## Supplement 1

# Selecting sites for storage facilities

## Technical supplement to WHO Technical Report Series, No. 961, 2011

*Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*

May 2015

# Contents

# Abbreviations

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| GIS | geographical information system |
| TTSPP | time- and temperature-sensitive pharmaceutical product |

## Acknowledgements

The author of this document is Andrew Garnett, an independent consultant, London, England.

# Glossary

**Bunding or bund wall:** A constructed retaining wall or earth embankment designed to prevent inundation or breaches from a known source.

**Drainage swale:** Shallow, sloped channels designed to collect and move surface run-off toward streets or holding ponds and away from buildings or houses.

**Inventory turnover:** A measure of the number of times inventory is sold or used in a time period such as a year. The equation for inventory turnover equals the cost of goods sold divided by the average inventory. Inventory turnover is also known as inventory turns, stockturn, stock turns, turns, and stock turnover.

**Pharmaceutical product:** Any product intended for human use or veterinary product intended for administration to food producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. Medical devices are not included.[1]

**Standard operating procedure (SOP):** A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

**Time- and temperature-sensitive pharmaceutical product (TTSPP):** Any pharmaceutical good or product which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, is degraded to the extent that it no longer performs as originally intended.

[1] Definition from WHO/QAS/08.252 Rev 1 Sept 2009. *Proposal for revision of WHO good distribution practices for pharmaceutical products – Draft for comments.*

# 1. Introduction

This technical supplement has been written to amplify the recommendations given in Section 2 of WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*.[2] Related topics are covered in the following supplements:

- *Estimating the capacity of storage facilities*
- *Design of storage facilities*
- *Security and fire protection in storage facilities*

## 1.1 Requirements

Pharmaceutical warehouse sites and other places, such as pharmacies, where significant quantities of pharmaceutical products are stored, should be located so as to minimize risks from natural hazards such as floods, landslides and earthquakes and extreme weather conditions such as hurricanes and tornadoes. In addition, sites should be located in places that enable the target population to be served efficiently by making effective use of existing transport infrastructure.

## 1.2 Objectives

The objective of this Technical Supplement is to provide guidance on how to meet the above requirements. This document only covers the process of choosing suitable warehouse locations; it does not cover warehouse sizing or the layout and development of the site itself – for these topics, refer to the companion Technical Supplements listed above.

## 1.3 Target readership

This supplement provides guidance aimed at more senior operations staff. Principally these will be the owners and operators of warehouses, pharmacies and other buildings used to store TTSPPs and those responsible for property development and property acquisition on behalf of owners and operators.

[2] http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf

# 2. Guidance

The correct choice of warehouse site(s) and the associated pre-development site investigation process is a critical strategic decision for any logistics operation. The goal of supply chain system design is to minimize whole system inventory holding and distribution costs while ensuring an acceptable service level for patients and end-users. The overall efficiency of storage and distribution systems is a major driver for commercial organizations; consequently there is a large literature on this subject and much professional expertise. This supplement provides a simple introduction to some of the concepts involved and outlines some of the key decisions that need to be made.

Related topics are covered in the following supplements:

- *Design of storage facilities*
- *Estimating warehouse storage capacity*
- *Security and fire protection in storage facilities*
- *Maintenance of storage facilities*

## 2.1 Associated materials and equipment

Professional staff responsible for site surveys and investigations must have access to appropriate surveying and site investigation equipment.

## 2.2 Designing and costing the supply chain

The first step in supply chain planning is to establish the number of levels in the supply chain where storage points are required, and to determine the preferred geographical location of these stores. Traditionally, health commodities in the public sector are often stored at locations that reflect the country's administrative structure. Thus there will typically be a national-level or state-level pharmaceutical warehouse receiving products direct from manufacturers and suppliers, smaller lower level stores at provincial and district level, with hospitals and health facilities at the end of the chain. Therefore, there may be up to five storage levels before products reach the patient. This multi-level model can lead to major inefficiencies, with low inventory turnover and high inventory holding costs; it also increases the risk of product expiry during storage.

## 2.3 Logistics network planning

Providing the population with a reliable and uninterrupted supply of pharmaceutical products, including TTSPPs, is a nationally important strategic objective. Achieving this objective depends to a significant extent on choosing suitable storage sites that are served by secure transport routes.

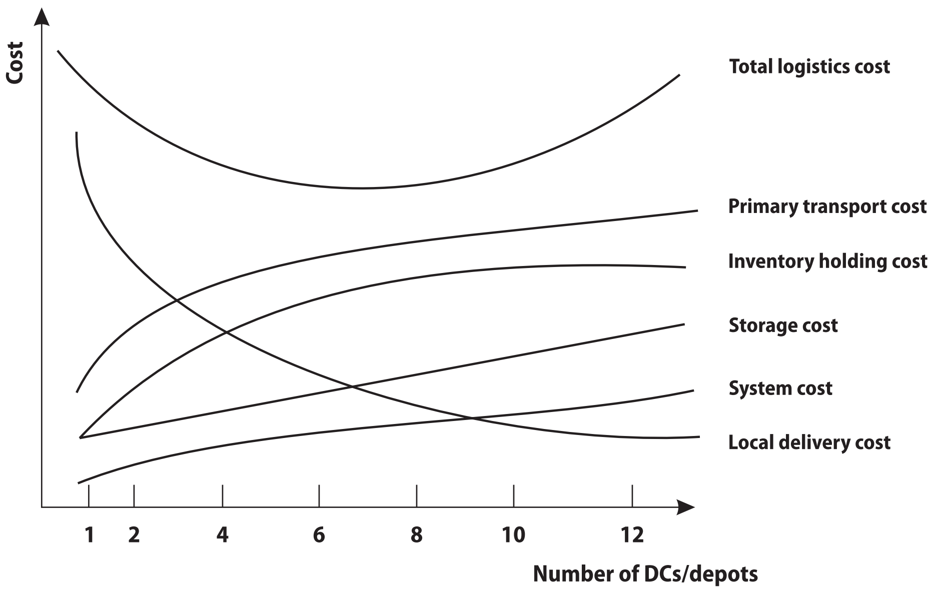
Logistics operations in large commercial organizations are very cost-sensitive because their profitability and survival is entirely dependent on customer satisfaction. A great deal of effort and resources are committed to planning distribution networks and optimizing the location of storage and transhipment points using sophisticated analytical techniques. The goal is to achieve the "six rights" of logistics – the *right product* in the *right quantity* delivered to the *right place* at the *right time* in the *right condition* at the *right cost*. Health service operations can and should be motivated by a similar desire for operational efficiency and patient satisfaction. However, in the public sector, historical choices and past patterns of development will have determined the siting of the distribution network infrastructure. Thus, the scope for radical reorganization is likely to be constrained by these decisions and also by lack of resources.

If it can be carried out, a thorough redesign of a public sector pharmaceutical distribution network should be based entirely on objective measures of cost and efficiency, rather than on preconception and historical location patterns. This is a sophisticated and specialized task. The analyst aims to achieve an optimal balance of multiple factors, including the following:

- distribution of the target population – the customers and patients;
- required service level(s) for supplied products;
- location of manufacturers and suppliers of pharmaceutical products feeding products into the distribution system;
- available transport networks (road, air, rail, water), including their condition, reliability and exposure to weather-induced delays and other hazards;
- preferred location of storage points;
- physical capacity of the storage points needed to ensure the defined level of service;
- inventory holding costs for storage facilities at the chosen locations;
- transport resources;
- transport costs.

To illustrate this approach, Figure 1 demonstrates how total logistics costs can be derived from an analysis of the individual cost elements of a logistics system – in this example a system with between one and 12 distribution centres. Here we see that the *total logistics cost* curve – the sum of the other five cost curves – shows that the lowest total system cost for this particular example is achieved with a network with six to eight distribution centres. *Primary transport* here is supply of products in full pallet loads from a central warehouse to the individual distribution centres. *Local delivery* is the distribution of product from the distribution centre(s) to the customer. In the case of a single distribution centre, this cost element is obviously very high. *Systems cost* is the cost of operating the information systems required to manage the network.[3]

Figure 1
**Total logistics costs and component cost elements**




DC, distribution centre.
Source: Rushton, Croucher & Baker (2006), p. 125.

This sort of optimization exercise is not something that can be done in an ad-hoc fashion. It requires systematic strategic investigation and analysis by people who have the relevant skills, and access to the relevant data and software tools. For these reasons, detailed technical guidance is beyond the scope of the current supplement.

As an example of what can be achieved in a public sector context, the HERMES team at the Johns Hopkins Bloomberg School of Public Health has conducted extensive modelling of existing vaccine supply chains with the goal of improving their efficiency.[4] Tools have also been developed to assess supply

[3] Extracted from Chapter 8, Figure 8.7 in Rushton, Croucher & Baker (2006).
[4] http://hermes.psc.edu/

chain costs and the operational factors that drive these costs in a pre-existing context.[5] Commercial consultancies and commercial software are also widely available to handle these modelling problems.

## 2.4 Finding a potential site

Once a preferred general location for the warehouse has been established, the next step is to find a suitable site in the vicinity. This section addresses the main issues that need to be considered.

### 2.4.1 Establish the size of the warehouse

It is pointless to search for sites without first knowing the size of the building required. Clearly the design of the final building will ultimately be determined by actual site conditions; however, it is perfectly possible to make a preliminary estimate of the building footprint before any site has been acquired. An efficient warehouse layout should be as compact as possible; typically square to rectangular in plan. Awkwardly shaped sites that require non-rectangular layouts are unlikely to be a good choice.

### 2.4.2 Narrow down the choices

Local knowledge is the ultimate key to site acquisition. In addition, online geographical information systems (GIS) such as Google Earth™[6] and Apple Maps™[7] provide the opportunity to explore potential site locations remotely and to measure them approximately. At the same time these resources can be used to map the local transport infrastructure and connections to national networks.

The reliability of an online assessment obviously depends on how up to date the images are,[8] and on the resolution of the images themselves. Both of these factors vary around the world. Additionally, in areas undergoing rapid change it is possible that empty sites identified in this way may already have been developed.

### 2.4.3 Choose a secure site

Political stability and security should clearly be borne in mind, but these aspects change over time and are beyond the scope of these guidelines. However,

[5] McCord, Tien & Sarley (2013) (http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/SuppChaiCostMeth.pdf).

[6] http://www.google.co.uk/intl/en_uk/earth/download/ge/agree.html

[7] http://www.apple.com/uk/ios/maps/

[8] For Google Earth, typically between 6 months and 3 years or more: http://www.gearthblog.com/blog/archives/2010/10/how_often_does_google_update_the_im.html

crime patterns do need to be considered because pharmaceutical warehouses contain valuable products and site protection and other security measures will be a significant factor in site development and operating costs. Consequently, bearing in mind the overarching need to serve the target population, a risk-based approach should be taken when candidate sites are evaluated with site security in mind and the following questions should be asked:

- Is the site in a high or low crime area relative to general levels of crime in the wider location?
- Will employees be able to reach the site safely?
- Will vehicles entering or leaving the site be at risk of hijacking?
- Is there a police station in the vicinity and what response time can be anticipated in the event of a crime?
- Is there a fire station in the vicinity and what response time can be anticipated in the event of a fire breaking out?
- Can the site perimeter be adequately secured?
- Can access to the site be controlled?

#### 2.4.4 Choose a future-proof site

Wherever possible the warehouse site chosen should provide space for future expansion and should have direct access to a well-maintained free-flowing road network. Access to rail connections and nearby air or sea ports may also be necessary.

Private sector industrial and warehouse operations have similar needs, so areas of a city that are zoned for these uses are likely to be preferred locations for a pharmaceutical warehouse.

Unfortunately many cities do not have, or do not enforce, strict zoning laws. Rapid urbanization may also engulf an otherwise suitable site, radically alter accessibility, and place a severe strain on the electricity supply and other site services. These medium- to long-term risks also need to be assessed.

#### 2.4.5 Ensure labour availability

The warehouse will require a reliable labour force, living within commuting distance. Depending upon the economic context and the availability of personal and public transport, the site evaluation needs to review the potential employee catchment area and the skills available within it.

#### 2.4.6 Assess flood risks

It is vital for the safety and security of the products stored on site that the warehouse building should not be exposed to flood risks. In order to ensure uninterrupted deliveries and distributions it is also essential that site access will not be affected by seasonally flooded roads. For this reason, pharmaceutical warehouses should preferably not be built on a flood plain or close to a coastline that is susceptible to inundation during storm surges. If no alternative site is available, the floor of the warehouse must be raised well above the predicted 100-year flood line, or the site must be fully protected by flood defences such as bunding or drainage swales. Such measures will inevitably increase building costs. In addition, site-specific flood defences may adversely affect neighbouring properties by locally increasing the flood risk outside the protected site.

### 2.4.7 Assess weather and climate-related risks

In addition to historical weather patterns, an increase in extreme weather events is a predicted effect of climate change. Pharmaceutical warehouses should be sited and constructed to minimize the consequences of these risks over the lifetime of the development – typically 30 years or more. Predictable risks include direct wind and rain damage, lightning strikes, and damage from flying debris and falling trees during high winds and tornadoes. In hilly or mountainous areas there is also a possibility of damage from rainfall-induced landslides or avalanches. The site assessment must include an evaluation of these risks and recommendations for risk mitigation. For example, a warehouse located adjacent to a shanty town area may be at greater risk of damage from flying debris than one located adjacent to well-constructed buildings.

### 2.4.8 Assess fire hazards

Protection of pharmaceutical warehouses against fire risks is crucial. Some risks may be a direct consequence of site location, so these risks need to be evaluated as part of the site procurement process. The first task is to establish whether there are significant hazards in the immediate vicinity – for example fire-prone bush land or fire-prone urban developments, such as nearby industrial facilities or informal settlements. The second task is to determine the location, effectiveness and likely response time of the local fire brigade and to establish whether the site has access to an adequate year-round supply of water for fire-fighting and/or operating a sprinkler-based fire suppression system[9] – see companion Technical Supplement: *Security and fire protection in storage facilities*.

### 2.4.9 Assess other natural hazards

Other natural hazards include earthquakes, volcanic eruptions and tidal waves. Warehouses can and should be engineered to withstand the former; volcanic

[9] Warehouses have large roof areas, so rainwater harvesting combined with on-site storage may be one way to ensure a reliable supply of water for firefighting.

eruptions and tidal waves are unpredictable and catastrophic events, which cannot be fully protected against at the level of an individual site. However, it should be possible to avoid locations that are close to known risks of this type.

## 2.5 Detailed site investigation: identifying risks and opportunities

Once a candidate site has been chosen for its development potential, the next step is to carry out a full site investigation. This will partly require desk-based studies and partly physical work on-site. A thorough investigation is essential as it will reveal problems that could affect the final decision to acquire the property as well as opportunities to make best use of the site.

### 2.5.1 Ground conditions and pollution hazards

It is prudent to dig trial holes and obtain a structural engineer's report before committing to the purchase or use of any site. Ground conditions significantly affect building costs. Building on poor ground such as landfill, shrinkable clays or expansive soils (black cotton soil) requires expensive piled foundations and/or reinforced concrete rafts. Buildings constructed on permanently frozen ground (permafrost) require highly engineered raised and ventilated floors. The cost of all these solutions is particularly high for warehouses because of their large ground floor footprint.

In mining areas there is a significant risk of settlement as a result of tunnel collapses and general ground movement. The costs associated with site remediation are high. Typically, site stabilization can only be achieved by grouting abandoned mine workings under the building with large quantities of concrete. If mining is still active, the risk of future settlement will remain, and may increase.

On brownfield sites previously used for industrial purposes there is a risk that the ground contains hazardous materials, including chemical pollutants and other toxic substances. Remediation of such sites is expensive because the affected soil must either be removed for safe disposal, or capped over.

Natural seepage of radioactive radon poses a health hazard in some geological areas because the gas can migrate through ground floor structures and accumulate inside poorly ventilated buildings. Geologically, radon is associated with uranium ores; phosphate rock; shales; igneous and metamorphic rocks such as granite, gneiss, and schist; and, occurs to a lesser degree in common rocks such as limestone.[10] The radon hazard can be managed by slab ventilation or by laying an impermeable membrane under the ground floor – again this has cost implications.

[10] http://en.wikipedia.org/wiki/Radon

Finally, ground conditions will affect the cost and effectiveness of rainwater disposal and foul water drainage. If there is no mains drainage and the ground is rocky, saturated or impermeable, septic tanks with soakaways are not effective and other solutions will have to be found.

### 2.5.2 Existing underground and overhead services

Sites in urban areas, especially those that have previously been developed, may well have services running across them. Buried services can include sewers, water mains, gas mains, electrical cables and telephone cables; in highly urbanized areas there may be subway lines which may prevent the use of piled foundations. In addition, there may also be overhead cables. It is essential to establish the location of such services and their ownership. Rerouting is expensive and some services may have to be retained – all of this will affect the development potential of the site.

### 2.5.3 Site survey

An accurate site survey needs to be carried out and a site plan drawn up; the survey should include an adequate number of spot levels to establish site contours and should also include the location of all existing buildings and identifiable above- and below-ground services and other features. This work must be completed before the design team can prepare accurate cost estimates and detailed building and site work drawings. A level survey is particularly important for a large warehouse development because significant falls across the site will affect the design of ground works and the layout of access roadways and the like. The cost of cutting and filling to create a level platform for the warehouse floor may be significant.

### 2.5.4 Site clearance costs

If the site has existing buildings that are to be demolished, the cost of demolition works should be assessed as part of the site investigation. Refer also to section 2.5.1 regarding potential pollution hazards arising from the demolition process and previous use of the site.

### 2.5.5 Building surveys

If any buildings on the site are to be retained for immediate use, or refurbished, adapted or extended, it is essential that they are included in the survey process. Each building should be physically measured and the survey team should draw up plans, sections and elevations. In addition there should be a full condition survey which includes a structural assessment by a qualified structural engineer and assessment of the mechanical and electrical services by a qualified mechanical and electrical services engineer. Checks should be carried out to determine the presence of hazardous materials, such as asbestos.

### 2.5.6 Service connections to the site

A warehouse site will need adequate electricity, water supply, telephone and Internet services. In addition, if it is available, there may need to be a piped gas and sewer connection. The capacity of all these connections and services needs to be sufficient to support the proposed building(s), including any future expansion.

Information about the location and capacity of site service connections should be obtained from the relevant service authorities. At the same time it is wise to enquire about future development plans in the area because any development is likely to affect future service capacity and reliability in the medium to long term. This is especially true in urban areas experiencing rapid growth.

In the absence of suitable mains services, the site development budget will have to cover on-site provision. Power can be supplied by a diesel generator; if site conditions are favourable, water may be available from a borehole. Both will be expensive to install. Generator running costs are also likely to be high, particularly for a warehouse storing TTSPPs in cold rooms and freezer rooms, because the generator will have to run continuously. In addition, an off-grid site may well have to have duplicate generators to ensure that products are kept at the correct temperature in the event of a generator failure.

### 2.5.7 Low carbon energy potential

Some sites offer the potential for on-site energy generation using renewable technologies. In countries with good solar potential,[11] photovoltaic panels or solar thermal water heaters can be installed on most sites. Warehouse buildings are particularly suitable because they have large roof areas on which to mount the panels. However, it is essential to ensure that the panels are not shaded by surrounding buildings or trees. Another renewable resource that could be exploited if there is a suitable river or stream nearby is small-scale hydro power.

Rural sites with reliable wind may be suitable for wind turbines[12] and geothermal (ground-source) or air-source heat pumps can also be used as a viable source of low-carbon cooling and/or heating.[13] Both geographical location and ground conditions affect the viability of these technologies.

[11] The WHO document: PQS solar autonomy calculation method includes a substantial database of solar radiation data (http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/catdocumentation.aspx?id_cat=17).

[12] It is essential that wind turbines are installed on sites where there are no nearby buildings or trees; as a general rule they do not operate effectively in urban areas.

[13] http://en.wikipedia.org/wiki/Geothermal_heat_pump

### 2.5.8 Environmental impact assessment

If the site is located in an area of high biodiversity, careful consideration should be given to the impact of the development on habitat loss. Sensitive development and careful landscaping treatments can limit damage, but will not prevent it. It is important to note that abandoned urban land (brownfield sites) often have high levels of biodiversity; especially of plants and invertebrates. Small-scale habitats such as these are relatively easy and inexpensive to maintain and protect.

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## Revision history

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