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Assessment of compliance of wholesale pharmaceutical establishments with Good Distribution Practices (GDP) and ISO 9001:2015 standards in Kinshasa Province, Democratic Republic of the Congo

Kisangala, J. M., Bayebila, T. M., & Mbinze, J. K.

Faculty of Pharmaceutical Sciences, University of Kinshasa, Kinshasa, Democratic Republic of the Congo

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Correspondence to:
José Kisangala Mfubilioni
jkisvita23@gmail.com

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ABSTRACT

Introduction
Two major trends have been observed in the Democratic Republic of the Congo (DRC) over the past decades: the increasing number of licences issued to open wholesale pharmaceutical establishments and the circulation of medicines of questionable quality. These trends raise serious concerns about population health.

Purpose
The aim of this study was to assess compliance with Good Distribution Practices (GDP) and ISO 9001:2015 standards among wholesale pharmaceutical establishments (WPEs) operating in the Democratic Republic of the Congo.

Methods
This cross-sectional study was conducted from January to June 2025 in the city of Kinshasa. Twenty-five pharmaceutical depots were randomly selected from a total of 110 wholesale pharmaceutical establishments listed by ACOREP in Kinshasa Province. Data were collected using two assessment tools (one for GDP and the other for ISO 9001:2015), direct observation of infrastructure, and semi-structured interviews with managers. The collected data were analysed using the chi-squared test to assess homogeneity and heterogeneity between establishments.

Results
Statistical analysis revealed significant heterogeneity among the studied establishments. Of the 25 pharmaceutical warehouses assessed, the reported p-values varied according to the evaluated standards and parameters. Regarding GDP, only one parameter demonstrated homogeneity, namely the documentation system ($p = 0.622$). All other parameters showed significant heterogeneity: quality system ($p = 0.0239$), personnel ($p = 0.001$), medicine storage ($p < 0.001$), and information technology systems ($p = 0.0295$). For ISO 9001:2015, homogeneity was observed for leadership ($p = 1$), planning ($p = 0.854$), and performance evaluation ($p = 0.638$). However, heterogeneity was identified in organisational context ($p < 0.001$), support ($p < 0.001$), operational activities ($p < 0.001$), and continuous improvement ($p = 0.0716$).

Conclusion
Compliance with GDP and ISO 9001:2015 standards remains insufficient in the Democratic Republic of the Congo, particularly with regard to ensuring the quality and safety of medicines. Continuous auditing and inspection of wholesale pharmaceutical establishments are required nationwide, especially in Kinshasa, where more than 70% of such establishments are located. Continuing professional education on GDP and ISO standards for pharmacists and their staff must be strengthened according to a structured schedule. The role of the responsible pharmacist should also be reinforced, and warehouse owners must make substantial contributions to quality assurance efforts. The observed operational heterogeneity among wholesale pharmaceutical establishments compromises medicine quality assurance in Kinshasa. Urgent action by health authorities is required to safeguard the health security of the Congolese population.

INTRODUCTION

The quality of pharmaceutical products is a major public health concern, particularly in low- and middle-income countries, where counterfeit and substandard medicines are widespread (Khurelbat et al., 2020). The Democratic Republic of the Congo (DRC), and more specifically its capital city, Kinshasa, faces substantial challenges in the management, storage, and distribution of medicines (Schiavetti et al., 2018).

Wholesale pharmaceutical establishments occupy a strategic position within the pharmaceutical supply chain, serving as intermediaries between manufacturers, importers, and healthcare facilities. Their performance directly influences the availability of quality medicines, continuity of treatment, and patient safety.

In response to these challenges, the implementation of internationally recognised quality management systems has become a priority. ISO 9001:2015, the global benchmark for quality management systems, provides a structured and methodological framework that enables organisations to improve processes, strengthen document control, systematise risk assessment, and promote continuous improvement (International Organization for Standardization [ISO], 2015). In the pharmaceutical sector, this standard contributes to enhanced operational reliability, improved customer satisfaction, and strengthened organisational performance.

In parallel, Good Distribution Practices (GDP), published by the World Health Organization (WHO) and incorporated into many national regulatory frameworks, define the minimum requirements for the consistent storage, handling, and transportation of pharmaceutical products under conditions that preserve their quality (WHO, 2010, 2014). GDP constitutes a fundamental pillar for preventing product deterioration, contamination, cold-chain disruptions, and the circulation of non-compliant medicines.

Despite regulatory efforts by the Ministry of Health and the Directorate of Pharmacy and Medicines (DPM), several studies have reported persistent deficiencies in the implementation of quality management systems and GDP in pharmaceutical warehouses in the DRC. These deficiencies include incomplete documentation, inadequate infrastructure, inaccurate stock management, insufficient staff training, and the absence of structured monitoring and evaluation mechanisms. Such weaknesses expose patients to significant risks, including the distribution of degraded or ineffective medicines, and undermine confidence in the health system.

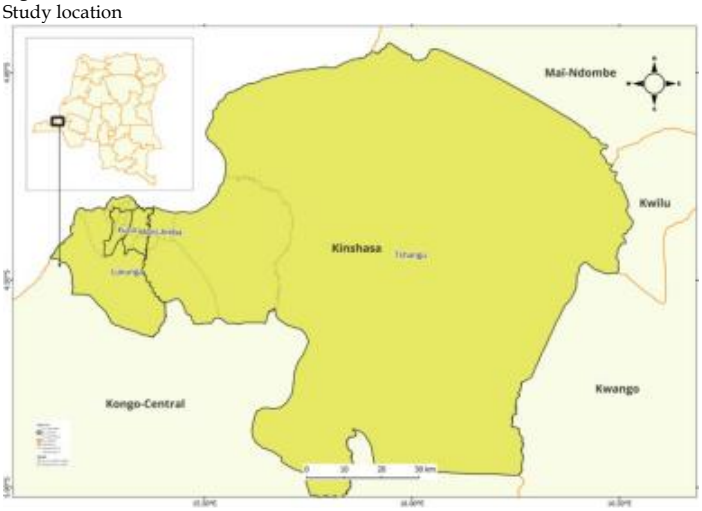
This study aims to assess the level of compliance of wholesale pharmaceutical establishments (WPEs) in Kinshasa with GDP and ISO 9001:2015 requirements, identify existing gaps, and propose corrective recommendations. To the best of our knowledge, this is the first study to comprehensively evaluate the quality of pharmaceutical wholesale distribution operations in the DRC, with a particular focus on Kinshasa.

METHODS

Study Location

This study was conducted in the city of Kinshasa, the capital of the Democratic Republic of the Congo, between January and June 2025 **(Figure 1)**. It focused exclusively on wholesale pharmaceutical establishments (WPEs) and assessed compliance with criteria defined by the WHO reference guidelines on Good Distribution Practices and the GDP guidelines issued by ACOREP. Retail distribution to pharmacies and pharmaceutical supply to healthcare facilities were not included in the scope of this study.

Figure 1:
Study location



Sampling

A descriptive and analytical study design was applied to pharmaceutical depots operating in Kinshasa. Of the 110 wholesale pharmaceutical establishments listed by ACOREP, 25 were randomly selected for inclusion. Eligible establishments were those that were legally authorised and operational at the time of the study. Closed depots and establishments that declined participation were excluded.

Stratified sampling was employed to ensure representative geographic coverage. Four strata were defined based on areas of concentration: Gombe, Bitabe, Rond-point Ngaba, and Université Pédagogique Nationale (UPN). Samples were selected proportionally from each stratum, and

individual depots were randomly chosen from the ACOREP list in accordance with the inclusion and exclusion criteria.

Data Collection

Data were collected by the principal investigator using three primary methods:

1. A structured assessment form based on the GDP reference framework;
2. Direct on-site observations of infrastructure, hygiene, equipment, and storage conditions;
3. Semi-structured interviews with depot managers and responsible pharmacists.

Observation Criteria

Observation criteria were defined in accordance with both GDP and ISO 9001:2015 requirements and included, among others: general cleanliness of premises; separation of functional areas; presence of designated areas for sensitive products and psychotropic substances; security measures such as locked doors; temperature control and lighting; organisational charts; availability of personal protective equipment; pallet-based storage; existence of standard operating procedures, records, and a quality manual; management involvement; appropriate storage practices; handling of rejected and returned products; regulatory authorisations; personnel hygiene; equipment cleanliness; and waste management systems.

Interview Guide

At the beginning of each interview, respondents were asked to provide general information about their establishment, including its name, their professional role, length of service, and responsibilities. The purpose of the interview was briefly reiterated. Participants were then asked general questions about organisational practices, followed by specific questions related to GDP and ISO 9001:2015 standards.

Questionnaire Validation

The questionnaire was reviewed to ensure that all questions were clear, neutral, relevant to the applicable standards, precise, and specific.

Statistical Data Processing

Collected data were summarised using descriptive statistical methods appropriate for qualitative variables. As specified in the observation criteria, the chi-square test of homogeneity was used to analyse variables related to GDP and ISO 9001:2015 compliance. A p-value of less than 0.05 was considered statistically significant. Statistical analyses were performed using R software (version 3.6.3; Comprehensive R Archive Network) and Microsoft Excel 2013 (Microsoft Corporation, Redmond, WA, USA).

Ethical Considerations

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and was approved by the National Health Ethics Committee of the Democratic Republic of the Congo under approval number 699/BN/PNMF/2025.

RESULTS

Characteristics of Establishments

All wholesale pharmaceutical establishments that participated in the study met the predefined inclusion criteria, as described in the sampling section.

Compliance with Good Distribution Practices (GDP)

Tables 1–5 present the results related to compliance with GDP requirements across the assessed domains.

Quality System

Table 1a:
Compliance with GDP requirements for the quality system (Items A–J)

Response	A	B	C	D	E	F	G	H	I	J
Yes (+)	16	15	14	6	7	10	7	8	9	10
No (–)	9	10	11	19	18	15	18	17	16	15

Table 1b:
Compliance with GDP requirements for the quality system (Items K–S)

Response	K	L	M	N	O	P	Q	R	S
Yes (+)	11	6	10	9	6	16	16	10	12
No (–)	14	19	15	16	19	9	9	15	13

Legend (Tables 1a–1b):
A: Knowledge of the quality system
B: Availability of a quality manual
C: Appointment of a quality system manager
D: Existence of a change control system
E: Availability of records
F: Evaluation of the quality system
G: Evaluation of key performance indicators (KPIs)
H: Evaluation of regulatory changes affecting quality
I: Documentation of quality-improving innovations
K: Compliance of outputs with requirements
L: Measurement of outputs
M: Defined evaluation timeline
N: Availability of evaluation reports
O: Conduct of management reviews
P: Documentation of management reviews
Q: Implementation of corrective actions
R: Retention of quality information
S: Documentation of conclusions from evaluations

Staff

Table 2:
Compliance with GDP requirements related to staff

Response	A	B	C	D	E	F
Yes (+)	25	23	10	11	11	10
No (–)	0	2	15	14	14	15

Legend:

A: Organisational chart available
B: Manager knowledgeable in legislation
C: Job descriptions available
D: Staff trained in GDP
E: Training on narcotics and psychotropic substances
F: Availability of hygiene procedures

Premises and Storage of Medicines

Table 3:
Compliance with GDP requirements for premises and medicine storage

Response	A	B	C	D	E	F	G	H
Yes (+)	16	17	21	8	6	11	25	11
No (–)	9	8	4	17	19	14	0	14

Response	I	J	K	L
Yes (+)	13	14	11	15
No (–)	12	11	14	10

Legend:

A: Separate storage areas for medicines
B: Clearly delineated areas
C: Restricted access for unauthorised persons
D: Validated delimitation systems
E: Separation of products pending distribution decisions
F: Proper handling of expired and falsified medicines
G: Adequate preservation of cold-chain products
H: Availability of a reception area
I: Separation of reception, storage, and dispatch areas
J: Availability of cleaning procedures
K: Calibration of temperature-control equipment
L: Dedicated area for falsified medicines

Computer System

Table 4:
Compliance with GDP requirements for computer systems

Response	A	B	C	D	E
Yes (+)	15	9	7	15	16
No (–)	10	16	18	10	9

Legend:
A: Availability of a computerised system
B: System validation
C: Written system description
D: System access control
E: Data backup and restoration system

Documentation System

Table 5:
Compliance with GDP requirements for documentation

Response	A	B	C	D	E	F	G	H	I	J
Yes (+)	8	5	9	4	6	9	6	9	5	9
No (–)	17	20	16	21	19	16	19	16	20	16

Legend:

A: Validation reports for equipment and procedures
B: Temperature excursion procedures
C: Drug safety procedures
D: Management of active and radioactive materials
E: Reuse reports for refrigerant blocks
F: Procedures for delivery of materials and medicines
G: Manufacturer emergency recall plan
H: Complaint handling procedures
I: Procedures for detecting falsified medicines
J: Supplier approval procedures

Compliance with ISO 9001:2015

Tables 6–12 summarise compliance with ISO 9001:2015 requirements.

Context of the organization

Table 6:
Data collected for context of the organization

	A	B	C
+	2	1	15
-	23	24	10

Caption: +: yes -: no

A: Have you identified the needs and expectations of interested parties (e.g. customers, suppliers, regulatory authorities and staff)?
B. Has your depot defined the scope of application of its quality management system (QMS)?
C. Is a quality manual available and up to date?

Leadership

Table 7:
Data collected for the leadership

	A	B	C
+	3	3	3
-	22	22	22

Caption: +: yes -: no

A: Is management clearly committed to quality? (For example, is there a signed quality policy?)
B: Is there a quality policy that is displayed and known to staff?
C. Are the responsibilities and authorities of quality roles clearly defined?

Planning

Table 8:
Data collected for the planning

	A	B	C
+	2	3	2
-	23	22	23

Caption: +: yes -: no

A: Have you identified the risks and opportunities associated with your activities?
B: Do you have an action plan in place to manage these risks and opportunities?
C: Are your quality objectives clearly defined, measurable and monitored?

Support

Table 9:
Data collected for the support

	A	B	C	D	E
+	5	3	2	8	15
-	20	22	23	17	10

Caption: +: yes -: no

A: Do you have the necessary human, material and technical resources to ensure quality?
B: Is your staff trained in the QMS?
C: Are training records kept up to date?
D: Do you have a document management system?
E. Do you have a secure IT system to ensure product traceability?

Implementation of activities

Table 10:
Data collected for the implementation of activities

	A	B	C	D	E
+	9	25	25	1	9
-	16	0	0	24	16

Caption: +: yes -: no

A: Do you have written procedures for receiving, storing, preparing and delivering medicines?
B: Are storage conditions (temperature and humidity) monitored and recorded?
C. Do you have a procedure for managing non-compliant products (e.g. expired or damaged items)?
D: Is there complete traceability of batches from receipt to delivery?
E: Do you have a complaint management system?

Performance evaluation

Table 11:
Data collected for the performance evaluation

	A	B	C
+	6	9	7
-	19	16	18

Caption: +: yes -: no

A: Do you conduct regular internal audits?
B: Are management reviews held periodically?
C: Do you monitor quality performance indicators (KPIs)?

Improvement

Table 12:
Data collected for improvement

	A	B	C
+	16	9	9
-	9	16	16

Caption: +: yes -: no

A: Do you have a system in place for managing non-compliance and corrective actions?
B: Do you implement continuous improvement measures for your processes?
C: Do you keep a record of corrective and preventive actions (CAPA)?

Inferential Statistics

GDP Compliance

Table 13:
Chi-square test results for GDP compliance

Domain	Parameters	p-value
Quality system	A–J, K–S	0.0239; 0.0268
Staff	A–F	< 0.001
Premises and storage	A–L	< 0.001
Computer system	A–E	0.0295
Documentation system	A–J	0.622

ISO 9001:2015 Compliance

Table 14:
Chi-square test results for ISO 9001:2015 compliance

Domain	Parameters	p-value
Context of the organisation	A–C	< 0.001
Leadership	A–C	1.000
Planning	A–C	0.854
Support	A–E	< 0.001
Operational activities	A–E	< 0.001
Performance evaluation	A–C	0.638
Continuous improvement	A–C	0.0716

DISCUSSION

Interpretation of the Results

A statistical analysis was conducted to determine whether the operational practices of wholesale pharmaceutical establishments were homogeneous or heterogeneous, using the chi-square test **(Table 13)**. Most of the variables assessed under Good Distribution Practices (GDP) showed statistically significant heterogeneity ($p < 0.05$), indicating substantial variability in practices among the 25 establishments surveyed.

Among all GDP-related domains, only the documentation system showed statistical homogeneity ($p = 0.622$), suggesting similar practices across establishments. However, qualitative observations revealed that these practices were largely inadequate, indicating that homogeneity in this case reflects uniformly weak compliance rather than acceptable performance.

Table 14 summarises the statistical outcomes of the ISO 9001:2015 assessment. The chi-square analysis revealed significant non-homogeneity ($p < 0.05$) in organisational context, support, operational activities, and continuous improvement, demonstrating wide variability in implementation across establishments. Conversely, homogeneity ($p > 0.05$) was observed for leadership, planning, and performance evaluation. This suggests that weaknesses in these critical areas are widespread and consistently present across most establishments.

Discussion of GDP Compliance

The findings indicate significant non-compliance in the quality system domain ($p = 0.0239$ and $p = 0.0268$), highlighting deficiencies in quality policy implementation, internal audits, management reviews, and document control. These results are consistent with studies conducted in other countries within the subregion. For example, research in Nigeria reported that more than 60% of pharmaceutical warehouses lacked a functional quality management system (Abubakar et al., 2020), while inspections in Ghana revealed poor standardisation of operational procedures (Owusu-Daaku & Kretchy, 2019). These findings confirm that the implementation of structured quality management systems remains a regional challenge, often due to limited resources and inadequate training (World Health Organization [WHO], 2020).

Staff-related indicators demonstrated comparatively high compliance ($p < 0.001$), suggesting that most establishments employ responsible pharmacists or trained personnel. This observation aligns with findings from Rwanda, where over 80% of pharmaceutical establishments reportedly have qualified managers (Musafiri et al., 2018). Nevertheless, despite the presence of qualified personnel, continuing professional development in GDP remains insufficient, as noted in several African studies (WHO, 2021).

Non-compliance related to premises and medicine storage ($p < 0.001$) was frequently associated with inadequate infrastructure, absence of temperature-monitoring devices, poor storage conditions, and insufficient safety equipment. Similar deficiencies have been reported in Cameroon, where more than half of inspected warehouses failed to meet storage standards (Mbanya et al., 2019). In Nigeria, poor storage conditions have also been identified as a major contributor to medicine degradation (Nafiu et al., 2020). These findings suggest that Kinshasa faces challenges comparable to those observed elsewhere in the region, including ageing infrastructure, insufficient investment, and limited electronic monitoring systems.

Compliance with computerised systems was low ($p = 0.0295$), reflecting limited use of digital tools for traceability, inventory management, and prevention of stockouts. Evidence from pilot projects in Ghana and Kenya demonstrates that computerised supply chain systems can significantly reduce distribution errors and improve inventory visibility (Kinzang et al., 2020; Mwangi et al., 2017). However, the present study indicates that most wholesale pharmaceutical establishments in Kinshasa remain at an early stage of supply chain digitisation.

Although the documentation system showed statistical homogeneity ($p = 0.622$), overall compliance remained low, indicating limited availability and poor quality of documentation. This finding is consistent with observations across the subregion, where documentation systems are often present but incomplete, outdated, or inconsistently applied (WHO, 2020).

Discussion of ISO 9001:2015 Compliance

In Central Africa, inadequate strategic analysis tools and limited training in quality management are recognised as major weaknesses in health and pharmaceutical organisations (WHO, 2021). Studies conducted in Cameroon and Nigeria have shown that fewer than 30% of organisations perform formal organisational context or risk analyses (Ndomondo & Adeola, 2020). The significant non-compliance observed in the present study for organisational context ($p < 0.001$) is therefore consistent with regional trends.

Leadership showed homogeneous results across establishments ($p = 1.000$), indicating that management commitment is similarly distributed regardless of overall compliance levels. Although this finding may appear counterintuitive, it reflects a situation commonly observed in African pharmaceutical organisations, where leadership commitment is often formally expressed but inadequately translated into operational action. According to the African Union (2022), quality management systems in African pharmaceutical companies tend to fail more due to weak implementation than to the absence of quality policies. The present findings support this observation and align with results reported in West Africa (Kouamé et al., 2021).

Low compliance in planning-related activities, including risk management and quality objective setting, mirrors patterns observed in many African small and medium-sized enterprises. Pharmaceutical warehouses often lack formal mechanisms for systematic risk identification, performance indicator definition, and monitoring of quality objectives. The African Development Bank (AfDB, 2020) reports that fewer than 40% of companies formalise risk management within pharmaceutical supply chains, corroborating the high level of non-compliance observed in this study (approximately 90%).

Support-related requirements, including human resources, infrastructure, documentation, and communication, also showed low compliance ($p < 0.001$). These deficiencies reflect well-documented structural challenges across the continent. According to the WHO (2021), pharmaceutical warehouses in Africa commonly face inadequate storage infrastructure, insufficient staff training in good logistics practices, and the absence of structured documentation systems. The present study confirms that inadequate organisational support constitutes a major barrier to quality system implementation.

Operational activities, particularly those related to receipt, verification, storage, traceability, and distribution of medicines, were also characterised by significant non-compliance ($p < 0.001$). Similar challenges have been reported in Ghana, Kenya, and Rwanda, including lack of written procedures, insufficient performance indicators, and inadequate cold-chain monitoring (WHO, 2022).

Performance evaluation demonstrated moderate compliance ($p = 0.638$), which is relatively encouraging given that internal audits and systematic performance reviews are still uncommon in many African

pharmaceutical settings, largely due to limited internal expertise (Kaboré et al., 2019). Nevertheless, the current level of performance evaluation remains insufficient when measured against international standards.

Continuous improvement showed mixed compliance (p = 0.0716), a pattern frequently observed in organisations with limited analytical capacity and weak feedback mechanisms. In many African contexts, continuous improvement is often reduced to ad hoc problem-solving rather than being implemented as a structured, data-driven process (African Union, 2022). The findings of this study confirm that, while corrective actions may be taken, formal systems for monitoring and evaluating their effectiveness are largely absent.

Limitations of the Study

This study has several limitations that should be acknowledged. Methodologically, data collection relied primarily on questionnaires administered to quality managers and pharmacists, which may have introduced response bias due to subjectivity or the desire to present establishments in a favourable manner. Additionally, the study sample included a relatively small number of establishments, limiting the generalisability of the findings to all wholesale pharmaceutical warehouses in the Democratic Republic of the Congo.

CONCLUSION

This study evaluated compliance with Good Distribution Practices and ISO 9001:2015 standards among wholesale pharmaceutical establishments in Kinshasa. The findings revealed substantial shortcomings in quality management systems, human resources, infrastructure, documentation, and digitalisation. These deficiencies compromise the quality and safety of medicines distributed and pose significant risks to patient safety. Strong commitment from health authorities, coupled with effective collaboration among stakeholders in the pharmaceutical sector, is essential to establish and sustain a robust quality culture.

Recommendations

Based on the findings of this study, the following actions are strongly recommended for key stakeholders in the pharmaceutical sector in the Democratic Republic of the Congo, including ACOREP, the Order of Pharmacists, and managers of wholesale pharmaceutical establishments:

- Strengthening regulatory enforcement mechanisms
- Implementing structured and continuous training programmes on GDP and quality management systems
- Upgrading storage infrastructure and cold-chain facilities
- Developing and implementing digitalisation strategies for traceability and inventory management
- Conducting regular and independent internal and external audits

Ethical Approval: This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and was approved by the National Health Ethics Committee of the Democratic Republic of the Congo under approval number 699/BN/PNMF/2025.

Conflicts of Interest: None declared.

ORCID iDs:
Kisangala, J. M.: https://orcid.org/0009-0000-4461-3288
Bayebila, T. M.: https://orcid.org/0000-0002-2734-3148
Mbinze, J. K.: https://orcid.org/0000-0001-6906-5329

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