15
WAREHOUSING, HANDLING AND DISTRIBUTION

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This chapter brings to the attention of the reader the general hazards suffered by all products and those most common to the full range of pharmaceutical packs. Methods of preventing damage in the warehousing, handling and distribution of products will be fully discussed. In addition, both internal UK packaging and packaging for export will be covered.

Products anywhere in the warehousing, handling and distribution chain are either static or in motion. This is an obvious statement, but both phases may involve 'risks' to the products. These risks can be broken down, identified and corrected by a number of contributory factors, as detailed in the following text.

Hazards in warehousing, handling and distribution

The hazards the product will be exposed to are physical (mechanical), climatic (environmental), biological, chemical, and some others. In practice the greatest risk is posed by physical or mechanical damage.

Physical or mechanical damage

Weak areas must be clearly identified and all physical forms of damage considered. Thus in addition to the effects of acceleration or deceleration (i.e. impact, drop, shock or distortion damage), compression, crush, vibration (including resonance and friction) and puncture during handling must always be checked. For example, an item can be damaged by top compression during warehousing or transit stacking, (with additional vibration effects).

It is important that the outer packaging:

1 does not collapse in warehousing or transit stacking
2 will withstand the total forces for the requisite storage and distribution time with adequate reserves in hand.

However, both these observations are dependent on other factors: e.g. type of pallet, how stacked on pallet, stacking of pallets, etc.

Impact, drop, shock, and to an extent distortion are caused generally by acceleration or deceleration of the pack itself or an object 'hitting' the pack, e.g. slips off a bench, kicked, dropped, slides about loose inside a container. Crush is the slow result of compression usually over a period of time and is covered under stacking.

Vibration is the term used where an object is oscillated back and forth in a direction at a certain speed (frequency) and by a distance (amplitude). The frequency of vibration (cycles of movement per second) will not in itself cause damage and is not really a concern except in the special case of resonance, which is the natural frequency of vibration at which a object will vibrate most freely. At the resonant frequency the amplitude increases quite dramatically and can lead to the pack/product being severely damaged.

It is very difficult to predict the resonant frequency of a pack, but a reasonable prediction of the transport frequencies that the pack is liable to meet can be made. This occurrence is not too common, but should be borne in mind if no other obvious solution to a breakage in transit problem occurs. Solutions to resonance can be:

1 cushion the goods from damage (see 'Cushioning' below)
2 isolate the vibration (use shock absorbers)
3 change the resonant frequency (alter weight or material)
4 change the driving frequency (lorry or conveyor speed etc.).

Vibration also leads to friction, causing abrasion and possible text damage. Certain surfaces (plastic, enamels, etc.) or decorated/printed items must avoid contact with abrasive materials (wood, fibreboard, paper and board, etc.) and be overwrapped in a less damaging material, e.g. PE/PP film, bags or an air cap.

Puncture is normally seen from some other external object which penetrates the pack, e.g. fork lift truck. However, sharp items may penetrate the pack from within, hence such sharp features may need some external protective cover or be restrained/contained in carefully designed packs.

Climatic (environmental) hazards

Temperature

Around the world the overall temperature can change from at least −50 to +60°C. Don't underestimate the heat and lack of heat attraction of the mode of transport, e.g. dark coloured containers can, during hot sunny days and cold clear nights, have a temperature difference of 60°C+ at their skin.

Liquid water

Relative humidity (0–100%), humidity, moisture and condensation are terms for the intrusion of moisture into the packaging system which individually or in combination with other contaminants can lead to corrosion in metals or can soften papers and boards.

Humidity is the level of water vapour in the atmosphere. It is usually defined as the relative (RH) and absolute humidity. The effect of a temperature change is that in saturated air, if the temperature drops there is precipitation of water, e.g. rain or conden sation onto exposed surfaces. Bear in mind the concept of equilibrium between atmosphere and water-absorbing products, e.g. cellulosic materials which may be considered as both moisture-absorbing and water-losing packaging.

Corrosion usually occurs on metals in the presence of water (or vapour), oxygen or acid on the product as well as the package. If the outer packaging is of cellulosic material and is wet, then the conditions for corrosion exist and the outer packaging has failed.

Radiation

The sun and artificial light, ultraviolet (UV) and infrared (IR) content of the source light can have serious effects on the printed text and identification, i.e. fading of inks, colours, etc. on the exposed surfaces of the outer packaging.

Air pressure

Either increased or decreased air pressure can create damaging forces on the pack and closure (e.g. changing altitudes).

Biological hazards

1 Microbial growth, bacteria, yeast, fungi and moulds can breed in favourable conditions, so specific precautions may have to be taken. Mould may grow on moist outer packaging.
2 Biological attack from rodents, birds, insects, termites, etc.

Chemical hazards

Seepage from nearby damaged product is obvious, but less so is contamination by stray by-products resulting from abrasion or mating surfaces (even though the primary cause is vibration).

Other hazards

Pilferages from criminal activities is not uncommon, so anti-theft devices and measures might be required as transportation has been a traditionally vulnerable point in the security system.

Hazards the product creates

Having dealt with the hazards to the product during warehousing and distribution, we now consider any hazards that the product or its packaging might hold for the community at large. At the pack design stage, the following checklist should be used.

1 Hazards of weight.
2 Hazards produced if there is a spillage.
3 Is the product toxic?
4 Is the product radioactive?
5 Is it an infectious substance?
6 Flammability of product?
7 Projections or protrusions which might catch on something.

All these questions about hazards must be asked at an early stage of the pack design so that the packaging may be designed to minimise any rejections in the storage and distribution stages.

Nature of the product

It is essential that the physical state of the product and its route of administration into the body are known, as the more facts that are known the easier it is to decide on the warehousing and distribution conditions and limitations, e.g. is the product an aqueous liquid needing to be kept cool but not frozen i.e. stored and transported between 2 and 8°C? The product itself will belong to one of the following categories:

1 solids, including tablets, capsules, powders, lozenges, suppositories, pessaries, pills, dressings and devices
2 liquids and semi-liquids, including oral liquids, emulsions, suspensions, solutions, lotions, creams, ointments, gels, aerosols and foams
3 vapours, vaporisers, propellants and gases, e.g. O_2, CO_2.

The routes of administration must also be taken into account in the assessment of firstly how to package the product and secondly how to protect it from all the hazards mentioned earlier. There might be special cases in compound packs where the fragility of an administration device has to be considered, as well as the risk to the product. These administration routes affect the overall design of the package and the protection necessary in warehousing or distribution.

Packaging materials and systems used

Several basic types of materials are used, all of which have been detailed in previous chapters, i.e. glass, metals, paper and board, plastics, wood and compound (comprising two or more of the above). Only those aspects of packaging design related to the warehousing and distribution modes will be addressed here.

1 Glass packaging today does not contribute anything to the discussion on warehousing and distribution packaging, save that it is fragile and needs good quality protection and as little handling as possible.
2 Metal packaging includes tins, cans, drums, pails, etc., which may be the primary, secondary and tertiary packaging in the case of transportation of bulk pharmaceuticals or pharmaceutical ingredients. Occasionally used for metal pallets and cage pallets. A common problem is that small containers can be easily dented.
3 Paper and board packaging is used mainly for secondary or tertiary packaging labels, cartons, and corrugated cases—and is the main material used to protect the product in warehousing and distribution.
4 Plastics packaging is used in only a few minor roles in warehousing and distribution, namely shrink-wrap used as alternatives to metals (often has less to offer in terms of stacking strength).
5 Wood is used primarily for pallets and skillets, but is not considered as a ‘clean’ material, and can introduce physical or microbial contamination.
6 Compound materials are any two or more of the above five, e.g. foil-lined corrugated or plastic-lined fibreboard kegs may occasionally be used where an extra moisture barrier may be needed.

Nature of primary pack

The primary pack, i.e. that which immediately contains the product, is likely to be either rigid (securitainer or bottle, etc.) or flexible (blister pack, collapsible tube, etc.) and could be fragile, hence readily damaged in some way.

Although warehousing and distribution may be primarily associated with ‘bulk’ or the unit load packaging, they are also related to secondary packaging because sometimes these secondary packs are broken down (e.g. at the wholesaler) and sent out to their final destination as singles or twos. If this happens and the unit packaging is poor (e.g. poor quality carton), damage is likely to occur (rucking, creasing or crushing) thereby creating a substandard, unsightly or unsaleable pack, even though the contents may remain undamaged.

The interpretation of 'Bulk' may be as follows:

1 *x* cartoned products in a transit pack
2 *x* products in a divisional transit pack
3 one or more pallets of an item in its own transit outer (e.g. drums or sacks)
4 a pallet stacked in layers then stretch or shrink wrapped
5 any combination of the above.

In categories (1) and (2) above, removing single items from the transit pack for individual dispatch, or in the case of (3) and (4) removing single items from the pallet, may impose entirely new transit and stacking hazards on the product. This situation can be extended to complete transit loads, containerised loads, and systems involving specific palletised systems (e.g. cage pallets, box pallets, converter pallets) where materials can be stacked to pre-controlled heights.

HandlingÐmanual or mechanical

All goods will be handled many times from the end of the packaging line to the final consumer (the patient). An example is cartoned bottles to a UK retail pharmacy then dispensed to the patient.

The cartoned bottles will be collated into a dispatch amount, which will be either a tray and wrapping or a case. This will be handled probably manually and stacked to a predetermined pattern onto a pallet. The pallet will be moved off the packaging line when full to a holding area for QC passing, then to a warehouse and stacked (probably more than one high) awaiting dispatch. Upon dispatch either a pallet load or, more likely, a case or part case is moved from storage, stacked onto another pallet containing other products as a 'mixed load' (it will require additional protective packaging), moved onto a lorry and secured. From the lorry at the wholesaler's warehouse onto the ground, then into a stack, from which it will be placed in a 'picking' area where the outer case may be removed and picked into baskets/trays/Jiffy bags for van dispatch to the retail pharmacy. The retail pharmacist will give the bottle to the patient, probably in a paper bag.

This adds up to around fourteen handling/movements, and could include stacking, loading, unloading, repalletising, breaking down containers, breaking down secondary packs, etc. The warehouse handling of goods in recent years has become much more complex, starting with manual handling, passing through various mechanical transfer systems to fully automatic robotic systems.

Manual handling usually includes hands and feet (including kicking) and various non-motorised aids, e.g. wheel barrows, sack trucks, trolleys, mobile bins or cages. These involve the physical actions of lifting, lowering (dropping), pushing, pulling, throwing, catching. In each of the above, hazards to the handler (as well as the product/pack) must be considered, particularly in light of health and safety legislation.

Mechanical handling should present fewer hazards, provided that the goods are palletised and are properly stacked, stable and secure, and in good condition for their purpose.

Quantities involved

These will range over the industry from one or two ampoules or vials right up to shipping containers containing thousands of individual packages or even intermediate bulk containers (IBCs) for pharmaceutical chemicals.

It is difficult to quantify, but the classical pharmaceutical pack of filled containers will be of prime concern to the reader. The smaller the quantity, the more likely it is to become lost in a large warehouse and the more manual handling it will encounter.

Environmental changes during storage, handling and distribution

In the UK atmospheric changes are relatively mild, both naturally and due to changes in altitude above and below sea level. Severe changes in altitude can occur in air transport mode and within certain countries in the world. In air transport there are both pressurised and unpressurised aircraft. 'Pressurised' means that in flight the pressure is stabilised at 8,000 ft, equivalent, while non-pressurised means no control. If you are likely to export to Mexico City or Johannesburg, take note that their altitudes are 7,500 and 6,500 ft respectively. The pressure varies at about 0.475 lb/in^2 per 1000 ft of difference in altitude.

Other environmental changes could include:

1 temperature changes and their effect on dimensional stability, flexibility or rigidity of corrugated and cartonboard

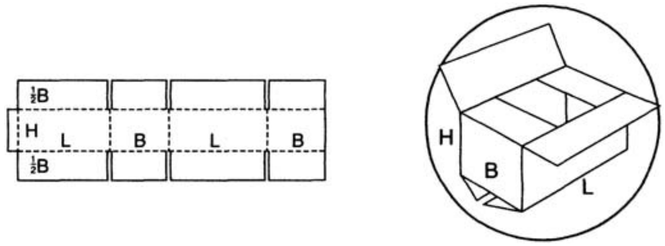

Figure 15.1 Example of FEFCO design

2 static electricity pick-up is increased in warm dry conditions and excessive handling
3 condensation on the pack through bringing cold items into a warm, moist atmosphere
4 physical instability, e.g. 'dumb-bell' reels due to preferential moisture absorption at reel edges and the reverse.
5 RH changes as referred to earlier.

Corrugated boards and casing used for transit protection

Too little attention is usually paid to this important area of packaging. If the transit packaging is poorly designed, then the product will not reach the market in usable condition.

Structure of boards

Please refer to Chapter 5 for the construction of solid and corrugated boards.

Collation and casing of packs

In a packaging design there may or may not be a carton covering the prime container. If not, then a number of containers will have to be held together either in a tray or with some form of film wrap, e.g. deadfold wrapping, shrink wrap or stretch wrap. Product in a carton must be arranged so that the longest side of the carton is vertical, as this is the way to use the maximum strength of the carton. The cartons should then be collated into suitable numbers to suit the particular distribution system.

Structure of cases and design parameters

Cases should be designed to the FEFCO, sometimes called the International Fibreboard Case Code (IFFC), system. This is an international system which has codified the various designs of cases into a simple book of basic designs, to which the designer has only to add the dimensions and board specification (see Figure 15.1).

Moving and storage methods

Handling of goods was discussed earlier in the chapter, so that movement can be defined as either manual or mechanical. However at some point in the warehouse it is usual to store the goods, and this can be done in two ways.

1 Random or floor storing, which is useful for single containers of bulk or single cases, but has the major disadvantage of the goods needing to be raised up from the floor to move them again. This imposes additional mechanical hazards, to say nothing of the problems of floor contact (cleanliness and moisture). Pallets or stillages may also be stored on the floor, but the space utilisation in a warehouse is limited.
2 Rack storing, which is preferable, may be on shelves, pallets on shelves, or moveable racking. The latter two usually require specialised lift trucks to operate the system successfully. This is discussed in detail later.

Palletised and non-palletised loads

Palletisation enables a unit load to be lifted, transported, loaded for distribution, unloaded, etc. with the minimum of manual handling. Pallets are designed to be stacked, and usually one onto another if the product/pack/pallet design permits. Pallets come in different sizes, styles and are designed to be handled by fork lift systems.

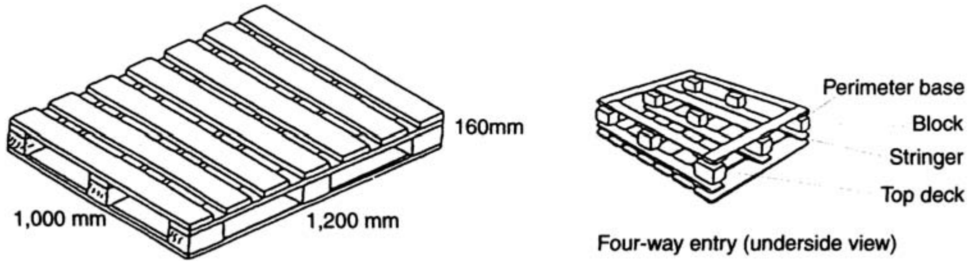

Figure 15.2 Types of pallet

As stacks grow higher and weights increase, specialised and more costly high stacking trucks, cranes and robots could be employed. Manoeuvrability of these is vital as this relates to overall space utilisation (See 'Costs').

Using the non-palletised methods and depalletising to optimise transit vehicle space, warehouse space, etc. substantially increases manual handling. This can be reduced by the use of mechanical transfer systems (lifts, hoists, chutes, roller conveyors, etc.). Placing loads directly onto the floor in warehouses, vehicles, etc. is not recommended for pharmaceutical products. It is therefore advisable to try to raise the packaging 'off the floor' by the use of boards, duck boards, hardboard, slip pallets, slip sheets, etc., but these may cause other problems.

Pallet types

Pallets are usually divided between two-way and four-way entry styles. The two-way offers entry of lifting forks from two opposite sides of the pallet; the four-way from all four sides of the pallet. Various styles of pallet are shown in Figure 15.2. Please note in particular the variation in deck board gaps, which vary from a solid deck to gaps as wide as 6–7 inches. This will influence the choice of strength of secondary packaging material. Note also that the bases of the pallets are different, in that the number and types of cross-member in the base may differ from only two side bearers up to perime ter base and centre cross bearer. This has a significant effect when pallets are stacked more than one high, e.g. in a lorry, trailer or container.

A pallet is a flat portable platform constructed to sustain a load, be stackable and permit handling by equipment. A stillage is a flat portable platform constructed to sustain a load and permit handling by equipment. Stillages are not designed to be stacked one upon the other.

A cage pallet is exactly what it says it is, usually a metal solid decked two-way entry pallet with demountable cage sides and lid. A box pallet is similar to the cage pallet but is usually of plywood sheet or heavy corrugated board construction (triwall).

Selection of pallet or stillage type requires consideration of the following factors.

1 Nature of goods being handled and whether the pallet is for one specific purpose or for general purpose use.
2 Distribution system(s) with particular attention to:

- number of directions that a fork lift truck needs to enter the pallet (two, four)
- handling by hand operated pallet trucks, as the base design may need to be different
- general handling and storage methods
- pallet 'footprint', i.e. the formation of the base of the pallet—this particularly applies when loading direct to aircraft floors and in stacking loads to greater than one pallet high
- gaps between the deck boards
- cleanliness and general pallet maintenance (to facilitate overall cleanliness and, in particular, use in 'controlled' areas, many companies are now specifying 'plastic' or aluminium pallets).

3 Cost in relation to goods carried and service life.
4 Destination, as there are several sizes of pallet in use. There are several 'standards' for pallet size, some of the more usual ones being:

- UK standard pallet size=1000×1200 mm
- Europallet=800×1200 mm
- US pallet=1200×1200 mm approx.
- ISO pallet=1200×1800 mm.

Note that pallets going to China, Australia and New Zealand must be 'treated' or tannalised to rid them of wood mites.

Fit to pallet

The palletisation of cases is probably the most frequently used safe method of transporting packaged product. There are certain factors that help, e.g. the load should not overhang the pallet perimeter, and must be stacked with the case edges on the perimeter vertically over each other to transmit the downward forces in the line of the strongest part of the case.

In addition there are several types of stack that can be designed, depending primarily on the case and pallet sizes chosen. Usually use a divided load which may be of interlocking or spiral stack types, but avoid columnar stacks as far as possible as they tend to fall off pallets when they are picked up by trucks, due to the pallet flexing under load, unless adequately stabilised.

To give an indication of pallet design, the following is a typical pallet specification.

1 Type: four-way entry, perimeter base 1,000×1,200 mm.
2 Materials: specify timber and blocks.
3 Timber components:

- top deck boards—7 off 125×19×1,000 mm
- base boards—2 off 100×19×1,000 mm 3 off 100×19×1,200 mm
- stringers—3 off 100×22×1,200 mm
- blocks—6 off 138×100×100 mm. 3 off 100×100×100 mm.

4 Construction: top deck boards will be evenly spaced so as to give 21 mm gaps. Annular ring nails are to be used for all joints, and each nail must be more than 20 mm from the wood edge.
5 Marking: brand 'user name' on two diagonally opposing blocks if required.

Load stability

The techniques of load stabilisation are designed to hold the load securely (whether just collated or cased) whatever type of pallet loading has been used. Load stabilisation facilitates handling and enhances the protection afforded to the contents by the package, while providing the means of effecting safe handling throughout the distribution chain.

Stablisation methods

Bonding

Drums, crates and trays are designed in such a way that when stacked in multi-tiered layers each interlocks with the one below. Trays, for example, can have plastic inserts or integral designs at each corner to support the tray above.

Interlocking stacking patterns

This is where rectangular packages are arranged in alternating stacking patterns to provide an overlapping bond on each layer. Although improving the stability, with corrugated cases it reduces the stacking strength.

Interleaving sheets

Otherwise known as tie layers. Low slip sheet material, normally paper or thin card, is placed between a set number of layers. This method is generally used for small packages or where the interlocking patterns cannot be achieved. The sheets can be applied automatically on the palletiser.

Incorporation of low slip materials

Used particularly for paper, plastic and composite sacks. With paper sacks use a creped Kraft paper on the outside ply. Even with dusty materials this increases the coefficient of friction of the contact areas, thereby reducing the chances of unwanted movement of one sack over another. Other treatments of paper use colloidal silica or compounds containing alumina.

Palletising adhesives

Used between the packaging to hold the load into one mass.

Strapping

In use today for the heavier end of the market, e.g. cases of filled vials. Care should be taken as strapping that is too tight on a load can cause severe crushing as it goes round right angles, unless edge/corner guards are used.

Stretch wrapping

One of the most popular forms of load stability in recent years. It consists of an anchored sheet of film being tightly wound around a load, manually or automatically. The control of tension is of great importance since if the wrap is too tight then crush damage occurs, particularly to the corners of the load.

Shrink wrapping

Can be used on either palletised or unpalletised loads. Properly applied it holds the load together well, forms a reasonable tamper-evident barrier and adds positive protection against vapour and water. If it is required the shrink or stretch wrap can be opaque, thereby obscuring the individual labels on cases.

Slings and sling bags

An alternative form of palletless loading, where the slings are arranged (may be with a shrink or stretch wrap) so that the load can be hoisted safely onto and off transport. Sling bags are a form of fabric IBC and can be used to utilise smaller loads, e.g. bags.

Height stacked and stack configuration

Round containers such as drums, pails and buckets have a poor space utilisation. Although a cube offers best utilisation of space it is not necessarily the best shape for stacking, as load interlocking by pattern arrangement is either difficult or wasteful of space. Rectangular or brick shaped outers which fit the pallet dimensions are preferable.

Computer software programs are available so that both stacking and transportation space can be optimised. In certain instances one might design ‘backwards’, i.e. select the optimum for the pallet and then produce a primary container size to fit this space. This is significantly different to the classical design methods where the primary container was designed, then the outer pack size was calculated and these packs were then used to find the best arrangement for the pallet. This classical design method often does not fully utilise the area of the pallet, which can be important for warehousing costs.

The ideal height to which a single pallet should be loaded usually lies between 1 m and 1.25 m. However, the height to which a pallet or series of pallets can be stacked depends on a number of factors:

1. the compression strength of the transit outer
2. whether the primary pack will withstand compression, e.g. metal components, glass bottles (and note that compression and vibration may have an effect on the closure torque)
3. configuration of the stack
4. effects of environmental changes, particularly relative humidity (RH)
5. clearances between outer and contents, i.e. aiding or reducing compression, strength
6. base onto which the load is stacked, i.e. pallet deck footprint
7. type of pallet—feet or non-feet, pallet ‘footprint’
8. security of loads for both stacking and movement can be improved by interlocking, corner stays, shrink wrap, stretch wrap, netting, or any combination of these.

The effects of the stacking height on the pack and product depend on whether loads are palletised or non-palletised. The height to which a product/pack can be safely stacked will depend on a series of factors. It should be noted that the word ‘safely’ can be interpreted in two ways:

1 the legal need for 'safety' conditions in the workplace, i.e. if the stack falls down and someone is injured the company could be legally liable
2 the protection of the product in terms of preventing physical damage by stack collapse or compression.

Any stacked product, even a static load, is still at risk from other elements, e.g. environment and movement of people, fork lift trucks, etc., which may be operating in the vicinity of the stack.

Modes of distribution and transport

Although UK distribution is today predominantly by road, distribution can take place worldwide using a number of different ways and modes, as follows.

1 Type of load.

- Mixed load.
- Bulk load.
- Unit load (may be an intermediate bulk container (IBC)).
- Container load.

2 Journey: distance, time, environmental conditions, stop-overs, etc. must be taken into account.

- Local.
- Internal UK short haul or long haul.
- Overseas to the continent.
- Overseas intercontinental.

3 Type of transportation used.

- If land transportation, this can involve road vehicles, end loading, side loading, with hydraulic tailboards or hoists, or on board cranes with varying degrees of protection. If the rail system, then container or package usually in a closed vehicle.
- Inland waterways face similar conditions to coastal shipping, while deep sea ships might be passenger or loose cargo or container and be coastal, crosschannel or intercontinental journeys. (Note that the time taken can be several weeks.)
- Air transport can use either passenger or custom-built cargo planes. Note that outside the 'Western world' there are many planes that are not pressurised.

Containerisation

This may be used for road, rail and water transportation, and is a useful method of ensuring that the goods are kept as much under the parent company's control as possible.

There are several sizes of container, but most are designed to be just over 2 m high, 2.5 m wide internally and of a suitable length to fit onto a 32 t lorry chassis. The container will probably be made of aluminium sheeting with reinforcing ribs internally, a solid steel/wood floor and, for shipping, steel reinforcing external ribs for stacking on docksides or onto ships. There are usually safety-locking doors only at one end.

The container can be loaded in one of two ways: by the pharmaceutical company itself, which has the advantage that once customs sealed it should not be interfered with; by an agent who will endeavour to fill the container to its maximum with a variety of goods, e.g. heavy loads on top of your goods.

It is generally accepted that the contents of containers will be stacked two pallets high, so it is essential that the goods are adequately attached to the pallet. The load will need to be stabilised as much as possible and this is done by systems of air bags blown up to take up the vacant load spaces, sacks of straw or plastic chips, or sometimes expanding plastic foams in specialised applications.

Each combination of transportation tends to produce different advantages and disadvantages, costs, etc. Each will also involve differing climatic, biological, drop, vibration, etc. hazards. Packaging designers must look all the way down the distribution chain before deciding on the final pack design.

Utilisation of warehouse space

Warehouse space is expensive, but it can be utilised most economically by the selective use of free stacking, shelving, bins, pallet racking, mobile racking, live racking (gravity feed systems), automatic (stacker cranes) or automatic flow-through using robotic systems.

There are several methods of optimising the space available. It is sensible to have the most popular product lines as close to the warehouse dispatch point as practical, thereby minimising the length of movement (and therefore time of operators, trucks, etc.) taken up in closing orders.

Several popular styles of warehouse space utilisation will now be described. Bear in mind that there is no theoretical 'right answer' to warehouse space utilisation problems without a thorough examination of all the operation and options of that warehousing system.

1 Free stacking of pallets is viable if the warehouse has a low roof and the goods do not occupy space for long periods of time, e.g. a QC quarantine area.
2 Shelving for small individual light items (which may have to be held for a short time) up to individual pallet loads. It is possible with proper design to have shelving designed to be as high as possible, with the operators using either mobile steps (for light items) or fork lift trucks (FLTs) for heavier items.
3 Bins would normally be used for small light items, particularly in wholesale warehouses, for individual pharmacy order picking. There could also be a gravity feed system of depalletised cases from a bulk stock area.
4 Pallet racking is fixed skeletal racking designed to fill from floor to ceiling.
5 Wide aisle is a term given to fixed pallet racking, where the aisle is wide enough for a standard FLT to turn and swing its forward projecting forks into the pallet pickingup apertures.
6 Narrow aisle is the term given to the configuration of fixed pallet racking where a specially designed side-lift FLT runs in a straight line between the racks, carrying a four-way entry pallet only in its short direction i.e. the 1 m dimension of the British pallet.
7 Mobile racking is a narrow aisle system with only one aisle per group of racks. The racks themselves are electrically driven so that the 'bin' is located by computer and the racks moved automatically so that the specific aisle is opened up to the lift FLT. There are of course safety features which prevent the racks from moving while picking operations are being undertaken.
8 Gravity feed systems (live racking) are a simple system of rollers where the product is fed on from the back and picked from the front, gravity providing the restocking force.

The decision whether to choose a simple or fully robotic warehouse rests with the inventory, type of pack involved, volume to be handled, destination, etc. Whatever is used, there is an increasing probability that computerised systems will be used for booking-in, stock location, booking-out, reconciliation, automatic label production, automatic routing, etc. Warehouses may be dedicated to only one function or several, i.e. a goods inward warehouse, production holding warehouse, QC quarantine warehouse, goods outward warehouse, which might be dispatching to either a wholesaler or to an individual.

It is essential in all cases to have quarantine areas, in which quarantine identified incoming goods and finished goods can be held pending QC release. The computer system must reflect the situation in the warehouse by 'locking out' any movement documentation until QC release is obtained.

Where warehouses are involved with the breaking down of outers (usually known as order picking), an analysis of orders should tell whether the ideal outer size is in use. This is particularly relevant where pick and place packaging is involved, as this is normally an expensive, labour-intensive, boring operation. Warehouse staff build up considerable knowledge on good and bad packaging, thus they have a valuable contribution to make to the consideration of the total pack design. It is advisable that consultation with the warehouse occurs, particularly in the field of minimising warehousing costs.

Storage and handling of packaging materials and components

Factors that need consideration in the storage and handling of packaging materials and components include:

1 the type of item, physical and chemical changes that might take place
2 the way the items are packed
3 the way the items are palletised and or stacked
4 the warehouse environment
5 whether the item is likely to change or deteriorate on storage, whether it needs a limited shelf life backed up by a re-test at intervals

6 facility for QC sampling, how the sample is taken, the pack resealed, inventory changes
7 the importance and level of cleanliness, hygiene, particulate contamination, bioburden, etc.
8 area segregation for quarantined goods
9 write-off procedures for out-of-date items—note that there are security aspects to this as well; goods should be destroyed if they are company-specific to prevent 'pass-offs'
10 control on pallets—all pallets should be the same, particularly where pallet exchange systems operate
11 contamination, e.g. spillage, roof leaking
12 physical or chemical changes of stock
13 avoiding the obvious hazards of overhead heaters, radiators, draughts, leaking roofs, light/heat/cold from windows, etc.
14 improper or inadequate packaging, overtensioned strapping, stretch wraps too tight.

Order picking

This may occur in the UK in either of two scenarios:

(A) the manufacturing company system catering for distribution to regional destinations
(B) the regional warehouse providing a service, usually twice per day, to every retail, community and hospital pharmacy and to dispensing doctors of any drug commercially available.

An order picking warehouse has different problems to the more conventional 'bulk' warehouse. Goods are picked from racking or bins, either by hand or lately by more sophisticated electronically controlled robotic systems for despatch. Depending on the warehouse type, the journey may be long distance by lorry with manual and/or mechanical handling in example 'A' above, or into a basket into the back of a van in example B.

The collation of picked retail packs for distribution from wholesale to retail is a very difficult area, as most of the individual items are of differing sizes and shapes, need protection during handling, packing, loading to transport, unloading, then movements within the retail environment. 'Mixed loads' are inevitable in this scenario and the packaging and protection of these loads is a skill acquired only with some thought:

1 put the heaviest, least crushable, items at the bottom of the load
2 ensure, as far as practical, that no part of the load overhangs the pallet
3 try to build up the mixed load with the most fragile materials inside gaining some protection from the surrounding packs
4 do not build up a mixed load too high, i.e. over about 1.2 m
5 ensure that the mixed load is secured by means of an anchored shrink or stretch wrap.

Remember that the retail unit, out of its secondary packaging, is very vulnerable to manual and mechanical handling—shock, vibration, drops, etc.

There may be occasions where there needs to be a system of distributing certain specialist products direct from the manufacturer to the individual patient, e.g. unlicensed drugs. This will involve sending probably only one container/course of treatment. This pack will be very small, i.e. too small for industrial distribution. The obvious method is by using the postal service. This service is usually very quick, economical and efficient, but carries a higher degree of risk of physical damage. It is essential that those products to be posted are carefully assessed for fragility and the secondary/tertiary packaging designed so that maximum protection is given for impact, low and medium vibration and crush.

Costs

Warehousing involves space, heating, lighting and labour. Typical 'space' costs (at 1994 figures) about £5–10 per year per ft , with overheads of £10–20. Based on this, pallets stacked three high (~4 m) on a 1000×1200 mm base area (~ 315), plus £ handling space (2.5), would cost ~ £790 per annum. If outers of 12 are assumed, 40/pallet, 3 pallets high=1,440 units. Therefore one year's storage/item=about 55p per unit. Since keeping a unit in the warehouse for say 3.5 days will cost 0.53p or, if 4 weeks, 4.22p per pack, such costs need serious consideration. Involving stock in an order picking operation usually multiplies the costs by about 10 times.

Example:

- Load, unload and transport 1000 kg: assume 75p.
- Stack 1000 kg 1 pallet for 3.5 days, storage: assume £7.58
- Warehouse handling: assume £1.5

- To order pick 1000 kg, each item individually: £22.00 (expressed as a handling cost).

However, although considerable, distribution costs (or rather the proportion of product cost to distribution costs) are relatively small for pharmaceutical products (typically 2% of overall product sales revenue).

UN certification

There are various pharmaceutical products that fall into the UN dangerous goods category, e.g. aerosols. The UN dangerous goods regulations provide a structured method of assessing package performance and the requirements of performance of a package to carry dangerous goods safely, based on the defined degree of hazard.

The UN 'Orange Book' is the definitive guideline to the proper classification of products into one of nine classes, some with subdivisions (see Table 15.1). Each class and/or subdivision has three packaging groups: I, II, III. Each group defines a level of risk posed by the product, thereby defining the severity of the package testing required.

Group I contains the most dangerous goods of any classification and is likely to require that smaller amounts of the goods are carried, in addition to having much higher test specification. The limitations on the mass of product carried either per container or per load are usually applied to aircraft.

All substances to be carried by any means should be checked against the UN listings for dangerous substances (available from the Department of Transport). There are different limitations and definitions as to what is dangerous in each of the transport modes. ICAO, IATA, IMDG, ADR, RID are the abbreviations for the various bodies representing international air, sea, and European road and rail transport. Note that

Table 15.1 UN classification of products

Class	*Material*	*Details*		
1	Explosives	Of no interest to pharmaceuticals.		
2	Gases	2.1 Flammable gases, e.g., continuous spray aerosols		
with		butane propellant.		
2.2 Non-flammable, non-toxic gases, e.g. continuous spray aerosols with CFC propellant.				
Division 2.3 Toxic gases, e.g. chlorine.				
3	Flammable liquids	e.g. Liquids containing alcohol.		
			boiling point	*flash point*
		(i)	≤35°C	–
		(ii)	>35°C	<23°C
		(iii)	>35°C	>23°C, ≤60.5°C
4	Flammable solids	Not likely to be of interest to pharmaceuticals.		
5	Oxidising substances and organic peroxides	5.1	Oxidising substances which may contribute to combustion by producing oxygen.	
		5.2	Organic peroxides may be considered derivatives of hydrogen peroxide.	
6	Poisonous (toxic) and infectious substances	6.1	Poisonous (toxic) substances, e.g. potassium cyanide.	
		6.2	Infectious substances, e.g. AIDS virus.	
7	Radioactive materials	e.g. Medical isotopes.		
8	Corrosive materials	e.g. Acetic acid.		
9	Miscellaneous dangerous	Items not covered by the previous eight classes, e.g.		

ICAO is the legal UN definition of what may and may not be carried. IATA covers the airlines and may not correspond to ICAO, but the classification and group testing specifications are the same.

All packaging must be tested by approved test methods by approved testing stations. All possible variations of packaging from all potential suppliers must be tested. The results are then scrutinised by PIRA (in the UK) and, if satisfactory, a certificate is issued. There are strict rules about the marking and labelling of UN approved packaging which must be followed to the letter, or the product which is classified as dangerous may be refused transport of any kind.

Cushioning of fragile packs

Cushioning is defined as the protection from physical damage afforded to an item by surrounding its outer surfaces with materials that have been designed to absorb the shocks or reactions caused by external forces. There are three major ways of achieving the prevention of damage using cushioning.

1 Spread the load caused by impact over a wider area, e.g. contrast a 50 kg package, size 250×200×200 mm dropped from 1 m onto a corner and onto one flat base. The force to be dissipated is 50 kg m/s^2 (50 N). On the corner, only a few square centimetres take all the load, say 10 cm^2. Therefore load per unit area of contact is 5 kg m/s^2 (5 N). On the flat base the area is 25×20=500 cm^2; therefore the load per unit area is 0.1 kg m/s^2 (0.1 N).
2 Localise the forces, i.e. direct forces to the strongest parts of the package.
3 Absorb the energy in a resilient material by using a cushioning system, e.g.

- space fillers, e.g. powders and granules, shredded materials, wrapping materials
- crushing or non-resilience, e.g. foams, papers
- resilient cushioning devices, e.g. rubber, springs, steel or bulk materials.

When an object contained in a container falls, it accelerates. When it stops suddenly, the outside of the object stops before the inside of the object. This time is in milliseconds. The package must be designed so that the fragility of the prime container is taken into consideration and adequately protected.

Cushion packaging materials

Cushioning materials in widespread use include air bubble sheet, cellulose padding, cork-based granules/sheet, corrugated plastic corners, corrugated sleeves, embossed paper, expanded polystyrene, other expanded plastics, foam in place, free flow polystyrene, sawdust and shavings, straw, wood wool.

These materials have to be assessed on their cost, efficiency, versatility, compatibility, storage volume before use, fire risk, hygiene and disposability or reuse. There might also be an association with the product and sales image for marketing.

Conclusions

The objectives of warehousing and distribution can be summarised as:

- minimising total delivered cost
- storage for a minimum time period, involving the minimum quantity to meet all order demands while retaining an in-stock situation
- preventing damage or containing it to an economic minimum
- retaining customer goodwill
- minimising the cost of replacement/return and the need for repair/re-sorting.