# SAAPI Conference 2019

## Understanding the impact of Good Pharmacy Practice Board Notice 50 on Cold Chain Compliance

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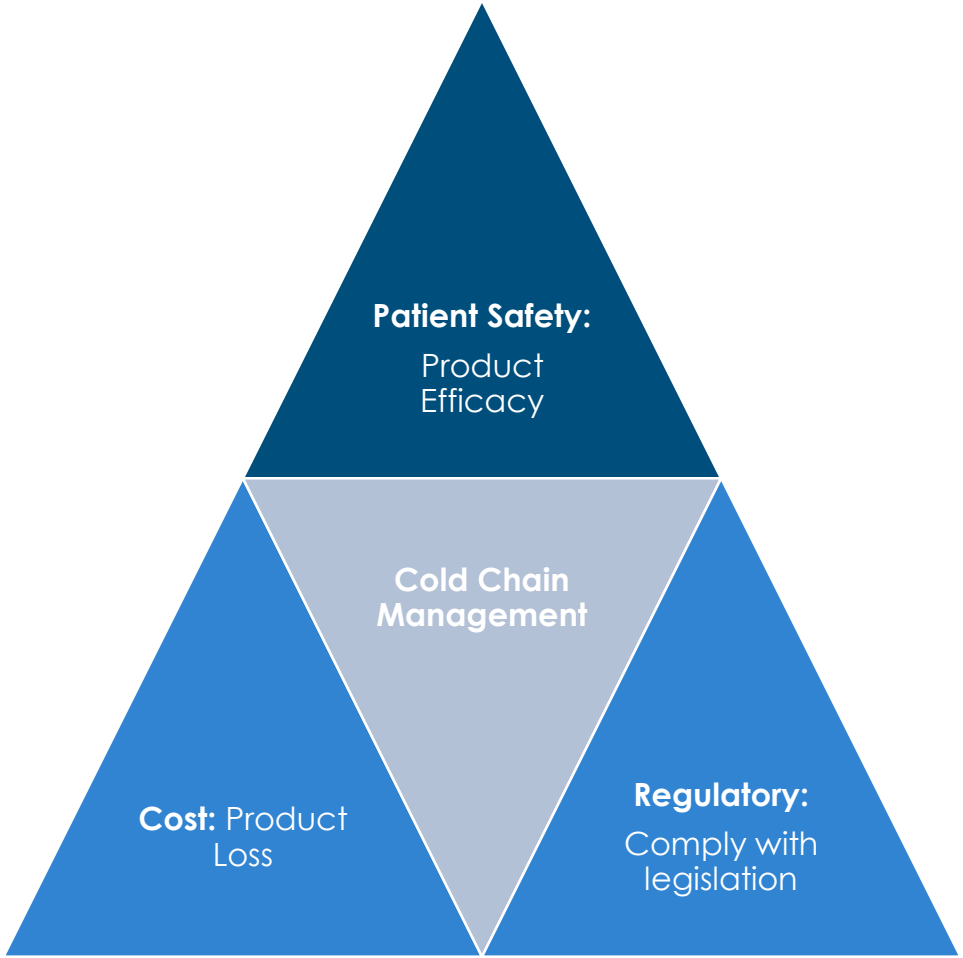
BUILDING BUSINESS THROUGH STRATEGY & KNOWLEDGE

# Overview

- Cold Cain Compliance
- Board Notice 50
  - Overview
  - Storage
  - Distribution
  - Transportation
  - Receiving

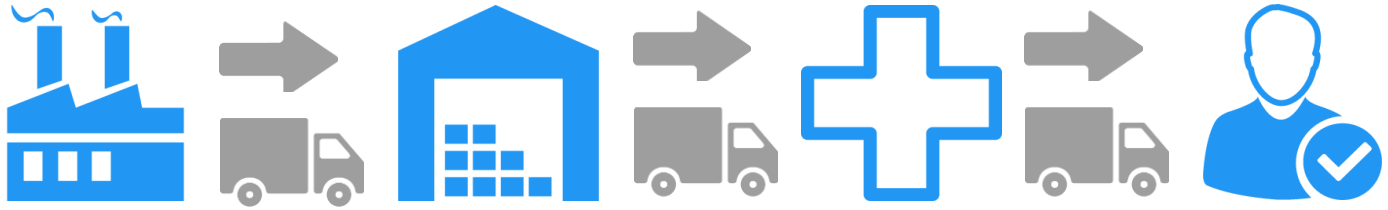
# Cold Chain Compliance

## Importance of Cold Chain Management



# Cold Chain Compliance

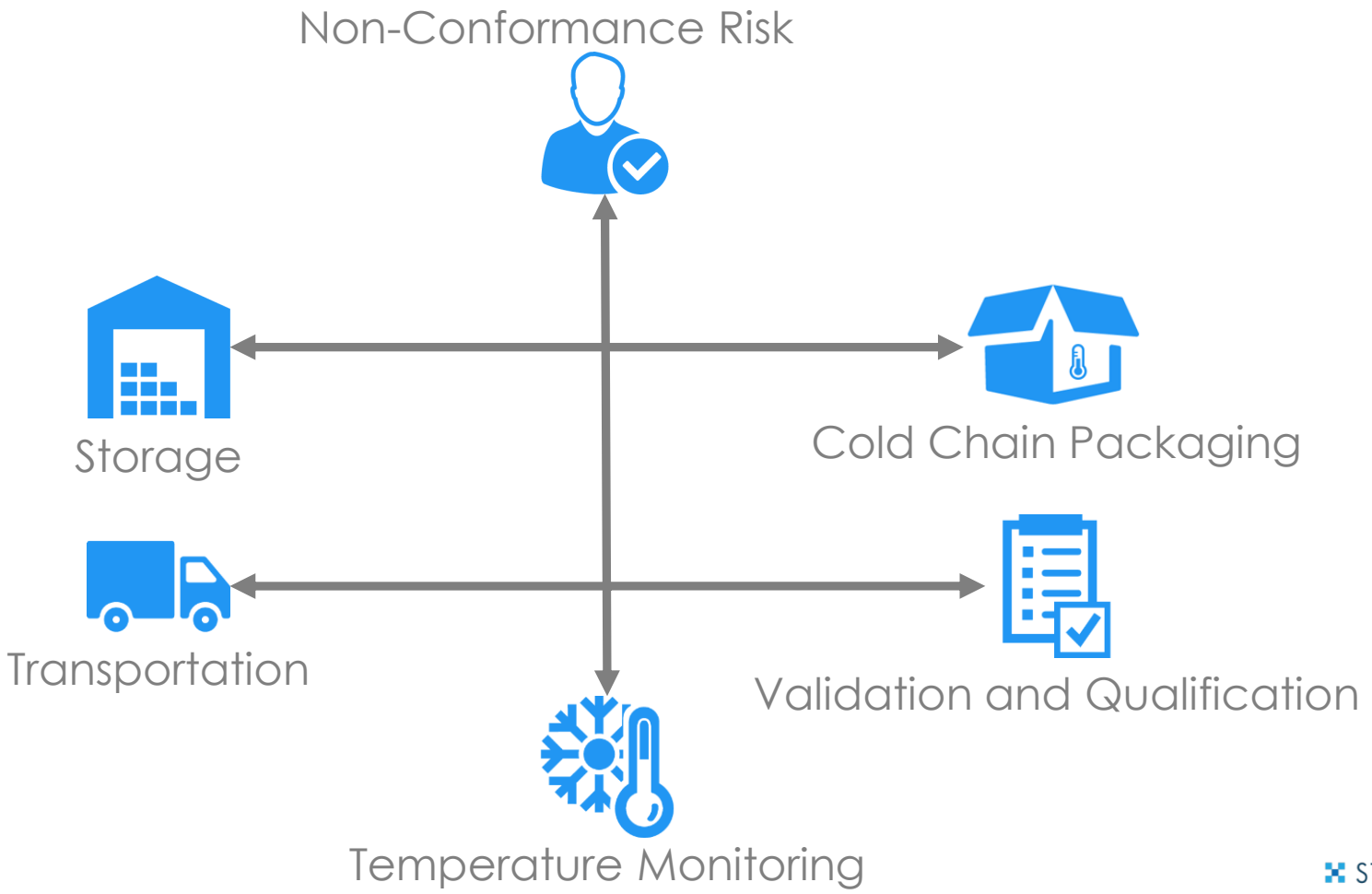
## Regulatory Environment Through the Supply Chain



| Manufacture | Distributor/ Wholesale | Pharmacy | Patient |
|---|---|---|---|
| SAHPRA GMP Updated 2017 | SAHPRA GWP Updated 2016 | Pharmacy Council GPP Updated 2015 | Packaging Label ? |

# Cold Chain Compliance

## Cold Chain Management Framework



# Board Notice 50

**Rules relating to what constitutes good pharmacy practice**

1. In these rules "the Act" shall mean the Pharmacy Act, 53 of 1974, as amended, and any expression to which a meaning has been assigned in the Act shall bear such meaning.

2. The following rules to Annexure A of the *Rules relating to good pharmacy practice* are hereby amended –

   (a) Rule 1.2.1, paragraphs (d) and (e);

   (b) Amendments to Rule 2.3.5

   *Minimum standards for the procurement, storage and distribution of thermolabile pharmaceutical products*; and

   (c) Annexure A: Rule 2.1.1.2.

The following minimum standard as published herewith shall constitute an additional standard as identified as Rule 1.9 to Annexure A of the *Rules relating to good pharmacy practice* in accordance with section 35A(b) (ii) of the Act -

   (a) Rule 1.9

   *Minimum standards relating to automated dispensing units for the purpose of dispensing medicines and medical devices.*

**2.3.5 COLD STORAGE OF PHARMACEUTICALS**

(a) Thermolabile medicines must be kept in a refrigerator.

(b) The refrigerator must be inside the dispensary or clinic and must be readily accessible to the pharmacist.

(c) The refrigerator must only be used for storing pharmaceuticals.

(d) The size of the refrigerator must enable the pharmacist to keep the necessary stock in an organised manner. The size must therefore prevent overloading of the refrigerator at any time.

(e) The refrigerator must be connected to a standby generator or other emergency power system to ensure uninterrupted power supply in case of power (current) failure.

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| Element | Good Pharmacy Practice | Board Notice 50 |
|---|---|---|
| Cold Chain packaging | No | Yes |
| Validation and Qualification | No | Yes |
| Temperature monitoring | Partial | Yes |
| Transportation | No | Yes |
| Storage | Partial | Yes |

Board Notice 50

- 2.3.5.1 Introduction
- 2.3.5.2 Procurement
- 2.3.5.3 Storage area
- 2.3.5.4 Distribution
- 2.3.5.5 Transportation
- 2.3.5.6 Receiving
- 2.3.5.7 Documentation
- 2.3.5.8 Personnel
- 2.3.5.9 Disruption in the procurement, storage and distribution

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## 2.3.5.3. Storage Areas

- Temperature Mapping
  - (b) The storage area must be large enough to allow for orderly arrangement of products, to permit air circulation especially between shelving and for proper product rotation. If it is **filled to capacity, the effect on temperature distribution must be investigated.**
  - (c) The storage area must be kept clean. **Internal air temperature distribution must be mapped** on installation of the storage area **while empty and thereafter fully stocked**. This must be **done annually** under conditions of normal use. Thermolabile pharmaceutical products must **not be stored in areas shown by temperature mapping to present a risk** (e.g. in the airflow from the refrigeration unit).

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## 2.3.5.3. Storage Areas

- Temperature Monitoring
  - (f) A **suitable number of temperature recording instruments that complies with or meets WHO specifications**, **being at least a logging device**, **must be installed to record temperatures** and to provide temperature and profiles as per the temperature mapping of the storage area. Monitors that complies with or meets WHO specifications, must be adequate to monitor and record temperature ranges in all parts of the area within the specified temperature range.
  - (g) Temperatures must be **monitored and recorded at least twice daily**, with a minimum of seven hour interval and the records from such monitoring must be reviewed daily.
  - (h) Large commercial refrigerators and **walk-in cold rooms must be monitored with an electronic temperature-recording device that measures load temperature in one or more location**, depending on the size of the unit.

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## 2.3.5.3. Storage Areas

- Temperature Monitoring
  - (i) In the monitoring of large commercial refrigerators and walk-in cold rooms, **portable data-loggers that can be downloaded onto a computer may be used instead of a fixed device**.
  - (k) The refrigerator**, cold room or freezer must be connected to an alarm system** and/or warning system in the event of a **power failure** or if the **storage area temperature limits are exceeded**.
  - (l) Any recording devices/instruments must **be calibrated annually against a certificated standard**.

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## 2.3.5.4. Distribution

- A distribution system must have in place:
  - (a) a comprehensive **quality system**;
  - (b) a process for **continual quality improvement**;
  - (c) an ambient and **cold chain distribution strategy**;
  - (d) a **risk assessment programme**.

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## 2.3.5.4. Distribution

- Insulated Container
  - (a) Packaging system of thermolabile pharmaceutical products, for purposes of distribution must be **quality assured** to ensure that it **occurs within the cold room** environment, fulfils the manufacturers' specifications requirements, is **thermally designed and validated**, and is related to **Temperature Profile(s)/Logistic history**.
  - (b) There must be clear, **visible labelling** on the packaging with **instructions regarding storage conditions, special precautions and warnings for the shipment**.

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## 2.3.5.5. Transportation

- Transport Method
  - (b) Mode(s) of transportation must be **approved for transporting thermolabile pharmaceutical products**. Examples include refrigerator trucks, cars, ships, and containers. Thermolabile pharmaceutical products shall be transported in any mode(s) of transportation which **is permanently enclosed and sealed**. No open vehicles shall be permitted for purposes of transporting thermolabile pharmaceutical products.
  - (c) In the event of the mode(s) of transport not being specific for the transportation of thermolabile pharmaceutical products, the **specialised packaging like validated cooler bag packaging** must be used.

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## 2.3.5.5. Transportation

- Route Qualification
  - (d) For purposes of transportation, the **route must be planned and assessed and/or validated to ensure that delays and/or exposure to extreme temperatures are correctly assessed.** Transportation between South Africa and other neighbouring countries and within South Africa, due **to large geographical areas, must be treated as unique** in terms of the range of temperatures that the thermolabile pharmaceutical products may experience.

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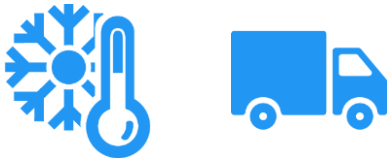
## 2.3.5.5. Transportation



- Temperature Monitoring
  - (h) Temperature data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards **that complies with or meets WHO specifications** must monitor the **temperature of the loaded area of the transportation** throughout the trip, and the **validated cooler box packaging must have at least a temperature monitoring device** that complies or meets with WHO specifications.

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## 2.3.5.5. Receiving

- Temperature Monitoring
  - (d) **The delivery document must be reviewed for evidence that transportation requirements, inter alia temperature control, have been met;**
  - (e) Check temperature data loggers, refrigeration tags, freezer tags, log tags or cold chain monitoring cards to ensure **the temperature history of the transport and the temperature history of the thermolabile pharmaceutical product** being transported were maintained within in limits.
  - (j) Delivery documents must be **signed off on temperature data** and condition of other control devices used.
  - (k) The **thermolabile pharmaceutical products must be removed from the transportation container** or cooler bag **prior to storage in the main store area** to prevent temperature deviation.

# Questions