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The Implementation of Proper Drug Distribution Methods in Handling Cold Chain Products at a Major Pharmaceutical Distributor in Manado City

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ABSTRACT
Good Drug Distribution Practices (CDOB) is a drug distribution method that aims to ensure quality in the distribution process according to the requirements and intended use. Pharmaceutical Wholesalers (PBF) must ensure that the quality and efficacy of products during distribution are in accordance with applicable laws and regulations including Cold Chain Products (CCP) or cold chain products, namely vaccines, biological products, oncology treatments, several types of insulin and other medicines. Pharmaceutical Wholesalers (PBF) play an important role in handling and distributing preparations, including preparations that are sensitive to environmental conditions such as CCP products. This study aims to evaluate the implementation of CDOB in handling CCP products at one of the Pharmaceutical Wholesalers (PBF X) located in Manado City using the BPOM RI self-inspection checklist. The study was conducted in July 2025 with an observational method that is descriptive and evaluative. The results of the study indicate that PBF X has fulfilled all aspects of cold chain product handling related to receipt, storage, and distribution. It can be concluded that PBF X has implemented CDOB aspects in accordance with applicable regulations.

Keyword: CDOB; CCP; PBF

INTRODUCTION

The pharmaceutical supply chain represents one of the most complex and highly regulated distribution systems globally, requiring meticulous attention to product integrity at every stage from manufacturer to end consumer. According to the World Health Organization, temperature-sensitive pharmaceutical products—including vaccines, insulin, biological products, and certain oncology treatments—constitute an increasingly significant portion of the global pharmaceutical market, with the cold chain logistics market projected to reach $16.5 billion by 2025. The efficacy and safety of these products are critically dependent on maintaining strict temperature control throughout the distribution process, typically between 2°C and 8°C, as even brief excursions outside this range can lead to reduced potency, therapeutic failure, or adverse patient outcomes (Tsang et al., 2018).

The cold chain is a form of product supply chain. The product supply chain ensures that cold chain products remain within the specified range during the distribution process. The purpose of the cold chain distribution process is to prevent product damage due to sensitivity to high temperatures and humidity (Priyandari et al., 2017). Cold chain management in the pharmaceutical industry is related to the storage and distribution process, namely maintaining temperature both by air and land. Monitoring the condition and storage of the cold chain is crucial in maintaining the specified environmental conditions, as stated in various regulations, such as the Food and Drug Administration and Hazard Analysis Critical Control Point (Marine et al, 2015). Fluctuating changes in environmental conditions can reduce product quality, which may have negative effects on consumers (Tsang et al, 2018).

PBFs play a crucial role in handling and distributing various products, including environmentally sensitive products such as cold chain products (CCPs). PBFs are required to ensure the quality and effectiveness of distributed products in accordance with applicable laws and regulations. Therefore, based on the Food and Drug Monitoring Agency Regulation Number 6 of 2020 concerning Technical Guidelines for Good Drug Distribution Practices (CDOB), every PBF is required to have a CDOB CCP certificate to ensure that drug quality is maintained throughout the distribution process according to established standards (Astiani and Musfiroh, 2022).

The focus of PBF is to ensure that the quality and efficacy of the product at the time of distribution are in accordance with applicable laws and regulations. Because the selection of a logistics supplier or PBF for the cold chain of drugs usually involves evaluating several alternatives (Kaplinski, 2019), in accordance with BPOM regulation number 6 of 2020 concerning amendments to BPOM regulation number 9 of 2019 concerning Technical Guidelines for Good Drug Distribution Practices (CDOB), PBF must have a CCP Good Drug Distribution Practices (CDOB) certificate to ensure good drug quality, so that the products provided maintain their efficacy. Cold chain logistics in the pharmaceutical industry are largely related to storage and transportation as well as temperature maintenance both in the air and on land.

The urgency of this research stems from several critical factors. First, Indonesia has committed to strengthening its healthcare system, including vaccine distribution for national immunization programs, which requires robust cold chain infrastructure at all levels of the pharmaceutical supply chain. Second, the tropical climate in Indonesia, with high ambient temperatures and humidity, presents particular challenges for maintaining cold chain integrity, increasing the risk of temperature excursions during storage and transportation (Pajic, Andrejic, & Chatterjee, 2024). Third, the expansion of pharmaceutical manufacturing and distribution in Eastern Indonesia necessitates evaluation of cold chain capabilities in this region to ensure equitable access to quality-assured temperature-sensitive medications. Fourth, the COVID-19 pandemic has highlighted the critical importance of vaccine distribution infrastructure, with mRNA vaccines requiring ultra-cold chain conditions that demand even more rigorous temperature control. Fifth, regulatory requirements continue to evolve, with the recent issuance of BPOM Regulation Number 20 of 2025 updating CDOB standards, necessitating current assessments of industry compliance.

The novelty of this research lies in several aspects. First, it provides a comprehensive evaluation of CCP handling covering all three critical stages—receiving, storage, and distribution—using a standardized self-inspection checklist based on current BPOM regulations. This holistic approach enables identification of potential vulnerabilities throughout the entire distribution process rather than isolated segments. Second, the study is conducted in Manado City, Eastern Indonesia, providing valuable regional data that can inform policy development and quality improvement initiatives in areas with unique logistical challenges. Third, the research employs direct observation supplemented by in-depth interviews with key personnel (Pharmacist in Charge, warehouse manager, expedition manager), enabling triangulation of findings and deeper understanding of implementation practices beyond

checklist compliance. Fourth, the study examines both infrastructure requirements (facilities, equipment, temperature monitoring systems) and process elements (standard operating procedures, documentation, personnel training, contingency planning), providing a multidimensional assessment of CDOB implementation.

The primary objective of this study is to evaluate the implementation of Good Drug Distribution Practices (CDOB) in handling Cold Chain Products (CCP) at a major Pharmaceutical Wholesaler (PBF X) in Manado City. Specifically, it aims to: (1) assess compliance with CDOB requirements for CCP receiving procedures; (2) evaluate CCP storage practices including facility requirements, temperature monitoring, and contingency planning; (3) examine CCP distribution processes including packaging, transportation, and documentation; and (4) identify areas for improvement and best practices that can serve as references for other PBF facilities. By achieving these objectives, the research contributes both practically and theoretically to pharmaceutical supply chain management.

The practical contribution of this study lies in providing evidence-based assessment of CDOB implementation that can inform quality improvement initiatives at the study facility and serve as a benchmarking reference for other PBFs in Indonesia. The findings can support regulatory compliance efforts, identify training needs, and highlight areas requiring additional investment or process improvement. Theoretically, the research contributes to the literature on pharmaceutical cold chain management by providing empirical data on implementation practices in the Indonesian context, extending understanding of how regulatory requirements translate into operational practices in real-world settings (Amuta, Muonde, Mustapha, & Mbata, 2021). The study also offers insights into the challenges and solutions associated with cold chain maintenance in tropical developing country contexts, contributing to the broader global discourse on pharmaceutical supply chain integrity. Ultimately, this research aims to support efforts to ensure that patients throughout Indonesia receive temperature-sensitive pharmaceutical products that have maintained their full efficacy and safety throughout the distribution process.

METHOD

The research was conducted in July 2025 at a Pharmaceutical Wholesaler (PBF X) in Manado City. This study used an observational method that was descriptive and evaluative. The research stages included observation and evaluation during the activity. Interviews were conducted with the PBF Pharmacist in Charge (APJ), the warehouse manager, and the expedition manager to confirm each process. Data collection used a checklist developed based on Good Drug Distribution Practices (CDOB).

RESULTS AND DISCUSSION

Pharmaceutical Wholesaler (PBF X) was selected as the research location because it is one of the PBFs that distributes Cold Chain Products (CCP) in significant quantities. The research followed established guidelines. Observations were conducted at each stage of CCP handling based on Good Drug Distribution Practices (CDOB) guidelines, including receiving, storage, and distribution. The research results are shown in Table 1.

Table 1. Observation Results of CCP Handling Based on CDOB

No	CDOB elements	Implementation
	CCP Specific Documentation	
1	Standard operating procedures for receiving, storing and shipping	Yes
2	Storage instructions to customers	Yes
	CCP Building and Storage	
3	There is a separate place for storing cold chain products	Yes
4	Storage space according to criteria (minimum chiller)	Yes
5	Validation of storage areas is carried out periodically at least once a year	Yes
6	Storage room temperature according to specifications	Yes
7	The temperature of the storage room is monitored and recorded periodically (at least three times a day)	Yes
8	There is a calibrated temperature data logger to monitor the temperature.	Yes
9	There is an alarm that can provide critical warnings and regular checks are carried out	Yes
10	There is a generator (automatic or manual) that works well	Yes
11	Procedure for handling CCP products if the storage area experiences disruption/damage (contingency plan)	Yes
12	CCP handling procedures in the event of damage, expiration and unsaleability	Yes
	CCP Distribution	
13	CCP distribution uses airtight containers containing ice packs or dry ice to achieve the appropriate temperature	Yes
14	During transportation, vaccines are handled in accordance with the provisions	Ya

CCP handling aims to ensure the quality of CCPs during the receiving and storage processes, thereby preventing losses due to improper handling and storage. This involves various parties, including the Responsible Pharmacist, who is responsible for ensuring the accuracy and conformity of product receipts until they are inputted manually or by the warehouse system; the Head of Logistics/Warehouse, who is responsible for the conformity of product receipts, coordinating storage and recording; and warehouse staff, who are responsible for ensuring the conformity of storage and recording on stock cards.

Temperature-sensitive pharmaceutical products are perishable and require monitoring and distribution in a controlled environment. These products include ergometrine, oxytocin, and insulin, vaccines, cold chain supplies, and diagnostic reagents (rapid HIV test kits). The potency of these products may be reduced or even lost if exposed to temperatures outside the recommended range. Therefore, storage should be maintained between 2°C and 8°C throughout the supply chain. All activities related to CCP management must be carried out in accordance with CDOB guidelines (Desai, Colandene, & Adams, 2020). The CCP management process encompasses product receipt, storage, and distribution. Temperature monitoring at each stage of the distribution chain plays a crucial role in ensuring product quality is maintained until it reaches the end consumer.

Temperature-sensitive pharmaceutical products require stable and consistent storage conditions. Therefore, routine maintenance is necessary to ensure optimal operation of equipment such as chillers, cold rooms, and freezers, ensuring temperatures are maintained within established standards. Furthermore, operational efficiency can be maintained through

regular maintenance and an adequate control system that minimizes the risk of equipment failure that could potentially hinder the distribution process. An effective monitoring system also allows for early identification of potential problems, allowing for prompt corrective action before product quality declines (Sari and Amalia, 2024).

The PBF's ability to maintain the quality of its CCPs (Cutting Points) can enhance consumer and business partner confidence in pharmaceutical products. The PBF's consistency in ensuring product quality is maintained throughout the distribution process is a key factor in maintaining CCP integrity. Three critical aspects of good CCP management include the availability of trained personnel, the use of reliable storage and temperature monitoring equipment, and the implementation of appropriate CCP inventory management (Cvetanovski et al., 2020; Ogboghodo et al., 2017).

The research results in Table 1 indicate that PBF X has implemented CDOB effectively in handling CCPs. The CCP product handling process at PBF X is carried out by personnel who understand their responsibilities, particularly in CCP handling, and have received relevant training. Inadequate training will impact efforts to maintain CCP quality. Inadequate personnel training poses a risk to CCP quality (Hibbs, 2018). Training is also provided to drivers responsible for CCP transportation. For CCPs, there are specific requirements for cold chain product storage, namely in a chiller or cold room (temperature 2°C to 8°C).

Self-inspections and internal audits are mandatory for companies to evaluate the progress and results of implementation over a period of time. Each company has a policy regarding self-inspections and internal audits. Evaluation of drug handling includes not only the preparation of the product, but also the equipment and facilities supporting drug storage, as well as other evaluations to ensure that drug quality remains good until distribution (Organization, 2024). Of the many pharmaceutical preparations stored at PBF, subject to various factors such as drug stability, dosage form, and so on, cold chain products are one of the most vital preparations and must be stored very well to prevent drug damage before distribution and cause losses to the company. Temperature-sensitive pharmaceutical products are sensitive and easily damaged, thus requiring supervision and distribution in a controlled environment.

Reception

Before being received, CCP products are moved to the cold storage/frozen storage receiving area, where they are unpacked and stored. All personnel involved are required to wear Personal Protective Equipment (PPE), such as gloves and masks. The next step is to inspect the goods by a receiving checker. This is to ensure the quality of the CCP remains unchanged during the product handover process from the supplier driver to the PBF warehouse. The next step is to provide the CCP with a thermometer to record the temperature when the product first enters the warehouse, which is then recorded on a temperature recording card. If there are any issues with product receipt, and if the temperature does not fall within the specified range or if a thermometer is missing, a goods receipt report is prepared and sent to the responsible pharmacist (APJ) at the central office.

Upon receipt, CCP products must be checked to ensure they are in good condition upon arrival from the shipping service, are equipped with the correct number of ice packs, and maintain a stable temperature according to the CCP product storage guidelines (BPOM RI,

2020). CCP products must be handled carefully to ensure they remain in good condition until they are received by the PBF, and to ensure there are no irregularities. Deviations that occur can result in delays in patient care, ineffective therapy, and also financial losses (ASHP Innovation Center, 2022).

PBF X has a dedicated POB for CCP acceptance. CCP products are highly temperature-sensitive and require a dedicated POB that is distinct from other product acceptance POBs. This is because if CCP products are not properly checked upon acceptance, the impact can be fatal, as deviations may already be present from the initial acceptance. Based on the CDOB guidelines, the following inspections must be performed upon acceptance:

a. name of cold chain product received;
b. number of cold chain products received;
c. physical condition of cold chain products;
d. batch number;
e. expiration date
f. condition of the temperature monitoring device; and
g. Vaccine Vial Monitor (VVM) condition (specifically for vaccines equipped with VVM) (BPOM RI, 2020).

Storage

Based on the CDOB guidelines, buildings used for cold chain product storage must have adequate security to prevent unauthorized access. Furthermore, adequate areas must be available for receiving and shipping cold chain products to be shipped at controlled temperatures, and these areas must be close to the temperature-controlled storage areas. Furthermore, buildings used to store cold chain products must be ensured to have adequate security to prevent unauthorized access (BPOM RI, 2020; ASHP Innovation Center, 2022). Any deviations from the above factors during product receipt inspection must be immediately reported to the CCP (Container Controlled Product Processing Unit) sending the product for further investigation and a report of the deviation.

Based on the 2020 CDOB, cold chain products must be stored in a temperature-controlled room, a cold room/chiller (+2°C to +8°C), and a freezer/freezer (-25°C to -15°C) (BPOM RI, 2020). With Standard Operational Procedures (SOPs), SOPs can help maintain organization in facilities, serve as a reference and training tool, and ensure proper product management (CDC US, 2023). During storage, temperature checks must be conducted regularly. This ensures that the temperature in the room is recorded and controlled by the responsible pharmacist to ensure product quality does not change. To determine the overall room temperature, temperature mapping is performed. Temperature mapping is an activity carried out to determine the diversity or distribution of temperature in the room. The objectives of temperature mapping are:

1. Knowing the temperature fluctuations in the storage area
2. Determining the critical temperature location in the storage area
3. Base for placing the thermometer sensor
4. Done once a year/according to changes in storage layout

5. The recorded temperature is then documented.

Temperature mapping is the activity of monitoring temperatures at several points within a room. The temperature recording device is placed at the worst point, the location with the highest temperature fluctuations. This point serves as a reference for the placement of the data recording sensor. The purpose of temperature mapping is to determine the temperature variations and ranges in the drug storage warehouse. Furthermore, temperature mapping also aims to identify critical points that will later be used as a reference for temperature sensor placement in the chiller. Through this activity, data will be obtained regarding the points with the lowest and highest temperatures in the chiller. The lowest point is the location that tends to have a lower temperature than other areas, while the highest point is the location with a higher temperature trend than the surrounding area. In addition to the highest and lowest points, temperature mapping can also detect critical points, namely locations with extreme temperature fluctuations that approach the limits or range of the room's storage temperature. Temperature mapping activities are carried out routinely once a year or when there are changes in the storage area layout. Temperatures that do not comply with drug storage specifications have the potential to alter the therapeutic effect and can lead to the emergence of dangerous, unexpected side effects from drug use. One type of drug that requires special storage conditions is Cold Chain Products (CCP) (Pamungkas and Musfiroh, 2023).

At PBF X, CCPs are stored separately from other products in the PBF. This storage area is a special room with controlled temperature, so that each product is stored at the required temperature. A chiller is used to store products in good condition as well as products that are unsaleable, damaged, and nearing the ED, but are stored separately. The use of a chiller is a very important and mandatory factor in storing CCP products for PBFs that distribute CCP products, and are included in the Critical category based on the criticality category that refers to the CDOB guidelines. The chiller is set at a temperature of 2-8°C in accordance with the CCP storage specifications stipulated in the CDOB guidelines (BPOM RI, 2020). After being checked by personnel delegated to the CCP receiving section, CCP products must be immediately stored in the chiller to minimize the risk of product damage. Good CCP storage is essential, especially for products such as vaccines. Failure to store and handle vaccines properly can reduce vaccine potency, resulting in an inadequate immune response in patients and poor protection against disease (US CDC, 2023).

Observations at PBF X revealed a refrigerator/freezer used for storing ice packs. The ice packs are stored in a freezer (-25°C to -15°C), separate from the CCP product storage area. Ice pack storage is categorized as critical on the self-inspection checklist. Ice packs, which will be shipped as supporting facilities for CCP product stability, must also be stored properly and in accordance with the conditions and requirements to ensure the product reaches the outlet in the same condition as when stored in the PBF warehouse.

Periodically, the storage area is validated at least once a year. The thermometer used is calibrated. Observations indicate that temperature monitoring is carried out routinely by warehouse staff three times daily. This aligns with the regulations stipulated in the 2020 CDOB, which stipulate that CCP product storage areas must have a continuous temperature monitoring system using sensors placed in locations that exhibit extreme temperature variations (BPOM RI, 2020).

In temperature monitoring efforts, a calibrated temperature data logger is used. A temperature data logger is a device used to measure temperature and humidity, recording temperatures at predetermined time intervals. The recorded temperature data can be downloaded to a computer for analysis and storage condition checks. Regularly verifying the calibration status of the temperature logger is crucial to ensure accurate and continuous information regarding product storage conditions. Furthermore, it is important to regularly clean the measuring device and take appropriate precautions to prevent damage to the sensor. Temperature and humidity sensors should be installed in areas with the highest temperatures, based on temperature mapping results at that location (Kumar and Jha, 2017). A warning alarm is set to monitor the temperature stability. This alarm is very important and is categorized as Major, as it can have fatal consequences if the product is not stored at the required temperature. If the temperature in the chiller is below 2°C or above 8°C, an alarm will sound and can be immediately checked by delegated personnel and reset to keep the temperature within the 2-8°C range. One of the tools for monitoring temperature or certain Temperature Monitoring Devices (TMD) recommended by the Centers for Disease Control and Prevention (CDC) is also called a Digital Data Logger (DDL), which can provide a lot of accurate storage unit temperature information, recorded at predetermined intervals, and including details about how long the unit has been operating outside the recommended temperature range (CDC US, 2023).

Product storage at PBF X complies with applicable regulations, as per the 2020 CDOB guidelines, which state that vaccines must be stored in chillers and freezers with a minimum distance of 1-2 cm between boxes to prevent overcrowding and maintain air circulation (BPOM RI, 2020). Furthermore, a minimum distance of 15 cm must be maintained between the chiller/freezer and the building walls. Observations at PBF X revealed that there is sufficient space between the freezer and the building walls, and each medicine box is spaced accordingly to prevent overcrowding.

BPOM RI guidelines require routine qualification of dedicated storage areas (coolers/cold rooms/freezers) for CCPs at least once a year, and if conditions change with their specifications. PBF X routinely performs performance qualification once a year for its chiller, which serves as a dedicated storage area. All qualification, calibration, and validation measures have been documented in accordance with CDOB requirements. Furthermore, shipping processes must be validated to ensure shipping temperatures do not exceed required levels. All these measures must also be documented (BPOM RI, 2020). All CCP product delivery methods and processes at PBF X have been validated.

PBF X has a well-functioning generator. This generator is particularly useful in the event of a power outage, as it is categorized as critical. PBF X has dedicated personnel responsible for ensuring the generator's 24-hour operation. There are rotating shifts for personnel. In the event of a power outage, personnel on duty promptly check the temperature and ensure the generator is functioning properly. They then continue monitoring until the power is restored.

PBF X has a contingency plan, or system for handling CCP products in the event of a storage facility malfunction. This is especially important for CCP products, which are highly sensitive to temperature and have a higher risk of rapid deterioration, requiring immediate

action. If damage to the chiller occurs and further action is required, a report should be filed immediately and follow-up instructions should be provided.

PBF X has a CCP handling procedure in the event of damage, expiration, and unsaleable products. The steps taken include separating and storing CCP products that are unsaleable by labeling them with the reasons. The products are stored in a separate, locked chiller, and a report is made regarding the product. Next, a decision is awaited regarding the action to be taken regarding the unsaleable product. PBF X has met the CCP storage requirements, where the CCP storage chiller must be equipped with a lockable door/cover (BPOM RI, 2020).

Distribution

CCP distribution must use airtight containers equipped with appropriate ice packs or cool packs to maintain the required temperature during shipping. CCPs must be shipped quickly to maintain the product's temperature. PBF X has validated the CCP delivery process. Maintaining the efficiency of the cold chain from the point of production to its use among beneficiaries is crucial. This is in accordance with procedures, where validated temperature control systems (e.g., thermal packaging, temperature-controlled containers, and refrigerated vehicles) must be in place to ensure proper transportation conditions are maintained between distribution facilities and customers. Customers must receive temperature data upon handover of the drugs and/or drug substances. If necessary, customers can obtain temperature data documentation to demonstrate that the drugs and/or drug substances remained at the required storage temperature conditions during transportation (BPOM, 2020).

PBF X has a special POB for CCP shipments, which differs from the shipment of other regular products. Transportation is a crucial aspect of CCP product delivery, and it must be carefully maintained to ensure drug quality during delivery (Aprini & Alfian, 2023). CCPs must also be considered not only during storage but also during delivery, as they are susceptible to damage if not properly stored in a cooler box. This can result in the product being out of specification or not meeting the requirements (TMS). Products with TMS may be rejected by outlets/facilities. CCP product delivery must consistently maintain the product in a safe and efficacious condition and comply with ever-increasing compliance requirements (PELI Biothermal, 2019).

Vaccine transportation at PBF X has been handled in accordance with regulations. Customer data has been well documented for easy tracking, including estimated product arrival times. PBF X routinely evaluates the CCP delivery process. The First Expire First Out (FEFO) principle is used in the product delivery process, where products with shorter expiration dates or those closest to the expiration date are distributed first, to avoid product buildup or undistributed expired products. Before storing and shipping CCPs, temperature checks are carried out according to those stated in the POB at PBF X. The checks are carried out to re-confirm that the products have been stored properly and that the products that will be sent to customers are products that meet requirements. Then, during the shipping process, the products are stored in cooler boxes with ice packs to maintain temperature stability.

During the CCP delivery process, officers carry a temperature monitoring form. This form contains temperature check data from storage, shipping, and receipt, which is documented by PBF X and the outlet. Products arriving at the facility are first inspected to ensure they are

in good condition and at a stable temperature before being received by the customer. An invoice is then signed confirming the product has been received in good condition.

According to applicable regulations, PBF must provide CCP storage instructions to customers upon product arrival. This includes a reminder label stating "Caution! Products must be stored at a temperature of 2-8°C" that is visible to customers upon arrival and is also directly reminded by the personnel on duty.

CCP handling must be handled by competent personnel. Therefore, PBF must provide training to Warehouse personnel who perform tasks in CCP management. Personnel must update appropriate storage and transportation methods, as well as temperature control during the process at the storage and transportation facilities. This is done to overcome the problem of breaking the chain in the distribution of CCP (Maglasang et al., 2018). PBF X provides opportunities for each personnel to participate in various activities in an effort to improve their competence according to their duties and responsibilities.

CONCLUSION

Based on the results of the research that has been conducted, it can be concluded that PBF X in Manado City has implemented the CDOB aspects in accordance with applicable regulations, where self-inspection of the CDOB aspects of handling CCP products has been carried out and fulfilled properly and in accordance with the requirements for acceptance, storage and distribution stated in the CDOB guidelines.

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