order plus:
- Any restows of sensitive or high value pharmaceuticals need to occur quickly or the containers must be plugged into the terminals' power supply.
- Transhipments are to be treated as units for import and export with all the relevant requirements applying.
- Ensure that inspections by customs and other authorities noted with any times off power recorded.

### **Outturns**

- Turn off refrigeration when ready to open doors.
- Remove security seals with customer's staff confirming numbers identical with those on documents.
- Outturn cargoes.
- Ensure containers leave outturn points internally clean and fully empty.
- Return empty containers to depots where data-logger downloads possible.
- Report any discrepancies.