

## Quality Assurance System for Pharmaceutical Wholesalers (PBF) by Implementing Good Drug Distribution Methods (CDOB) in Jayapura City

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### A B S T R A C T

Good Drug Distribution Methods (CDOB) aim to ensure quality along the drug distribution route according to the requirements and purposes of use. This study aims to evaluate the implementation of CDOB in 22 Pharmaceutical Wholesalers (PBF) in Jayapura City. This quantitative descriptive research uses a questionnaire to assess 9 aspects of CDOB. The results showed that the quality management aspect: 77.3% PBF was qualified, organization, management, and personnel: 59.1% PBF was qualified, building and equipment: 22.7% PBF was qualified, operations: 40.9% PBF was qualified, self-inspection: 50% PBF was qualified, product complaints, returns, suspected counterfeiting, and drug recalls: 72.7% PBF was qualified, transportation: 90.9% PBF was qualified, documentation: 72.7% of PBFs are eligible.

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## INTRODUCTION

Drugs are the main commodities used by humans to support their health. Drugs are very important in human life so that in their manufacture drugs must meet *efficacy, safety, and quality* standards. These standards must be met starting from the manufacture, storage, distribution to delivery of drugs to consumers (Hartini, 2014).

The Government of Indonesia has regulated the quality of medicines listed in Law No. 36 of 2009 concerning Health Article 98 Paragraph 1 states that drugs and medical devices must be safe, efficacious/useful, quality, and affordable. To maintain these criteria, it has been stipulated in the Regulation of the Minister of Health that Pharmaceutical Wholesalers (PBF) as drug distributors must implement Good Drug Distribution Practices (CDOB) which has the goal of ensuring that drug quality and the integrity of the distribution chain are maintained during the distribution process (BPOM, 2020).

The drugs that have been produced are not directly consumed by the public but must go through a journey from the factory warehouse to the hands of consumers at varying times. The trip has many influential environmental factors such as light, temperature, and humidity (BPOM, 2020).

The obligation to have quality assurance in drug distribution channels in Indonesia has been stipulated in the Decree of the Head of the Food and Drug Supervisory Agency Number HK.03.1.34.11.12.7542 of 2012 concerning Technical Guidelines for Good Drug Distribution Methods. This obligation is also strengthened by the issuance of a higher regulation, namely Permenkes No.1148/Menkes/Per/VI/2011 concerning PBF, wherein the regulation it is stated that PBF must implement CDOB provisions in its operations. PBFs that have met CDOB requirements in distributing drugs are given CDOB certificates.

Good Drug Distribution Method (CDOB) is a method of distribution/distribution of drugs and/or medicinal ingredients that aims to ensure quality along the distribution/distribution route according to the requirements and purposes of use (BPOM, 2020).

The lack of quality assurance in PBF can be seen from the results of the 2023 Inspection Report of the Food and Drug Supervisory Center in Jayapura concerning the Implementation of CDOB aspects in PBF in Jayapura City. The results of the examination found that not all aspects of CDOB have been implemented by PBF, there are PBF responsible persons who have never participated in CDOB training, there are PBFs that do not have Standard Operating Procedures according to CDOB Guidelines, there are PBFs who have drug warehouse temperature control devices that are not routinely calibrated, there are PBFs who do not record drugs on stock cards regularly, and there are PBFs that do not routinely carry out drug management reporting to the Indonesian Ministry of Health and the Indonesian POM Agency which can prevent the circulation of counterfeit drugs (BBPOM Jayapura, 2023)

Based on the facts and problems that occurred, the researcher felt the need to conduct research on the evaluation of the application of aspects of CDOB in PBF in Jayapura City, Papua Province in ensuring the quality of drugs in PBF.

## LITERATURE REVIEW

Good drug distribution practices (CDOB) are a set of standardized, routine working methods, which ensure that the quality, safety, and efficacy of pharmaceutical products remain intact from the beginning to the end of their expiration date. The all-encompassing characteristics of CDOB can provide many opportunities for greater efficiency in PBF operations. However, CDOB that covers all aspects also makes it vulnerable to the emergence of weak points that can facilitate the entry of illegal drug products (Cvetanovski et al., 2020).

The supply chain is associated with being part of the supply chain management process that plans, implements, and manages the distribution and storage of products efficiently and effectively (Permana et al., 2022). According to research by Agustyani et al (2017) 40 (97.56%) PBFs do not have CDOB certificates, there are 12.2% of PBF personnel who have not received CDOB training, 19.51% do not have a record of having conducted or participated in the training, and 43.9% do not conduct pre tests and post tests to evaluate the effectiveness of training. The results of the study from Yusuf and Avanti (2020) are known to describe the implementation of CDOB training in PBF 46.7% always organize, 33.3% frequently, 16.7% rarely, and 3.3% never. Based on the results of the study, it can be seen that not all PBFs have competent personnel in the field of CDOB.

## RESEARCH METHOD

This study uses a quantitative descriptive method conducted in December 2023, using a data collection instrument in the form of a questionnaire. The research sample is 22 PBFs which is 81% of the total population of 27 PBFs in Jayapura City. The data from the univariate analysis is presented in the form of frequency and percentage distribution tables.

## RESULT AND DISCUSSION

Pharmaceutical Wholesalers (PBF) in implementing CDOB must also have a good management system. A good management system must be supported by standard operating procedures (SOPs), human resources or personnel with integrity, and a good documentation system.

This study evaluates the application of 9 aspects of CDOB in a number of PBFs in Jayapura City, Papua Province. CDOB principles apply starting from the stages of procurement, storage, and distribution, including the return of drugs in the distribution chain. These stages are described through 9 aspects of CDOB. PBF in Indonesia is owned by the government and some are owned by the private sector. PBF must be able to guarantee the quality, efficacy, and safety of the drugs distributed. To prevent the distribution of poor-quality drugs, the implementation of CDOB must be of good quality in both government-owned PBFs and private-owned PBFs (Jeong & Ji, 2018; Van Assche et al., 2018).

The data from the study were obtained that the transportation aspect, quality management aspect, complaint aspect, requisition products, allegedly counterfeit drugs, and drug recalls are aspects in CDOB where most PBFs have very good implementation. This is because these three aspects have a strong influence on the quality of drugs in PBF, so PBF focuses more on applying these

three aspects. The transportation aspect is an aspect that regulates how to transport drugs in a good and safe manner that must be carried out by PBF with the aim that the quality of drugs is always maintained. The quality management aspect is a quality system management that has been determined, implemented, and studied with the aim of maintaining drug quality. The aspects of complaints, renewals, allegedly counterfeit, and recalls are aspects of how complaints and problems regarding existing drugs are immediately identified and followed up.

*Table 1. Analysis of research variables based on frequency and percentage distribution*

It	Variable	Criterion	n	%
1	Quality Management	Qualify	17	77,3
		Not Eligible	5	22,7
<b>Total</b>			22	100
2	Organization, management and personnel	Qualify	13	59,1
		Not Eligible	9	40,9
<b>Total</b>			22	100
3	Buildings and equipment	Qualify	5	22,7
		Not eligible	17	77,3
<b>Total</b>			22	100
4	Operational	Qualify	9	40,9
		Not eligible	13	59,1
<b>Total</b>			22	100
5	Self-Inspection	Qualify	11	50
		Not eligible	11	50
<b>Total</b>			22	100
6	Complaints, change products, drugs suspected of being counterfeit and drug recalls	Qualify	16	72,7
		Not eligible	6	27,3
<b>Total</b>			22	100
7	Transportation	Qualify	20	90,9
		Not eligible	2	9,1
<b>Total</b>			22	100
8	Distribution facilities on a contract basis	Qualify	16	72,7
		Not eligible	6	27,3
<b>Total</b>			22	100
9	Documentation	Qualify	16	72,7
		Not eligible	6	27,3
<b>Total</b>			22	100

### *Quality Management Aspects*

The quality management aspect is a quality system management that is determined, implemented, and reviewed with the aim of maintaining drug quality. From Table 1, it can be seen that 17 PBFs (77.3%) have implemented quality management aspects, although there are 5 PBFs (22.7%) who are not eligible. From the data, there are pbf that do not conduct periodic quality management studies related to change control which includes the obligation to investigate non-conformities in processes and results according to CDOB standards. Quality management needs to be applied in PBF distribution

activities, because distribution activities must be clearly defined, systematically reviewed, validated at every step, and documented. CDOB stated that the quality management review and monitoring actions were carried out by the PBF management and assisted by the Pharmacist in Charge of PBF (BPOM, 2020).

### ***Organizational, Management, and Personnel Aspects***

Aspects of organization, management, and personnel are personnel involved in activities in PBF including duties and responsibilities, experience, and competencies possessed in order to ensure the quality of drugs. Based on Table 1, it can be seen that in this aspect 13 PBFs (59.1%) and 9 PBFs (40.9%) are not eligible. Responsible Pharmacists who have not carried out their duties and responsibilities in accordance with CDOB. Some pharmacists have never prepared a CDOB training program for personnel in PBF. To be able to carry out their duties and responsibilities, a pharmacist and personnel in PBF must have received CDOB training regularly and periodically to ensure that the quality of drugs is maintained throughout the distribution chain, then it must be ensured that competent personnel are available. The effectiveness of the training can be carried out through pre and post-tests given during the training. All forms of training carried out at PBF must be documented and related to the records of training that have been carried out.

The Pharmacist in Charge (APJ) must have CDOB competence in carrying out their responsibilities in PBF obtained by participating in training. Training can be done internally or externally. Internally, the speakers can come from PBF or APJ management who have CDOB competencies (Wijaya & Chan 2018). The management, APJ and all personnel must be competent in CDOB so that in carrying out PBF operations have performance in accordance with CDOB standards (Bhaskaran & Venkatesh, 2019). Personnel who do not understand CDOB handling can lead to a decrease in the quality and safety of drugs (Kumar & Jha, 2015). Pharmaceutical wholesalers who regularly conduct audits will get good benefits because the CDOB process carried out by personnel will be evaluated and will produce recommendations for process improvement.

### ***Building and Equipment Aspects***

The building and equipment aspects in this study are the places used to store drugs and the tools used to maintain the condition of the storage place to meet the requirements in order to ensure the quality of drugs. From Table 1, the application of CDOB to the aspects of buildings and equipment met the requirements of 5 PBFs (22.7%) and 17 PBFs (77.3%) were not eligible. Data was obtained that the cleanliness of the drug storage room has not been well maintained. PBF does not have a schedule for cleaning the drug storage room and has never filled in the cleaning records of the drug storage room according to the set schedule. There are several PBFs that have not implemented pest control programs, PBFs have open ventilation so that insects can enter, and there are PBFs that do not install rat traps. For controlling the temperature of the drug storage room, there are PBFs that do not map the temperature of the drug storage room. PBF does not place the thermometer in a point that is prone to temperature changes. Equipment maintenance must be routinely carried out in order to

control the room temperature, some do not calibrate the thermometer used for monitoring the temperature of the room where the drug is stored. Buildings must be designed and adapted to PBF to ensure good storage conditions, adequate safety, sufficient storage capacity, guaranteed environmental conditions, cleanliness, free from pests, room temperature, and air circulation/ventilation (Kristanti & Ramadhania, 2020).

### ***Operational Aspects***

The operational aspect of this study is the activities carried out in distributing drugs in PBF starting from the procurement, receipt, and storage to distribution stages in order to ensure the quality of drugs. From Table 1, the implementation of operational aspects met the requirements of 9 PBFs (40.9%) and 13 PBFs (59.1%) did not meet the requirements. The Operational Aspect is an aspect that contains all activities carried out by PBF starting from the stages of procurement, receipt, and storage to the distribution of drugs. The procurement stage is carried out by supplier qualification, there are still many PBFs that do not requalify suppliers according to the requirements periodically. The drug acceptance stage must carry out several checks on the drugs received, including distribution permit numbers, batch numbers, expiration dates, physical inspections, and packaging inspections. There are still some PBFs who rarely do a complete examination when receiving medicine.

Procurement procedures must be issued officially, to ensure that the drug products to be distributed are sourced from legal suppliers (Mudin, 2018). Pharmaceutical wholesalers are the first transit places for drugs after being produced by the pharmaceutical industry, so that as long as the drug is in PBF, the storage conditions are in accordance with the provisions and can maintain the quality of the drug while still meeting the requirements. One storage method is *First Expired First Out* (FEFO) which means drugs that have a faster expiration that are issued or distributed first. Storage with the FEFO method can prevent the condition of the drug from being damaged due to expiration during storage (Kristianti & Ramadhania, 2020).

The preparation of drugs during storage must pay attention to the alphabet, drug classification, dosage form, and *look-alike sound-alike* (LASA). The storage space must also be safe from theft and fire. The more diverse items and the increasing volume of drugs, the more storage space is needed (Sinen et al, 2017). The distribution of drugs per PBF is prohibited from practicing retail distribution and serving doctors' prescriptions. Pharmaceutical wholesalers can only distribute drugs to other PBFs, and pharmaceutical service facilities include pharmacies, pharmacy installations, hospitals, health centers, clinics, or drug stores (Agustyani et al, 2017).

### ***Aspects of Self-Inspection***

The aspect of self-inspection in this study is an internal audit in PBF related to the implementation of CDOB which is carried out routinely and evaluated. Based on table 1, the implementation of self-inspection in PBF in this study was 11 PBFs (50%) who were eligible and 11 PBFs (50%) who were not eligible. Some PBFs have never conducted regular inspections and some have not

documented the implementation and corrective actions or improvement plans. PBF does not make documentation on deviations in the implementation of CDOB obtained from the results of self-inspection. There are PBFs that do not make CAPA (*Corrective Action Preventive Action*) as a form of improvement and preventive measures taken. The purpose of making CAPA is so that shortcomings or inconsistencies that occur can be identified, corrected, and prevented so that they will not be repeated (Agustyani, 2017).

### ***Aspects of Complaints, Replacement Products, Suspected Counterfeit Drugs and Drug Recalls***

The aspects of complaints, drug change, suspected counterfeit, and recall in this study are complaints and problems regarding drugs in PBF. Based on Table 1, 16 PBFs (72.7%) and 6 PBFs (27.3%) were not eligible. From the research, there are PBFs who have never documented complaints that occur and have never made a *trend analysis* of the type of complaints that occur to monitor complaints that often occur. Replacement drugs are drugs that are returned by outlets to PBF. There are several requirements that must be met by PBF if they receive change based on the delivery letter from the returning facility.

A drug recall is carried out immediately if the drug does not meet quality requirements. Drugs that are changed, expired, damaged, or recalled must be stored and handled specifically. There are PBFs that do not have clear labels on change, allegedly counterfeit and expired drugs. PBF does not have a separate room to store these medicines whose rooms are locked to store changed medicines, suspected counterfeit drugs, and expired drugs.

### ***Transportation Aspects***

The transportation aspect in this study is the transportation of drugs from PBF to other facilities with conditions according to the requirements in order to ensure the quality of drugs. Transportation is something that must be considered during the drug distribution process, this is because the quality of drugs during transportation must be maintained. Therefore, PBF must have a safe means of transportation.

The results of the research on the transportation aspect are the highest eligible aspects, namely 20 PBF (90.9%). Almost all PBFs already have a control mechanism for drug delivery documents to prevent irregularities in transportation and conformity with addresses that are in accordance with drug order letters, PBF has also implemented a system that regulates the handling of drug shipments that are not in accordance with the order to prevent diversion and misuse of documents. PBF has also guaranteed that the drug is delivered to the address in accordance with the drug order letter.

In general, the distribution of drugs from PBF uses PBF's own transportation fleet or third-party services. Some of the standards that need to be considered in the distribution or delivery process are the feasibility of the transportation fleet, the availability of a certain temperature storage place, and knowledge of the special treatment of drugs (Sykes, 2018). During the delivery process, the quality and quality standards of the drug preparation must not

change or decrease. Therefore, personnel who carry out drug shipments must have good knowledge (Cvetanovski et al., 2020).

### ***Aspects of Distribution Facilities Based on Contracts***

The aspect of distribution facilities based on contracts in this study is a third-party facility used by PBF by issuing contracts, and cooperation agreements, and can always maintain the quality of drugs. Based on table 1, there are 16 PBFs (72.7%) who have met the requirements who have contracts with third parties and conduct monitoring audits to ensure that shipments are carried out in accordance with the provisions so that the quality and safety of drugs are always guaranteed. Distribution facilities based on contracts are also called third-party distribution. These third parties usually handle the operational parts of storage and delivery (Yusuf, 2019).

### ***Documentation Aspects***

The documentation aspect in this study is the recording carried out in PBF in order to ensure the quality of the drug. Based on Table 1, it can be seen that 16 PBFs (72.7%) store documents in accordance with CDOB provisions, and 6 PBFs (27.3%) do not meet the requirements in the implementation of documentation aspects. There are still some PBFs that do not report drug management regularly to BPOM RI and the Ministry of Health of the Republic of Indonesia. There are still some PBFs that do not properly document copies of drug order letters, drug invoices, or road letters to ensure the legality of the procurement and traceability process. PBF still has a manual documentation system that is not able to trace its history all the time. Documentation is useful as evidence of monitoring, implementation, and prevention of every PBF operational activity so that it can run optimally. PBF must have documentation related to all PBF operations and distribution chain quality management. All PBF documentation archives must be kept for a minimum of 3 years (BPOM, 2020).

## **CONCLUSIONS AND RECOMMENDATIONS**

Based on the results of the research and discussion, it can be concluded as follows:

1. The implementation of CDOB in the aspect of quality management met the requirements of 17 PBFs (77.3%) and 5 PBFs (22.7%) were not eligible.
2. The implementation of CDOB in the aspects of organization, management, and personnel met the requirements of 13 PBFs (59.1%) and 9 PBFs (40.9%) were not eligible.
3. The application of CDOB in the aspect of buildings and equipment met the requirements of 5 PBFs (22.7%) and 17 PBFs (77.3%) did not meet the requirements.
4. The implementation of CDOB in operational aspects met the requirements of 9 PBFs (40.9%) and 13 PBFs (59.1%) did not meet the requirements.
5. The application of CDOB to the aspect of self-inspection met the requirements of 11 PBFs (50%) and 11 PBFs (50%) did not meet the requirements.

6. The application of CDOB to the aspects of complaints, renewed products, suspected counterfeiting and drug recalls met the requirements of 16 PBFs (72.7%) and 6 PBFs (27.3%) were not ineligible.
7. The application of CDOB in the transportation aspect met the requirements of 20 PBFs (90.9%) and 2 PBFs (9.1%) did not meet the requirements.
8. The application of CDOB to the aspect of distribution facilities based on contracts met the requirements of 16 PBFs (72.7%) and 6 PBFs (27.3%) were not eligible.
9. The application of CDOB to the documentation aspect met the requirements of 16 PBFs (72.7%) and 6 PBFs (27.3%) were not qualified

As a recommendation to improve the quality assurance system in PBF in Jayapura City by implementing CDOB, PBF management needs to show a strong commitment to the implementation of CDOB by allocating adequate resources, including training and human resource development. PBF needs to ensure that its facilities and infrastructure meet CDOB requirements, including adequate drug storage warehouses, well-maintained equipment, and effective environmental control systems. PBFs need to implement a comprehensive quality management system to ensure compliance with CDOB and to improve the quality of medicines and services. PBF needs to monitor and evaluate the effectiveness of CDOB implementation on a regular basis. PBF needs to collaborate with other stakeholders, such as the Food and Drug Supervisory Agency (BPOM), the Health Office, Health Higher Education Institutions, hospitals, and pharmacies to ensure the smooth distribution of drugs and to improve the overall quality of health services. This recommendation is expected to help PBF in Jayapura City in improving the quality assurance system and ensuring the distribution of safe, efficacious, and quality drugs to the community.

#### **FURTHER STUDY**

Further research suggestions are to conduct more in-depth research to identify the factors that significantly affect the implementation of CDOB in PBF and the impact of CDOB application on drug quality.

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#### **REFERENCES**

- Agustyani V., Utami, W., Sumaryono W., Athiyah, U., and Rahem, A, 2017. Evaluation of the Implementation of CDOB as a Quality Assurance System in a Number of PBFs in Surabaya. Indonesian Journal of Pharmaceutical Sciences.

- BPOM, 2020. Regulation of the Food and Drug Supervisory Agency Number 6 of 2020 concerning Amendments to the Regulation of the Food and Drug Supervisory Agency Number 9 of 2019 concerning Technical Guidelines on Good Drug Distribution Methods. Jakarta.
- Bhaskaran J., and Venkatesh, M.P. 2019. Good Storage and Distribution practices for Pharmaceuticals in European Union. *Journal of Pharmaceutical Sciences and Research*.
- BBPOM Jayapura. 2023. Annual Report of the Food and Drug Supervisory Center in Surabaya in 2023. Jayapura
- Cvetanovski, F., Kocev, N., Tonic-Ribarska, K., and Trajkovic-Jolesvka, S. 2020. Good Distribution Prctatice in preserving the integrity and safety of the supply chain of pharmaceuticals.
- Hartini I. S., 2014. Evaluation of the Implementation of Good Drug Distribution Methods in Pharmacies in Mlati District, Sleman Regency, Yogyakarta. UGM, Yogyakarta.
- Jeong, S., and Ji, E., 2018. Global perspectives on ensuring the safety of pharmaceutical products in the distribution process.
- Kristanti, M.W., and Ramadhania, Z.M. 2020. Evaluation of the Conformity of the Retail Storage System of Drugs, Supplements, and Cosmetics at One of the Pharmaceutical Wholesaler Warehouses (PBF) in Central Jakarta.
- Kumar, N., and Jha, A. 2015. Quality Perspective of Good Distribution Practices in Indian Pharmaceutical Industry. *IOSR Journal of Business and Management*.
- Permana, A. I., & Soediantono, D. 2022. The Role of Eco Supply Chain on Environment and Operational Performance of Indonesian Defense Industry.
- Sinen, Y. Lolo, W, A., amd Supriati, H, S., 2017. Evaluation of Drug Storage and Distribution at PT. Unggul Jaya Cipta Usaha Manado.
- Van Assche, K., Giralt, A. N., Caudron, J. M., Schiavetti, B., Pouget, C., Tsoumanis, A., Meessen, B., and Ravinetto, R., 2018. Pharmaceutical quality assurance of local private distributors: A secondary analysis in 13 low-income and middleincome countries
- Wijaya, m., Chan, A. 2018. Evaluation of the Implementation of Drug Distribution Methods at PBF Rajawali Nusindo. *World Pharmaceutical Journal*.
- Yusuf, B., & Avanti, C. 2020. Good Drug Distribution Methods (CDOB) and Its Implementation by Pharmaceutical Wholesalers (PBF) in Banjarmasin-Banjarbaru City in 2019