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PHARMACOECONOMIC IMPLICATIONS OF *CARA DISTRIBUSI OBAT YANG BAIK* NON-COMPLIANCE AMONG PHARMACEUTICAL WHOLESALERS IN INDONESIA: A NARRATIVE REVIEW

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ABSTRACT

Challenges and obstacles in the pharmaceutical distribution chain arising from misalignment between good distribution practice (GDP), locally referred to as cara distribusi obat yang baik (CDOB), and the operational interests of pharmaceutical wholesalers (Pedagang Besar Farmasi, [PBF]) may contribute to pharmaceutical and public health risks that undermine health system resilience. This study aimed to identify key forms of CDOB non-compliance and to analyse their pharmacoeconomic implications within the Indonesian pharmaceutical distribution system. This narrative review analysed 23 national and international journal articles retrieved from Google Scholar, PubMed and national journal portals using the keywords "good distribution practice", "good drug distribution methods", "pharmaceutical wholesalers", "CDOB", "distribution of medicines" and "pharmacoeconomic impact". The literature was analysed descriptively and thematically, with findings categorised according to major CDOB aspects (health, appropriateness and safeguarding) based on Indonesian National Agency of Drug and Food Control (BPOM) Regulation No. 6 of 2020 and BPOM Regulation No. 20 of 2025. The findings indicate that CDOB non-compliance in Indonesia is commonly associated with disruptions in medicine availability, distribution delays and deterioration of product quality during storage and transportation, all of which negatively affect health service delivery and generate avoidable economic burdens. Strengthened regulatory enforcement, continuous monitoring and improved alignment between CDOB requirements and PBF operational practices are essential to enhance distribution efficiency and minimise pharmacoeconomic losses within the national health system.

Keywords: Good distribution practice, Pharmaceutical distribution, Pharmaceutical wholesalers, Regulatory compliance, Pharmacoeconomics

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INTRODUCTION

The pharmaceutical distribution chain is a critical component of the global pharmaceutical service system, as it determines the quality, safety and availability of medicines until they reach healthcare facilities and end users. This view is consistent with Busola (2024), who explains that the scope of the pharmaceutical distribution chain encompasses processes that ensure the availability of medicines, vaccines and essential medical supplies required by healthcare providers and patients. In many countries, including Indonesia, challenges in maintaining medicine quality integrity have intensified due to the increasing complexity of pharmaceutical supply chains, geographical conditions and the large number of distribution stakeholders involved. Failure to comply with established distribution regulations may place healthcare facilities at risk of losing public trust, as inadequate pharmaceutical services and medicine availability can pose threats to patient safety (Nasihardani *et al.* 2025).

To ensure that medicine quality is maintained throughout storage, handling and distribution processes, regulatory authorities worldwide have implemented good distribution practices (GDP). The World Health Organization (WHO) emphasises that GDP plays a vital role in preventing quality degradation, minimising contamination risks and curbing the circulation of substandard and falsified medicines.

In Indonesia, GDP principles are implemented through *cara distribusi obat yang baik* (CDOB), as regulated by the Indonesian National Agency of Drug and Food Control (BPOM) under Regulation No. 9 of 2019, with subsequent technical amendments introduced through Regulation No. 6 of 2020 and the establishment of updated national standards under BPOM Regulation No. 20 of 2025. The most recent regulation further strengthens quality assurance mechanisms, risk management and supply chain integration within the national pharmaceutical distribution system. The pharmaceutical distribution system in Indonesia comprises a series of interconnected components responsible for maintaining medicine quality from production through to receipt by end users. BPOM Regulation No. 20 of 2025 on CDOB standards stipulates that medicines may only be distributed through authorised channels to ensure safety, quality and efficacy. Within this regulatory framework, the distribution process begins with pharmaceutical manufacturers or importers as the primary sources of medicinal products, followed by pharmaceutical wholesalers (Pedagang Besar Farmasi, [PBF]) as the principal distributors responsible for storage, transportation and large-scale distribution at national and regional levels. Medicines are subsequently supplied to healthcare facilities, including hospitals, pharmacies, primary healthcare centres and clinics, before ultimately reaching patients as end users. This supply chain therefore requires effective coordination and collaboration among multiple stakeholders, including suppliers, manufacturers, distributors, retailers and consumers (Momena, Gazi and Mondal 2025). Consequently, PBF represent a critical intermediary link, playing a pivotal role in maintaining medicine integrity and continuity of quality, while simultaneously serving as a focal point for CDOB implementation in Indonesia.

Traditionally, PBF have been responsible for the transportation and logistics of pharmaceutical products (Wong, Lo and Hu 2012). PBF therefore occupy a strategic position in ensuring that medicine quality and safety are preserved from the point of manufacture to healthcare facilities. To regulate this role, BPOM has issued several regulations governing CDOB, encompassing both technical guidelines and national standards. Among these regulations, BPOM Regulation No. 20 of 2025 and BPOM Regulation No. 6 of 2020 currently serve as the primary regulatory references. All PBF activities are required to comply with CDOB standards as stipulated in BPOM Regulation No. 20 of 2025, while operational details are further elaborated in the CDOB Technical Guidelines under BPOM Regulation No. 6 of 2020, which revised BPOM Regulation No. 9 of 2019. These regulations address

critical aspects that must be fulfilled by PBF, including quality management systems, personnel competence and training, adequacy of facilities and equipment, documentation systems, storage and transportation controls, as well as the handling of returned, damaged or expired products.

Despite the existence of comprehensive regulations, national monitoring results indicate that CDOB implementation among PBF remains suboptimal. A study by Dinianty, Rohendi and Mulyani (2025) reported that pharmaceutical distribution in Aceh Province continues to face stock-related challenges, including stagnant inventory, discrepancies between physical stock and stock records and the circulation of medicines nearing expiration during the distribution process. Quality deterioration of pharmacological products has also been identified as a major barrier to effective distribution. Suhendi and Darmawan (2022) found that Rumah Sakit Umum Daerah (RSUD) Kembangan, one of the largest healthcare facilities in West Jakarta, experienced declining medicine quality and shortened shelf life due to delays in distribution processes. Furthermore, insufficient support from PBF in developing adequate distribution facilities, coupled with inaccurate distribution forecasting systems, has been identified as a contributing factor to the suboptimal implementation of CDOB (Almahera 2024).

Similar challenges have been observed globally, particularly in developing countries facing infrastructural constraints, limited monitoring systems and insufficient digitalisation of distribution processes. These findings indicate that non-compliance with GDP or CDOB standards is not solely a local issue but represents a broader challenge within global pharmaceutical supply chains. Pezzola and Sweet (2016) reported that one contributing factor to suboptimal pharmaceutical distribution is the misalignment between wholesaler interests and local regulatory frameworks in developing countries. Challenges related to non-compliance with GDP standards are not limited to developing regions; countries in Southeast Europe also face risks associated with dynamic regulatory environments and complex distribution systems. This assertion is supported by Grujić, Morača and Fajsi (2020), who identified that pharmaceutical distribution disruptions and non-compliance with GDP standards in Southeast Europe are commonly associated with internal risks, such as organisational and resource-related factors, as well as external risks, including regulatory changes and technical distribution challenges. From a more contemporary perspective, Hertig, Baney and Weber (2019) examined emerging risks related to pharmaceutical counterfeiting within online distribution systems. Collectively, these risk factors demonstrate that pharmaceutical distribution integrity has not yet been fully assured and continues to pose potential threats to medicine quality within healthcare systems at both national and global levels.

Although numerous studies have examined CDOB and GDP compliance, literature integrating distribution quality with its economic implications remains limited, particularly within the Indonesian national context. Existing studies implicitly describe the economic losses that may be incurred when misalignment occurs between CDOB regulations and PBF practices; however, these impacts are rarely articulated explicitly. Consequently, scholarly work that systematically examines the pharmacoeconomic implications of CDOB non-compliance in relation to the role of PBF is warranted. Addressing this gap, the present narrative review aims to synthesise scientific evidence on CDOB and GDP implementation, patterns of non-compliance among PBF, the impact of such non-compliance on medicine quality and safety, and the associated economic burden from a pharmacoeconomic perspective. The review organises its discussion into key thematic areas to provide a systematic overview of CDOB implementation challenges and opportunities for improving efficiency within the national pharmaceutical distribution system.

METHODS

This study employed a qualitative narrative review design to analyse non-compliance between the implementation of CDOB and the practices of PBF, as well as its pharmacoeconomic implications. Qualitative research was selected to enable an in-depth and contextual understanding of regulatory misalignment and its impact on pharmacoeconomic outcomes (Lim 2024; Oranga and Matere 2023).

A narrative review approach was chosen to synthesise evidence from previously published studies and to integrate diverse perspectives related to CDOB and GDP implementation (Sukhera 2022; Agus *et al.* 2023; Nahdiyin 2023). Literature searches were conducted systematically across Google Scholar, PubMed and national journal portals, yielding 23 relevant national and international journal articles published between 2012 and 2025. The majority of the included studies were published within the last five years, indicating that the review reflects relatively recent developments in CDOB implementation and pharmaceutical distribution practices both nationally and internationally. Keywords used included "cara distribusi obat yang baik", "good distribution practice", "Pedagang Besar Farmasi", "CDOB", "GDP", "distribution of medicines", and "pharmacoeconomic impact". Eligible articles included observational studies, CDOB implementation evaluations, literature reviews, and narrative reviews that explicitly addressed CDOB or GDP compliance among PBF and were relevant to the Indonesian or comparable global regulatory contexts. Several articles were excluded due to lack of full-text availability and were therefore not included in the analysis, which may introduce a degree of selection bias and potentially limit the comprehensiveness of the review.

Data reduction was performed to extract key findings relevant to CDOB non-compliance and pharmacoeconomic impacts through summarisation and thematic categorisation (Rijali 2018). Data were analysed using thematic analysis to identify recurring patterns, risk factors and pharmacoeconomic barriers within the pharmaceutical distribution system (Heriyanto 2018). Findings were grouped according to the main CDOB aspects outlined in BPOM Regulation No. 6 of 2020 and BPOM Regulation No. 20 of 2025 and presented descriptively to provide a systematic and contextual synthesis of the literature (Rengkuan, Liando and Monintja 2023).

RESULTS

Regulatory Framework for Pharmaceutical Distribution in Indonesia

The regulatory authority responsible for pharmaceutical product circulation and distribution in BPOM. BPOM is mandated to supervise the safety, quality and efficacy of pharmaceutical products distributed nationwide through regulatory oversight, testing and licensing mechanisms prior to market authorisation (Silvia and Pitta Allagan 2024). Within the pharmaceutical sector, BPOM has established a structured national regulatory framework governing drug distribution, primarily through the implementation of GDP known as CDOB.

CDOB functions as the national equivalent of GDP and regulates pharmaceutical distribution activities conducted by PBF. The regulation aims to ensure that distributed medicines comply with health principles, prevent circulation through illegal channels, minimise the distribution of counterfeit products and reduce misuse and diversion within the supply chain (As'hari, Wiedyaningsih and Yasin 2024). In addition to safeguarding public health, CDOB serves as a mechanism to control the integrity of pharmaceutical distribution networks involving manufacturers, wholesalers, healthcare facilities and end

users. From a regulatory standpoint, the legal foundation for pharmaceutical distribution in Indonesia is anchored in the Ministry of Health Regulation No. 1010/MENKES/PER/XI/2008 concerning Drug Registration. This regulation stipulates that all pharmaceutical products distributed nationally must undergo proper registration, production and distribution processes to ensure compliance with quality standards and therapeutic safety. Consequently, medicines produced or distributed without regulatory approval are prohibited from entering the legal supply chain (Gondokusumo and Amir 2021). This framework demonstrates the government's effort to mitigate risks arising during distribution activities and to strengthen national pharmaceutical governance.

At the global level, pharmaceutical distribution is regulated under the framework of GDP, which provides guidelines for wholesale distribution to maintain product quality and integrity throughout the supply chain, from manufacturers to end users (Ukamaka *et al.* 2022). While GDP is designed to standardise distribution practices internationally, several studies have identified challenges in its implementation, particularly when global guidelines are not fully aligned with national regulations. Regulatory misalignment between GDP and national distribution policies has been associated with distribution delays, including the phenomenon of drug lag, where supply disruptions occur due to regulatory discrepancies (Cho and Han 2022).

Furthermore, inadequate alignment between regulatory requirements and operational capacities of PBF has been shown to impose additional operational burdens, leading to increased distribution costs, pricing pressures and stock instability within pharmaceutical supply chains (Yu and Lee 2023). These findings indicate that regulatory frameworks, while essential for safeguarding medicine quality and safety, may also generate operational and economic challenges when not implemented in a harmonised and context-appropriate manner. Based on these considerations, the present narrative review categorises and analyses reported deviations in CDOB implementation across specific regulatory and operational aspects to identify recurring patterns of non-compliance and their implications.

Quality Management and Personnel

Within the CDOB regulatory framework, quality management and personnel are comprehensively governed by two principal instruments: the CDOB Standards stipulated in BPOM Regulation No. 20 of 2025 and the CDOB Technical Guidelines outlined in BPOM Regulation No. 6 of 2020. Both regulations establish that the quality of pharmaceutical distribution can only be ensured through the integration of a structured quality management system and adequately competent personnel. BPOM Regulation No. 20 of 2025 defines core requirements, including quality policy, risk management, internal audit, change control, deviation management, and the central role of the Responsible Pharmacist (Apoteker Penanggung Jawab, [APJ]). In parallel, BPOM Regulation No. 6 of 2020 provides operational guidance for implementation through the development of standard operating procedures (SOPs), deviation investigations, Corrective and Preventive Action (CAPA), validation of distribution processes and initial as well as continuous training programmes for all personnel. Collectively, these regulations establish that compliance with CDOB depends on the effective functioning of the quality management system and the competency and active involvement of personnel, particularly the APJ.

Cross-analysis of six studies demonstrates that quality management and personnel constitute the aspect with the highest level of non-compliance in CDOB implementation among PBF in Indonesia (see Table 1). Studies conducted in Surabaya and Banjarmasin reported that internal audits were not conducted routinely, while an

evaluation by Balai Besar Pengawas Obat dan Makanan (BBPOM) Bandung revealed that the majority of PBF lacked adequate self-audit records (Agustyani *et al.* 2016; Santika, Srivinka and Ugrasena 2025; Yusuf and Avanti 2020). These findings are inconsistent with BPOM Regulation No. 20 of 2025, which mandates internal audit as a fundamental element of the quality management system. The absence of routine audits resulted in undetected and unaddressed quality deviations. In addition, several studies reported that quality reviews were not performed and CAPA processes were poorly monitored, as observed in the evaluation of PBF Y and national-level reviews (Darmayanti, Mahadewi and Ugrasena 2025; Mustaqimah *et al.* 2021). These findings indicate that PBF have not implemented continuous evaluation mechanisms that are essential for risk control within the CDOB framework.

Table 1: Summary of literature on quality management and personnel-related findings.

Title	Study Focus	Key Findings
CDOB and its implementation by PBF in Banjarmasin–Banjarbaru	Evaluation of CDOB implementation and quality management & human resource performance of PBF.	CDOB training was unevenly implemented. The APJ did not optimally perform quality oversight. Internal audits were not conducted routinely. Quality review processes were not implemented. Quality documentation was incomplete.
Evaluation of CDOB compliance at PBF and branches under BBPOM Bandung	Assessment of CDOB compliance and identification of weaknesses in quality management and personnel.	Organisational structure and personnel frequently failed to meet CDOB requirements. Most wholesalers did not conduct internal audits. Personnel demonstrated limited understanding of CDOB. CAPA implementation was incomplete. Quality documentation was inconsistent.
Evaluation of CDOB implementation as a quality assurance system at PBF in Surabaya	Assessment of CDOB implementation as a drug distribution quality assurance system.	The responsible pharmacist had not received formal CDOB training. Quality reviews were not conducted. Internal audits were weak. SOPs were not periodically reviewed. Logistics personnel competencies varied.
Implementation of CDOB in delivery SOPs at PBF Y (APJ perspective)	Evaluation of delivery SOPs compliance with CDOB and the role of the responsible pharmacist.	The responsible pharmacist was not involved in SOPs development. Training was provided but not comprehensive. CAPA was poorly monitored. Internal audits were conducted but ineffective. Quality documentation was suboptimal.
Implementation of CDOB in goods receiving SOPs at PBF X	Evaluation of goods receiving SOPs compliance as part of distribution quality assurance.	SOPs were not periodically reviewed, indicating weak quality management. Damage reporting remained manual, reflecting suboptimal documentation. The APJ's role was limited to final verification. Personnel required further training.

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Table 1: (*Continued*)

Title	Study Focus	Key Findings
Narrative review: Implementation of good distribution practice at PBF	National-level review of CDOB implementation patterns with a focus on quality management and personnel.	Quality management was the most frequently non-compliant aspect. Internal audits were not routine and CAPA was not implemented effectively. Personnel were often not trained in CDOB. Responsible Pharmacists tended to have passive or administrative roles. A quality culture was not well established.

Deficiencies were also evident in document control practices. Several PBF reported that SOPs were not reviewed periodically and that quality documentation was inconsistent, with some documentation still maintained manually (Asyifa and Raden 2025). This practice does not comply with CDOB requirements, which mandate regular SOP updates to reflect current distribution practices. In relation to BPOM Regulation No. 6 of 2020, the technical guidelines explicitly require competent personnel, continuous CDOB training and active involvement of the APJ in SOPs development, quality supervision and self-audit activities. However, the reviewed studies consistently reported uneven and incomplete training coverage, particularly among logistics and operational staff (Mustaqimah *et al.* 2021; Yusuf and Avanti 2020). In the case of PBF Y, although training programmes were conducted, understanding among personnel remained inconsistent, resulting in improper SOPs implementation (Darmayanti, Mahadewi and Ugrasena 2025).

Furthermore, suboptimal involvement of the APJ was identified across multiple PBF. Several studies reported that APJ were not involved in SOPs preparation, limited their role to document verification, or did not actively perform quality supervision (Asyifa and Raden 2025; Darmayanti, Mahadewi and Ugrasena 2025). These practices directly contradict the strategic role of the APJ as defined in both CDOB regulatory instruments. Limited APJ engagement and insufficient personnel training contributed to weaknesses in other quality management components, including audit implementation, quality review and CAPA effectiveness. Overall, the consistent pattern of non-compliance across studies indicates that deficiencies in quality management and personnel are systemic rather than isolated. The inability of PBF to conduct internal audits, perform quality reviews, control documentation, ensure comprehensive training, and secure active APJ involvement confirms that quality management and personnel represent the most vulnerable aspect of CDOB implementation and a primary source of non-compliance within pharmaceutical distribution in Indonesia.

Buildings and Equipment

Within the CDOB framework, buildings and equipment constitute a fundamental component in ensuring that pharmaceutical storage and distribution are conducted under conditions that preserve product quality, safety and stability. BPOM Regulation No. 20 of 2025 and BPOM Regulation No. 6 of 2020 stipulate that distribution facilities must be designed, constructed and maintained to minimise the risks of contamination, cross-contamination, exposure to inappropriate environmental conditions and physical damage to medicinal products. Accordingly, facilities are required to have a structured layout, clear segregation between receiving, storage and dispatch areas and designated zones for quarantined, returned, damaged or expired products. In addition, CDOB regulates environmental

control measures, including temperature, humidity, ventilation, cleanliness and access security. Storage and distribution equipment, including temperature monitoring devices and cold chain equipment, must be fit for purpose, validated and periodically calibrated, with appropriate records maintained as part of quality assurance. The scope of these requirements is summarised in Table 2.

Table 2: Building and equipment aspect elements.

Element	CDOB Requirement
Building design and layout	Facilities shall have clearly segregated areas for receiving, storage and distribution, including designated areas for quarantined, returned, damaged, expired or suspected counterfeit products.
Storage environment (temperature, humidity, ventilation, cleanliness)	Buildings should maintain environmental conditions in accordance with product requirements, including controlled temperature and humidity, adequate ventilation and cleanliness to prevent contamination and quality deterioration.
Security and access control	Storage areas shall be access-controlled to prevent theft, tampering, or misuse and to ensure medicinal products are not mixed with non-pharmaceutical materials.
Lighting and physical condition of the building	Adequate lighting should be provided to support operational activities, and the building shall be maintained in a suitable physical condition to protect medicinal products from external environmental risks.
Storage and supporting equipment appropriate to function	Racks, pallets, shelving systems, cold rooms, chillers, refrigerated vehicles and temperature/humidity monitoring devices shall be suitable for their intended purpose and comply with medicinal product storage standards.
Equipment calibration, qualification, and maintenance	All equipment shall be calibrated, qualified/validated and maintained periodically to ensure accuracy and prevent product quality degradation.
Recording and traceability systems for facilities and equipment	Documentation shall be available for temperature and humidity monitoring, pest control, warehouse inspections, equipment maintenance logs and calibration/validation records.

Analysis of six studies indicates that buildings and equipment represent one of the CDOB components most frequently associated with non-compliance and contribute substantially to the risk of quality deterioration during pharmaceutical storage and distribution (see Table 3). Yusuf and Avanti (2020) reported that several PBF operated storage areas that did not meet CDOB standards, including inadequate area segregation, insufficient storage facilities and reliance on manual temperature monitoring that was not conducted continuously. Consistent findings were reported by Asyifa and Raden (2025), who observed that 95.65% of PBF registered under BBPOM Bandung failed to comply with buildings and equipment requirements. Identified deficiencies included inadequate ventilation, poor cleanliness, uncalibrated temperature monitoring devices and storage layouts that did not conform to CDOB specifications. Similar patterns of non-compliance were further reinforced by Mustaqimah *et al.* (2021) and Hafizhuddin, Dewi and Pratama (2021), who reported recurrent deficiencies in physical facilities, environmental storage conditions and equipment quality across multiple regions in Indonesia. These studies documented inconsistent temperature control, insufficient segregation of quarantine and returned products and the absence of documented environmental monitoring systems.

Table 3: Summary of relevant literature on building and equipment aspects.

Title	Study Focus	Key Findings
CDOB implementation by PBF in Banjarmasin–Banjarbaru	Evaluation of nine CDOB aspects, including storage facilities and supporting equipment.	Storage facilities did not meet CDOB requirements; temperature monitoring was manual and non-continuous; storage areas were not segregated; environmental cleanliness and control were substandard; equipment was not calibrated.
Evaluation of CDOB compliance in PBF and branches under BBPOM Bandung	Assessment of 12 CDOB aspects, including buildings, physical facilities and equipment.	95.65% of facilities failed to comply with building and equipment requirements; temperature monitoring systems were inadequate; ventilation, cleanliness and construction materials were non-compliant; equipment was not calibrated; storage layout was inappropriate.
Narrative review: Implementation of good distribution practice in PBF	Identification of national deviation patterns related to facilities and equipment in Indonesian PBF.	Equipment was non-standard or uncalibrated; temperature control was inconsistent; warehouses did not meet CDOB standards; distribution vehicles were non-compliant; many facilities lacked adequate CDOB infrastructure.
Literature review: Evaluation of GDP (CDOB) in pharmaceutical distribution facilities	Review of fourteen studies on CDOB implementation in Indonesia, focusing on facility, infrastructure and operational deviations.	Many distribution facilities failed to meet physical infrastructure standards (building design, layout and area segregation); temperature monitoring was non-continuous and uncalibrated; common issues included inadequate storage space, poor cleanliness and substandard ventilation; facility and temperature log documentation was often incomplete.
Compliance analysis of building aspects in a PBF in Bandung with CDOB 2020	Evaluation of building design, storage facilities and warehouse environment using checklists and direct observation.	All building aspects complied with CDOB (layout, shelving, area segregation, cleanliness and sanitation); temperature monitoring was conducted three times daily; thermohygrometers were calibrated annually; temperature mapping was performed; adequate lighting, airflow, pallets, shelving and security systems were in place.
Pharmaceutical GDP: A review of the global scenario	Discussion of global GDP challenges and implementation, focusing on storage, cold chain, facilities and equipment across countries.	Medicinal product quality is strongly influenced by storage facilities and equipment; cold chain products must be maintained at 2°C–8°C using strict temperature-controlled systems; developing countries often lack compliant refrigerated vehicles and storage facilities; GDP requires environmental control, contamination prevention, monitoring systems and routine calibration and validation of equipment.

When compared with the CDOB requirements stipulated in BPOM Regulation No. 20 of 2025 and the technical guidance provided in BPOM Regulation No. 6 of 2020, the majority of non-compliance cases were associated with failure to meet basic physical infrastructure requirements. CDOB mandates that facilities be designed to prevent cross-contamination, support clear workflow, maintain appropriate physical conditions and be equipped with effective environmental control systems for temperature, humidity and cleanliness. However, the reviewed studies demonstrate that many PBF lacked adequate facilities to maintain product quality stability, particularly for temperature-sensitive products. Several studies reported that temperature monitoring was conducted manually, not in real-time or without validation, despite CDOB requirements for accurate, calibrated and continuously functioning monitoring devices. BBPOM evaluations further indicated that equipment such as thermometers and hygrometers were frequently uncalibrated or lacked maintenance records. In addition, documentation related to facility management, including temperature logs, equipment maintenance records and warehouse inspection reports, was often incomplete or unavailable.

International evidence further contextualises these findings. Kumar and Jha (2015) reported that deviations related to buildings and equipment are not solely attributable to infrastructure limitations but are also associated with limited understanding of global GDP standards. Their study emphasised that GDP requires appropriately designed storage facilities, structured area segregation, strict environmental controls and the routine use of validated and calibrated equipment, particularly for cold chain products. Furthermore, the authors noted that developing countries frequently face challenges related to infrastructure investment and environmental monitoring systems, increasing the vulnerability of medicinal products to temperature fluctuations and inappropriate storage conditions. This pattern aligns closely with findings from Indonesian studies, which indicate that several PBF have not met basic CDOB requirements, including purpose-designed storage facilities, adequate area segregation, robust temperature and humidity control systems and calibrated monitoring equipment. These findings suggest that challenges in CDOB implementation within the buildings and equipment domain reflect not only physical constraints but also gaps in technical understanding of CDOB and international GDP standards.

Only one study, conducted by Pangestu and Holik (2024), reported full compliance with buildings and equipment requirements, noting that all facility elements at a PBF in Bandung met CDOB standards, including layout design, cleanliness, lighting and equipment calibration. This finding highlights that compliance with building and equipment requirements is achievable when management commitment and systematic monitoring and maintenance practices are in place. Nevertheless, the contrast between compliant and non-compliant PBF underscores a substantial compliance gap. Overall, cross-study analysis reveals a consistent pattern of non-compliance characterised by inadequate physical infrastructure, weak environmental control, non-standard equipment and incomplete monitoring documentation. These deviations indicate that many PBF have not fully met the foundational infrastructure requirements of CDOB. Consequently, buildings and equipment emerge as one of the most vulnerable CDOB components, posing significant risks to the stability and quality of medicinal products, particularly those highly sensitive to environmental conditions.

Documentation

Within the CDOB framework, documentation is recognised as a fundamental component of the quality management system, as it serves as the basis for traceability and as formal evidence of all distribution activities. The core principle underlying this aspect is that any

activity that is not documented is considered not to have occurred. Therefore, all processes, including receipt, storage, environmental condition monitoring, packaging, distribution, returns and recalls, must be supported by complete, accurate and traceable records. BPOM Regulation No. 6 of 2020 emphasises that documentation must be comprehensive, unambiguous, consistent and supported by document control mechanisms and access management to ensure data integrity and security. Furthermore, BPOM Regulation No. 20 of 2025 expands the scope of documentation by integrating it across all operational processes, including internal audits, deviation investigations, risk management, quality reviews, cold chain distribution and recall activities.

Table 4 summarises the findings related to documentation compliance across the reviewed studies. Cross-analysis of six studies indicates that documentation practices among PBF remain largely inconsistent, incomplete or unavailable in critical areas. A study conducted at a PBF in Central Jakarta reported that temperature monitoring documentation was still performed manually and inconsistently, rendering it unsuitable as evidence of compliance with environmental control standards (Kristanti and Ramadhania 2020). In addition, limited documentation was observed for facility maintenance, warehouse inspection records, cleaning activities, and pest control reports, indicating that although storage practices were relatively adequate, the accompanying documentation did not meet CDOB requirements.

Table 4: Summary of relevant literature on documentation aspects.

Title	Study Focus	Key Findings
Evaluation of compliance of drug, supplement and cosmetic storage systems in PBF in central Jakarta	Assessment of storage systems and documentation compliance related to temperature control, inventory and warehouse activities.	Temperature documentation was manual and inconsistent; not all facility maintenance activities were documented; records of cleaning, pest control and warehouse inspections were incomplete.
Evaluation of cold chain product distribution practices by PBF in Bandung	Assessment of cold chain documentation compliance, including temperature monitoring, transport logs and deviation records.	Temperature logs were incomplete; equipment validation documentation was unavailable; temperature deviation records were absent; transport documentation did not comply with CDOB requirements.
Evaluation of psychotropic and precursor handling in a PBF in Bandung	Evaluation of documentation compliance for high-risk products, including receipt, storage, distribution and destruction.	Many mandatory forms were unavailable; inbound and outbound records were incomplete; documentation of audits and periodic reporting was absent.
Literature review: Evaluation of GDP (CDOB) in pharmaceutical distribution facilities	Analysis of 14 national studies on CDOB implementation, focusing on documentation-related deviations.	Documentation was identified as the most frequently non-compliant aspect; temperature logs, inventory records and maintenance documentation were incomplete; many SOPs were undocumented or not regularly updated.

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Table 4: (*Continued*)

Title	Study Focus	Key Findings
Narrative review: Implementation of good distribution practice in PBF	Identification of documentation weaknesses across PBF based on national study findings.	CAPA activities were not documented; no evidence of internal audits was available; training and personnel competency records were incomplete; operational documents often did not reflect actual practices.
Evaluation of CDOB compliance in PBF under BBPOM Bandung	Analysis of compliance with 12 CDOB aspects, highlighting the proportion of documentation-related non-compliance across wholesalers.	Documentation was among the aspects with the highest level of non-compliance; many wholesalers lacked temperature logs, pest control records, calibration certificates and facility inspection evidence; quality documents were inconsistent and not updated.

Similar findings were reported in a study on cold chain product distribution at a PBF in Bandung, where temperature logs were incomplete, temperature deviation records were absent, and equipment validation documentation was unavailable (Sembiring and Wathoni 2021). This condition is particularly critical given that cold chain products are highly sensitive to temperature fluctuations and CDOB explicitly requires continuous and validated temperature monitoring. The absence of adequate documentation undermines auditability and obstructs traceability in the event of product quality degradation. More severe documentation deficiencies were identified in a study on the handling of psychotropic and precursor products at PBF X in Bandung, where mandatory forms such as receipt-to-distribution records, specialised stock cards and regulatory reporting documents were either unavailable or incomplete (Yuliani, Mulyasyari and Holik 2025). The lack of audit documentation, monthly reports and destruction records demonstrates that documentation for high-risk products, which should be subject to the strictest controls, was among the weakest, thereby increasing regulatory compliance risks.

Two national-level studies further reinforced this pattern. A literature review analysing 14 studies concluded that documentation was one of the most frequently non-compliant CDOB aspects, with deficiencies observed in temperature logs, inventory records, equipment maintenance documentation, storage records and the absence of updated SOPs (Hafizhuddin, Dewi and Pratama 2021). Similarly, a narrative review by Mustaqimah *et al.* (2021) identified widespread weaknesses in internal audit documentation, CAPA records, personnel training documentation and operational traceability across most PBF. These findings indicate that documentation issues are systemic at the national-level rather than isolated incidents. The most comprehensive evidence was provided by an evaluation conducted by BBPOM Bandung, which identified documentation as one of the aspects with the highest non-compliance rates in CDOB audits. Many PBF were unable to present temperature logs, calibration certificates, pest control records, facility inspection logs or updated quality documents (Asyifa and Raden 2025), highlighting deficiencies not only in technical execution but also in managerial oversight and quality assurance.

When compared with the CDOB requirements stipulated in BPOM Regulation No. 20 of 2025 and the technical guidelines under BPOM Regulation No. 6 of 2020, documentation should comprehensively cover all distribution activities, including environmental monitoring, receipt, storage, distribution, equipment validation and calibration, internal audits, CAPA implementation and document control. These standards emphasise

the principle that undocumented activities are considered not to have occurred. However, all reviewed studies demonstrate a substantial gap between regulatory requirements and actual implementation. Overall, cross-study analysis indicates that documentation non-compliance is driven by several factors, including limited personnel awareness of the importance of documentation, reliance on manual recording systems prone to error, lack of digital or automated documentation systems, weak supervision by the APJ over document control and organisational cultures that do not prioritise documentation as an integral part of quality assurance. Consequently, documentation remains one of the most failure-prone components of CDOB implementation and poses a significant risk by impeding traceability, deviation investigation and assurance of medicine quality throughout the distribution process.

Operational and Drug Handling

The operational aspect of GDP or CDOB encompasses all technical activities performed by PBF, including product receipt, storage, environmental condition maintenance, distribution and cold chain product handling, which collectively determine whether medicine quality is preserved throughout the distribution chain. This aspect is regulated progressively through Ministry of Health Regulation No. 1148 of 2011, which establishes basic obligations for adequate storage and distribution facilities; BPOM Regulation No. 6 of 2020, which strengthens operational requirements related to receipt verification, temperature monitoring, FEFO implementation, equipment validation and traceable documentation; and BPOM Regulation No. 20 of 2025, which further expands requirements through a risk-based approach, full operational digitalisation and automated environmental monitoring systems with deviation alarms.

Table 5 summarises the findings related to the operational aspect across the reviewed studies. Cross-analysis of nine studies indicates substantial variability in operational compliance among PBF in Indonesia, with implementation often falling short of the most recent regulatory requirements. At the receipt stage, several studies reported relatively adequate implementation of physical and administrative verification procedures. A study conducted at PBF X in Bali showed that real-time receipt recording had been implemented using an SAP-based system; however, damage reporting was not fully integrated and deviation documentation was not consistently available, limiting traceability and quality investigation (Darmayanti, Mahadewi and Ugrasena 2025). Similar findings were observed at PT Parit Padang Global, where receipt procedures followed established SOPs and were supervised by the APJ, yet temperature recording and supporting documentation remained largely manual, increasing the risk of recording errors and non-compliance with CDOB 2025 requirements.

Table 5: Summary of relevant literature on operational and drug management aspects.

Title	Study Focus	Key Findings
Evaluation of drug storage practices at PT MPI Medan	Assessment of drug storage compliance with CDOB, including temperature control, FEFO implementation and facility quality.	Warehouse arrangement was inconsistent; temperature monitoring was still manual; evidence of facility maintenance was incomplete; potential non-compliance with FEFO principles was identified.

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Table 5: (*Continued*)

Title	Study Focus	Key Findings
Implementation of CDOB in the goods receiving SOPs at PBF X	Evaluation of goods receiving SOPs, including physical inspection, document verification and real-time recording via SAP.	Damage reporting was not digitally integrated; SOPs were not routinely reviewed; documentation of deviations was incomplete.
Evaluation of cold chain product distribution practices by PBF in Bandung	Assessment of cold chain management, including temperature monitoring, cold chain facilities and CCP distribution procedures.	Temperature logs were incomplete; no documentation of temperature deviations was available; validation evidence for cooling equipment was absent; a high risk of temperature fluctuation was identified.
Implementation of CDOB in the delivery SOPs at PBF Y (APJ Perspective)	Evaluation of distribution processes, including vehicle suitability, delivery documentation and temperature control during transportation.	Delivery vehicles lacked temperature monitoring systems; transport records were incomplete; shipment condition documentation did not comply with CDOB requirements.
CDOB and Its implementation in PBF in Banjarmasin–Banjarbaru (2019)	Assessment of nine CDOB aspects, including operational activities such as receipt, storage, product arrangement, temperature monitoring and distribution.	Product arrangement was inconsistent; operational quality reviews were rarely conducted; environmental condition monitoring was not performed routinely.
Implementation of CDOB in PBF X, Jambi City	Evaluation of compliance with all CDOB aspects, focusing on operational activities including receipt, storage, transportation and CCP management.	All operational aspects were fulfilled; however, processes relied heavily on manual procedures, posing risks to temperature documentation consistency.
Implementation of good distribution practice at PT Parit Padang Global	Observation of operational GDP implementation, including receipt, storage (FIFO/ FEFO), temperature mapping, distribution and CCP facilities.	Temperature monitoring was conducted three times daily but not automated; CCP areas met requirements, but records remained manual; dependence on central SOPs limited process updates.
Overview of CDOB implementation in PBF X, Tarakan	Focus on storage and distribution aspects, including temperature and humidity control, segregated areas, FEFO, pest control and cold room management.	Significant temperature fluctuations were observed; temperature logs were incomplete; pest control and sanitation records were inconsistently documented; stock and FEFO documentation was not consistently applied.

More pronounced deviations were identified during the storage stage, particularly in relation to temperature control, warehouse arrangement and area segregation. A study in Tarakan reported that despite adequate warehouse facilities, temperature fluctuations occurred and recording logs were inconsistent, rendering them unsuitable as evidence of environmental control compliance (Fadillah, Heriani and Wijayanti 2025). In Medan, manual temperature monitoring, incomplete facility maintenance records and inconsistent application of the First Expired, First Out (FEFO) principle were reported, all of which may compromise medicine stability (Yuliana Sianipar, Surbakti and Tarigan 2022). In contrast,

a study conducted at PBF X in Jambi reported full compliance with CDOB requirements, including appropriate temperature-controlled storage, clear area segregation and consistent FEFO implementation, although reliance on manual recording systems remained a potential weakness (Hadriyati, Sanuddin and Ananda 2021). These findings demonstrate that storage operations represent one of the most variable and sensitive areas of CDOB implementation.

Gaps were also observed in environmental condition maintenance, including temperature, humidity, cleanliness, equipment maintenance and pest control. At PT Parit Padang Global, temperature monitoring was conducted three times daily using calibrated equipment, indicating compliance with CDOB 2020 requirements. However, other studies reported incomplete or outdated calibration records, pest control documentation and cleaning logs, which contradict the requirements of Ministry of Health Regulation No. 1148 of 2011. Recurrent inconsistencies in temperature and humidity documentation suggest weak risk management practices, despite CDOB 2025 mandating continuous automated monitoring with deviation alarms.

During the distribution stage, most PBFs had established SOPs covering customer qualification, documentation completeness and product segregation. Nevertheless, a study on distribution practices at PBF Y found that delivery vehicles were not equipped with real-time temperature monitoring devices, transport condition documentation was incomplete, and deviation reports during transportation were not consistently available. This is particularly critical as transportation represents a high-risk point for temperature excursions, especially during long-distance distribution. Such conditions do not fully comply with BPOM Regulation No. 6 of 2020 and fall short of the traceability requirements introduced in CDOB 2025.

The most significant operational deviations were observed in the management of cold chain products (CCPs). Studies conducted in Bandung reported incomplete temperature logs, absence of temperature deviation documentation and non-validated refrigeration equipment, placing CCP stability at high-risk during both storage and distribution. Other studies identified limitations in cold room capacity, lack of automated sensors and delayed manual monitoring. These findings are inconsistent with CDOB 2020 requirements and particularly with CDOB 2025, which mandates continuous digital temperature monitoring, validated transport systems, automated alarms and comprehensive deviation documentation. In contrast, PT Parit Padang Global demonstrated relatively better CCP management using chillers, cold rooms and scheduled temperature recording, although further digitalisation is required to meet the latest regulatory standards (Oke, Lolo and Rundengan 2022).

Overall, comparison of cross-study findings with the national regulatory framework indicates that operational implementation among PBF in Indonesia has not yet fully aligned with CDOB 2020 and CDOB 2025 requirements. Common deviations, including manual temperature monitoring, incomplete logs, lack of facility maintenance evidence, absence of deviation documentation and insufficient distribution control, appear to be driven by limited infrastructure, low levels of digitalisation, inconsistent supervision by the responsible pharmacist and underdeveloped quality cultures within organisations. These findings position operational activities as one of the most non-compliant and high-risk aspects of CDOB implementation, requiring targeted improvement to ensure consistent medicine quality throughout the national distribution system.

Post-Distribution Surveillance, Audit, Contracted Activities and Supporting Facilities

Post-distribution surveillance, internal audit, management of contracted activities and the availability of supporting facilities constitute the final control layer within the GDP (CDOB) framework. This aspect functions to ensure that drug quality, safety and integrity are maintained not only during storage and distribution, but also after products have been released from PBF. Under CDOB 2020, these components are positioned as mandatory mechanisms supported by written procedures and documentation, while CDOB 2025 further strengthens the requirements through a risk-based approach, continuous monitoring, validation of outsourced activities and enhanced traceability. Therefore, evaluation of this aspect provides critical insight into the ability of PBFs to detect deviations, respond to quality issues and maintain control over the distribution chain beyond the warehouse level.

Analysis of six studies indicates that post-distribution surveillance, internal audit, contracted activities and supporting facilities represent one of the weakest components in the implementation of GDP (CDOB) among PBF in Indonesia (see Table 6). Across multiple regions, deficiencies were consistently identified in complaint handling, product returns, recall mechanisms, audit execution, oversight of outsourced activities and environmental monitoring systems.

Several studies reported inadequate implementation of complaint management, return and recall systems. Research conducted in Banjarmasin–Banjarbaru found that documentation related to product returns and recalls was inconsistent, complaint trend analysis was not performed and recall procedures lacked clarity and timeliness (Yusuf and Avanti 2020). Similar patterns were observed in the certification evaluation of 69 PBF in Bandung, where high levels of non-compliance were associated with incomplete complaint records and insufficient recall documentation (Asyifa and Raden 2025). These findings indicate that post-distribution control mechanisms were largely administrative and not supported by effective traceability or risk evaluation systems.

Table 6: Summary of relevant literature on post-distribution supervision, audit, contract, and additional facilities aspects.

Title	Study Focus	Key Findings
Evaluation of CDOB implementation for psychotropic products based on self-inspection checklists at a PBF in Bandung	Assessment of CDOB implementation for psychotropic products using self-inspection instruments, including internal audit and document control.	Self-inspection was incomplete and not conducted periodically; documentation of psychotropic control was non-compliant; security facilities for psychotropic storage (dedicated cabinets, access control) did not meet standards; no evidence of follow-up actions from internal audit findings.
Supply chain risk analysis of PBF using the house of risk (HOR) method	Identification of risks in procurement, storage, and distribution processes, including facility disruptions, documentation issues and security risks.	Major risks originated from facility failures (damage to monitoring equipment), reliance on manual records and weak temperature monitoring; cold chain systems were highly vulnerable due to non-real-time temperature control; no formal contractual system was in place for third-party (outsourced) transportation.

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Table 6: (*Continued*)

Title	Study Focus	Key Findings
GDP (CDOB) and its implementation by PBF in Banjarmasin–Banjarbaru	Evaluation of nine CDOB aspects, including complaint handling, returns, recalls and internal audits.	Internal audits were not conducted routinely; complaint handling was inadequately documented; CAPA was not implemented; no structured complaint management system was available; facility security and temperature monitoring were weak.
Evaluation of CDOB compliance at PBF and branches under BBPOM Bandung	Measurement of compliance with 12 CDOB aspects, including complaints/returns/ recalls, self-inspection, transportation and contract-based facilities.	Complaint, return and recall management showed high non-compliance; self-inspection (internal audit) was among the highest failure aspects (> 50% non-compliance); transportation and contract-based facilities were undocumented; additional facilities such as security systems and temperature monitoring were inadequate.
Narrative review: Implementation of GDP in PBF	Identification of national implementation patterns of CDOB, including post-distribution supervision, internal audits and outsourced facility control.	Complaint handling, returns and recalls were the most frequently unimplemented aspects; internal audits were inconsistent, with many wholesalers not conducting audits; outsourced transportation was poorly supervised; cold chain management and temperature monitoring frequently failed; facility security was minimal and non-compliant with CDOB.

Internal audit was identified as a recurring weakness across all reviewed studies. A national narrative review reported that most PBF either did not conduct internal audits regularly or performed them superficially without effective follow-up through CAPA (Mustaqimah *et al.* 2021). This was reinforced by findings from psychotropic distribution inspections in Bandung, which revealed the absence of structured annual audit plans, inadequate documentation and lack of independent verification (Nauroh, Alfian and Mulyasyari 2024). These findings demonstrate a significant gap between regulatory requirements and actual audit practices, undermining the effectiveness of quality management systems within PBF.

Non-compliance was also evident in the management of contracted and outsourced activities. Studies conducted in Banjarmasin and Bandung reported that several PBF utilised third-party transportation services without formal contracts meeting CDOB requirements, particularly regarding temperature control, traceability and quality responsibility during transit (Yusuf and Avanti 2020; Asyifa and Raden 2025). Moreover, outsourced facilities were often not subjected to periodic audits as mandated under CDOB 2025, indicating insufficient oversight of third-party operations and increased risk to product quality during distribution.

Supporting facilities, including environmental monitoring systems and security controls, were also frequently reported as inadequate. Supply chain risk analysis using the House of Risk (HOR) method identified temperature fluctuations, product damage during transportation and weak security systems as dominant risks affecting drug quality (Junus and Baihaqi 2025). These risks were exacerbated by reliance on manual temperature monitoring, absence of real-time data logging and lack of validated alarm systems, as highlighted in a national narrative review (Mustaqimah *et al.* 2021). In addition, inspections

of psychotropic distribution facilities revealed insufficient access control and inconsistent temperature monitoring records, despite CDOB requirements for continuous monitoring and regular calibration of equipment (Nauroh, Alfian and Mulyasyari 2024).

When compared with the requirements outlined in CDOB 2020 and strengthened under CDOB 2025, the findings collectively demonstrate substantial gaps in post-distribution surveillance and supporting control systems. While regulations mandate comprehensive documentation of complaints, returns and recalls, routine internal audits, strict oversight of contracted activities and risk-based environmental monitoring, many PBFs continue to rely on manual systems, limited verification and reactive rather than preventive controls. Overall, post-distribution surveillance, audit, contracted activities and supporting facilities emerge as highly vulnerable aspects of CDOB implementation, directly affecting the ability of PBF to detect deviations, manage risks and safeguard drug quality after products leave distribution facilities.

DISCUSSION

Analysis of CDOB Non-Compliance

The CDOB guidelines explicitly require all pharmaceutical distribution activities to be conducted within a documented quality system encompassing clearly defined procedures, internal audits, deviation handling and the implementation of appropriate CAPA. A cross-study analysis of all CDOB components identified ten recurrent patterns of non-compliance among PBF in Indonesia, covering deficiencies in quality management, human resource competence, buildings and equipment, documentation, operational activities, environmental control, third-party facilities, warehouse security and post-distribution surveillance. Among these findings, four issues emerged most consistently and represent the primary root causes underlying the failure of CDOB implementation.

First, most PBFs have not established a mature quality management system, as evidenced by the absence or irregular conduct of internal audits, the lack of effective follow-up on CAPA, the absence of routine quality reviews and the limited involvement of the APJ. This non-compliance reflects not merely procedural weaknesses but a failure to fulfil the fundamental CDOB principle of safeguarding medicine quality and integrity throughout the distribution chain, as mandated under Article 2 paragraph (1) of BPOM Regulation No. 6 of 2020, which requires comprehensive implementation of CDOB Technical Guidelines.

Second, documentation practices remain inadequate and inconsistently applied, particularly in temperature recording, operational logs, return and recall documentation and document control systems, resulting in weak product traceability. The CDOB guidelines explicitly state that all quality-related activities must be defined, recorded and traceable (Chapter IX, Documentation). However, many PBFs lack complete temperature logs, fail to document transport deviations, do not retain calibration records and are unable to present audit documentation. Such deficiencies constitute direct violations of CDOB requirements, including the obligation to document, investigate and follow-up all deviations through CAPA (Chapter I, Quality System, section 1.11). Without proper documentation and traceability, medicine quality cannot be assured, even when written procedures formally exist.

Third, risk management has not been systematically integrated into PBF operations. This is reflected in the absence of formal risk assessments for storage, transportation and cold chain management, allowing the same deviations to recur without effective preventive mechanisms. Fourth, internal audits are not utilised as a functional

control tool, either because they are not conducted regularly or because audit outcomes are not analysed and followed by corrective actions. Together, these four factors form the most dominant non-compliance pattern and constitute the fundamental causes of repeated CDOB implementation failures across different operational domains.

Critical non-compliance is particularly evident in the management of facilities and equipment. The CDOB guidelines require buildings and equipment to protect medicines from contamination, temperature fluctuations and physical damage during storage and distribution (Chapter III, Buildings and Equipment). Nevertheless, the reviewed literature consistently indicates that many PBFs fail to meet basic requirements such as continuous temperature monitoring, routine equipment calibration and adequate segregation of storage areas. Non-compliance is even more pronounced for CCPs, for which CDOB explicitly mandates validated temperature monitoring systems and qualified equipment (Chapter XI, Cold Chain Products). In practice, temperature monitoring is still largely manual and does not guarantee data accuracy or reliability. This condition represents a high-risk scenario, as temperature excursions may directly compromise product stability and quality.

Furthermore, self-inspection mechanisms have not functioned effectively. CDOB requires internal audits to be conducted periodically with complete documentation as an integral part of the quality management system (Chapter V, Self-Inspection). When internal audits are absent or ineffective, PBFs lack the capacity to identify systemic weaknesses and operational deviations at an early stage. Consequently, non-compliance becomes chronic and repetitive, particularly in organisations where audit programmes are unstructured or implemented merely as administrative formalities without meaningful CAPA follow-up, contrary to the risk-based quality management principles embedded in CDOB.

The root causes of CDOB non-compliance are further reinforced by inadequate human resource competence, particularly concerning the role of responsible pharmacist. CDOB guidelines clearly stipulate that the APJ must possess full authority, adequate competence and primary responsibility for ensuring the implementation of the quality management system (Chapter II, Responsible Person). In practice, however, the APJ role in many PBFs remains largely administrative, with limited involvement in internal audits, quality supervision and process validation. This reflects a structural failure within PBF organisations to fulfil regulatory mandates, given that CDOB explicitly requires the APJ to lead quality risk management, handle complaints and deviations, approve suppliers and customers and oversee the entire quality documentation system.

Figure 1 illustrates the conceptual relationship between CDOB non-compliance, resulting operational deficiencies and their downstream pharmacoeconomic and healthcare system impacts, highlighting the cascading effect of distribution failures on both operational efficiency and broader healthcare outcomes.

These deficiencies directly affect operational control, including receipt, storage, product segregation, distribution and transportation processes. CDOB requires every operational stage to be supported by validated SOPs and consistently applied practices, including physical and temperature checks upon receipt, appropriate product arrangement and the application of FIFO/FEFO principles (Chapter IV, Operations). When operational controls are inadequately implemented, the risks of quality degradation and loss of traceability increase substantially, particularly for temperature-sensitive products such as CCPs.

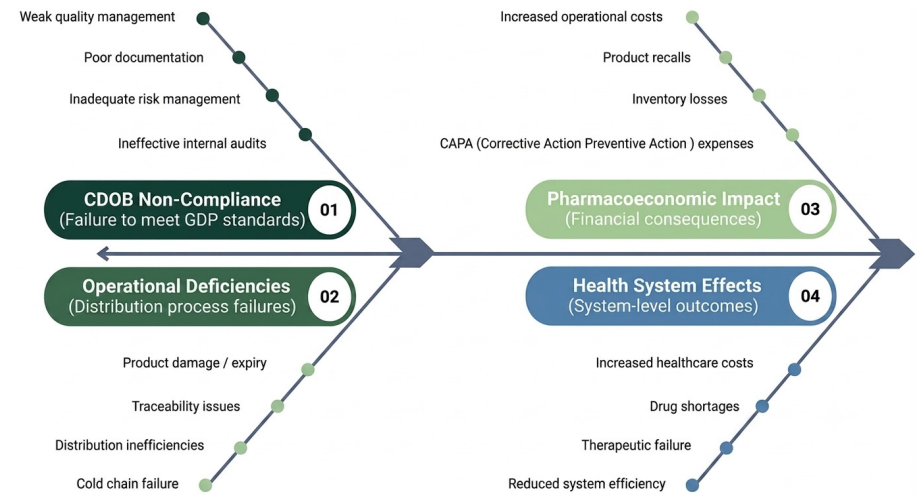

Figure 1: Conceptual framework of CDOB non-compliance and its pharmacoeconomic implications

Overall, CDOB non-compliance among PBFs in Indonesia should not be viewed as isolated technical failures but rather as a systemic issue reflecting a significant gap between regulatory expectations and organisational readiness. Although CDOB guidelines have been developed comprehensively and based on risk management principles, field implementation indicates that many PBFs lack mature quality systems, have not embedded risk management into daily operations and have not utilised internal audits as continuous control mechanisms. This condition suggests that CDOB principles have not yet been substantively internalised within PBF organisational culture, thereby preventing consistent assurance of medicine quality across the pharmaceutical distribution chain in accordance with regulatory mandates.

Pharmacoeconomic Analysis

Non-compliance with CDOB among PBF constitutes a multidimensional problem that extends beyond issues of medicine quality and safety, potentially generating economic consequences. Failure to comply with CDOB principles, which align with international GDP standards, increases operational inefficiencies and lead to both direct and indirect economic losses. Deficiencies such as weak quality management systems, ineffective distribution documentation, inadequate risk management and suboptimal internal audit practices cumulatively may increase operational costs, elevate the risk of product damage and reduce the reliability of the pharmaceutical supply chain (European Union agencies network 2025). Furthermore, regulatory complexity combined with economic pressures may exacerbate quality deterioration during distribution, forcing PBF to incur additional corrective and operational expenditures to mitigate resulting losses (Hasnida, Kok and Pisani 2021).

Weaknesses in quality management systems represent a primary driver of potential pharmacoeconomic loss. Robust quality management systems, as mandated by CDOB and GDP, function to prevent quality deviations during distribution and minimise the need for costly corrective actions. When such systems are inadequately implemented, PBF may face increased wastage due to damaged or expired medicines, higher frequencies of

returns and recalls and financial losses associated with inventory write-offs. These conditions generate not only direct economic losses but also reduce operational efficiency and increase distribution costs per unit, ultimately undermining the economic competitiveness of PBF (SafetyCulture 2025). These findings are supported by pharmaceutical recall analyses, which identify deficiencies in the quality management system as a significant contributor to product recalls and associated operational and economic consequences (Miglani *et al.* 2021).

Ineffective documentation practices further contribute to the economic impact of CDOB non-compliance. Incomplete or inaccurate records related to temperature monitoring, batch identification, distribution pathways, returns and recalls hinder the ability of PBF to conduct rapid and precise product traceability in the event of quality deviations. GDP standards emphasise comprehensive and accurate documentation as the foundation of traceability and quality control across the supply chain. Failure in this area may lead to increased investigation costs, excessive use of human and logistical resources and financial losses resulting from delayed or expanded product recalls. Evidence from pharmaceutical recall analyses indicates that deficiencies in documentation, labelling and distribution processes are among the key contributors to product recalls, which may result in substantial operational and economic consequences (Miglani *et al.*, 2021). From a pharmacoeconomic perspective, such deficiencies not only may contribute inventory losses but also increase administrative burdens and reduce the overall efficiency of pharmaceutical distribution systems (European Union agencies network 2025).

Deficiencies in distribution risk management, particularly in temperature and environmental control, carry important and measurable economic implications for temperature-sensitive products such as vaccines, insulin and biological medicines. CDOB and GDP require consistent temperature control and risk-based approaches to preserve product stability throughout distribution. Evidence from supply chain modelling studies indicates that temperature excursions in pharmaceutical distribution can result in substantial product losses and increased logistics and operational costs, particularly for CCPs requiring strict temperature control (Arias and Gweder 2022). Non-compliance in this area may result in quality degradation that is not immediately detectable, increasing the likelihood of therapeutic failure and large-scale product recalls. The resulting economic losses may therefore extend beyond the value of high-cost medicines to include additional logistics expenses, infrastructure adjustments and increased investment in workforce training (Buendia 2025).

Beyond direct product losses, inadequate risk management in distribution also generates indirect economic burdens on healthcare systems. Reduced medicine quality due to temperature excursions may compromise therapeutic effectiveness, prolong treatment durations and necessitate additional medical interventions. These outcomes may contribute to rising healthcare costs and disrupt medicine availability for patients, particularly for conditions reliant on biological therapies (Buendia 2025). This is consistent with global evidence indicating that poor-quality of ineffective medicines lead to treatment failure, increased healthcare utilisation and significant economic burden on health systems (WHO 2024)

Suboptimal implementation of internal audits as part of the CDOB quality management framework may further increase economic burdens for PBF. Ineffective or absent internal audits allow deviations to accumulate undetected, increasing systemic risk within distribution operations. When such issues are eventually identified—either through regulatory inspections or quality incidents, PBF face the need for urgent and costly CAPA, potential regulatory sanctions and large-scale product recalls. From a pharmacoeconomic perspective, these outcomes suggest that preventive compliance efforts may be more

cost-efficient compared to constant corrective action demonstrating that the cost of failure prevention is substantially lower than the costs incurred when compliance is not (SafetyCulture 2025).

These findings are consistent with challenges reported in other countries, where non-compliance with GDP is often associated with weaknesses in quality management systems, inadequate documentation and insufficient risk control measures (Grujić *et al.* 2020; Hertig, Baney and Weber 2019; Kumar and Jha 2015). Similar issues have also been observed in broader global contexts, where variations in regulatory enforcement, infrastructure capacity and resource availability contribute to gaps in pharmaceutical distribution practices (Pezzola and Sweet 2016).

Based on the reviewed studies (Tables 1–6), the Indonesian context demonstrates comparable patterns, particularly in terms of manual documentation practices, inconsistent temperature monitoring and limited implementation of internal audits. However, compared to more developed regions where GDP implementation is more standardised and supported by advanced technological systems, the challenges in Indonesia appear to be more complex due to variations in regulatory compliance, geographical distribution barriers and resource availability. This highlights the need for context-specific strategies to strengthen CDOB implementation while aligning with global standards.

Taken together, the findings across from Tables 1 to 6 demonstrate consistent patterns of CDOB non-compliance particularly in temperature control, documentation and internal audit systems which are associated with increased product loss, recall-related costs and operational inefficiencies, suggesting the presence of economic consequences. Although the included studies primarily report qualitative findings, these operational deficiencies can be linked to potential pharmacoeconomic consequences, including increased inventory losses, higher logistics and administrative costs and additional expenditures for CAPA.

Overall, CDOB non-compliance among PBF creates a complex and interconnected chain of potential economic consequences, ranging from increased operational costs at the distribution level to broader impacts on healthcare systems. Disruptions in medicine availability, distribution delays and potential therapeutic failures resulting from compromised medicine quality contribute to increased healthcare utilisation and expenditures. Consequently, consistent and effective implementation of CDOB should be regarded not only as a regulatory obligation but also as an important operational and economic strategy enhance distribution efficiency, ensure the sustainability of PBF operations and support the resilience of the national healthcare system. However, it is important to note that most of the included studies were conducted in urban or semi-urban settings such as Bandung, Jakarta, and Surabaya, indicating a dominance of evidence from more developed and accessible regions. This may limit the generalisability of the findings to remote or rural areas of Indonesia, where pharmaceutical distribution challenges and associated economic impacts may differ

Recommendations for Improving CDOB Implementation by PBFs

Findings from Tables 1 to 6 indicate that key non-compliance issues such as temperature control failure, inadequate documentation and weak internal audits are consistently associated with increased product loss, recall costs and operational inefficiencies.

In response to the identified barriers in pharmaceutical distribution that conflict with CDOB requirements and generate pharmacoeconomic losses, both PBF and BPOM require more effective monitoring and control mechanisms to ensure that pharmaceutical distribution processes remain economically sustainable and compliant. One emerging recommendation is the adoption of blockchain-based systems within pharmaceutical

distribution chains, as proposed by Irawan, Putri Abidin and Alamsyah (2025). Blockchain-based prototypes have demonstrated enhanced traceability, reduced circulation of counterfeit medicines, and improved coordination among key stakeholders, including manufacturers, regulators, healthcare professionals and patients (Irawan, Putri Abidin and Alamsyah 2025).

The integration of blockchain technology into pharmaceutical distribution systems offers the potential to address inefficiencies without imposing excessive economic burdens. By enabling real-time traceability, immutable documentation and transparent accountability across the supply chain, blockchain-based systems support stronger compliance with CDOB requirements while simultaneously reducing pharmacoeconomic risks. Such approaches encourage all stakeholders to fulfil their professional responsibilities in accordance with CDOB standards, thereby mitigating economic losses associated with distribution inefficiencies, quality failures and regulatory non-compliance.

CONCLUSION

Misalignment between the regulatory requirements of CDOB and the operational interests of PBF presents a complex and interrelated challenge within a pharmacoeconomic context. Disruptions in medicine availability, delays in distribution processes and potential declines in product quality have been shown to contribute negatively to the overall healthcare cost burden. These challenges generate increased operational expenditures at the distribution level and hinder the efficient supply of medicines to healthcare facilities nationwide. Consequently, such conditions may exert broader pharmacological and public health impacts, including an elevated risk of delayed or disrupted access to essential medical and pharmaceutical services for the population.

In response to these challenges, sustained synergy and alignment between CDOB regulations and the operational realities of PBF are essential to establish more effective and efficient pharmaceutical distribution strategies. Therefore, CDOB implementation should not be regarded merely as a regulatory obligation imposed on PBF, but rather as a strategic pharmacoeconomic approach that supports national health system resilience and sustainability. Strengthened regulatory oversight and more vigilant monitoring of CDOB implementation are also recommended to minimise non-compliant practices by PBF that may lead to inefficiencies and economic losses within the pharmaceutical distribution sector.

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