Collective Analysis of Pharmacy Inspection Observations Data Report
Quarter 3 Year 2025

1. Executive Summary

Total No. of Pharmacy Inspections: **39,288 inspection**

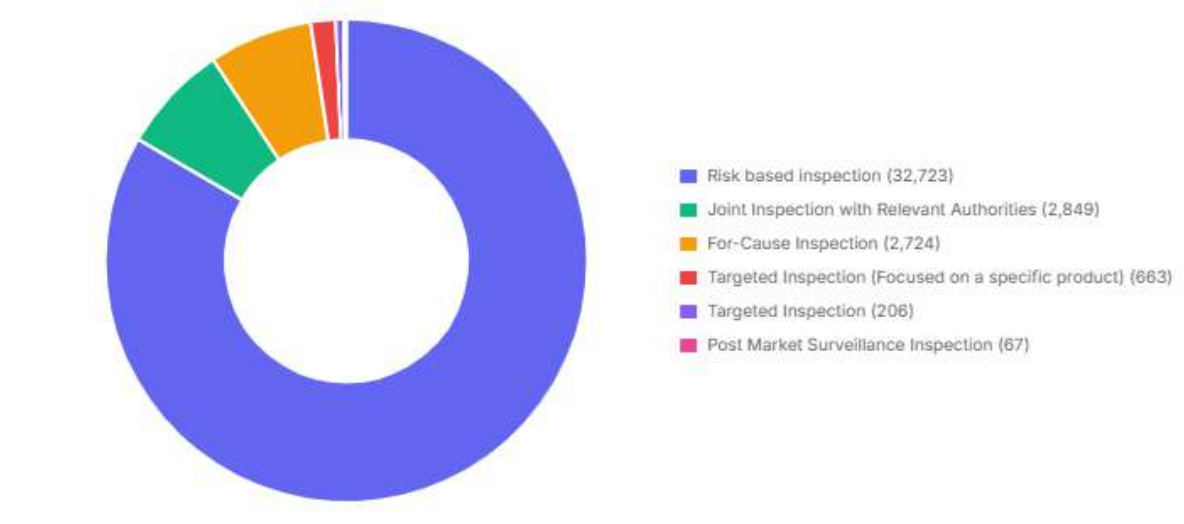
Type of Pharmacy Establishment

- Community Pharmacy: **39,232 inspection**
- Hospital Pharmacy: **56 inspection**

Note: Pharmacies may be inspected more than once during a quarter. For this analysis, only the most recent inspection result for each pharmacy is included, ensuring that each pharmacy is counted once and reducing the risk of duplicate or misleading results.

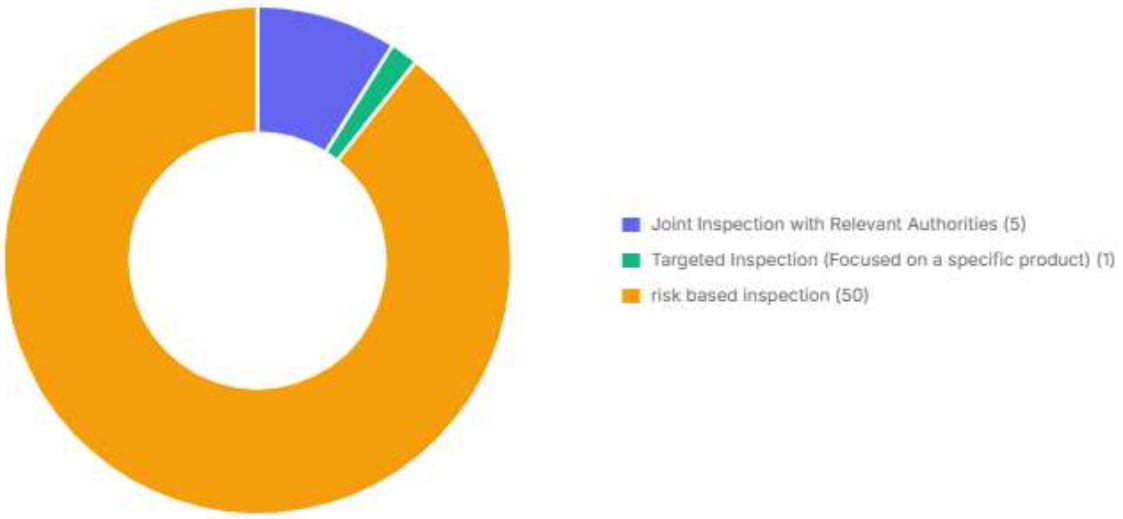
Type of Inspection
For Community pharmacies

- Targeted Inspection (Focused on a Specific Product): **663 inspections**
- Risk-Based Inspection: **32,723 inspections**
- Joint Inspection with Relevant Authorities: **2,849 inspections**
- Post-Market Surveillance Inspection: **67 inspections**
- For-Cause Inspection: **2,724 inspections**
- Target Inspection: **206 inspections**
- Recall Follow-Up Inspection: **0 inspections**



For Hospital pharmacies

- Targeted Inspection (Focused on a Specific Product): **1**
- Risk-Based Inspection: **50**
- Joint Inspection with Relevant Authorities: **5**



2. Overview Section

A) Total Number of Violations

For Community Pharmacies

Total No. of Violations: **6,586 violation** (Note: The same violation may be recorded more than once for the same pharmacy.)

Violation Category	No.	%
Licensing & Professional Practice	**5,961**	**90.5%**
Product Legality, Authenticity & Traceability	**493**	**7.5%**
Controlled Products & Regulatory Compliance	**98**	**1.5%**
Storage & Operational Requirements	**34**	**0.5%**

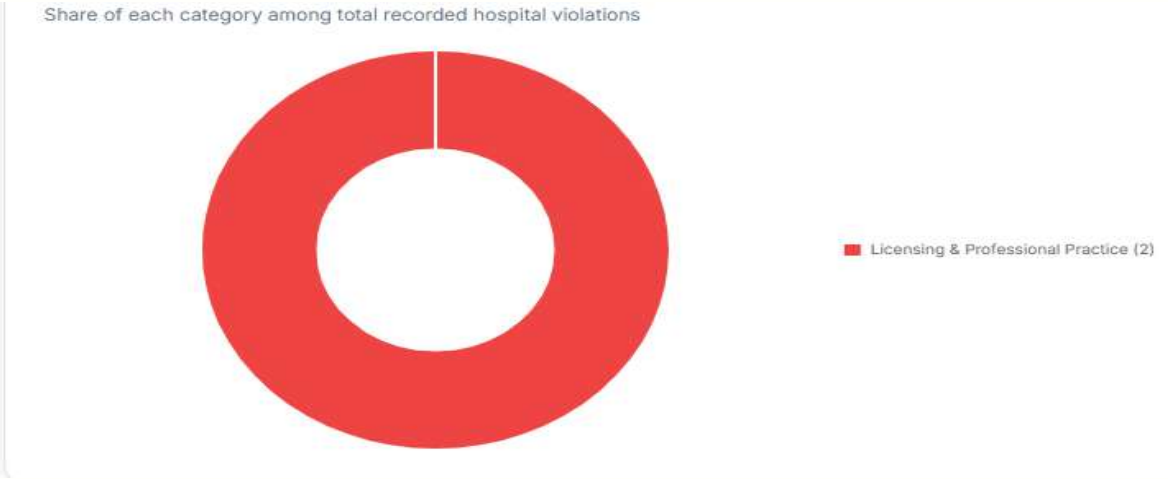


For For Hospital Pharmacies

Total No. of Violations: **2 violation** (Note: The same violation may be recorded more than once for the same pharmacy.)

Violation Category	No.	%
Licensing & Professional Practice	2	100.0%
Product Legality, Authenticity & Traceability	0	0.0%
Controlled Products & Regulatory Compliance	0	0.0%
Storage & Operational Requirements	0	0.0%

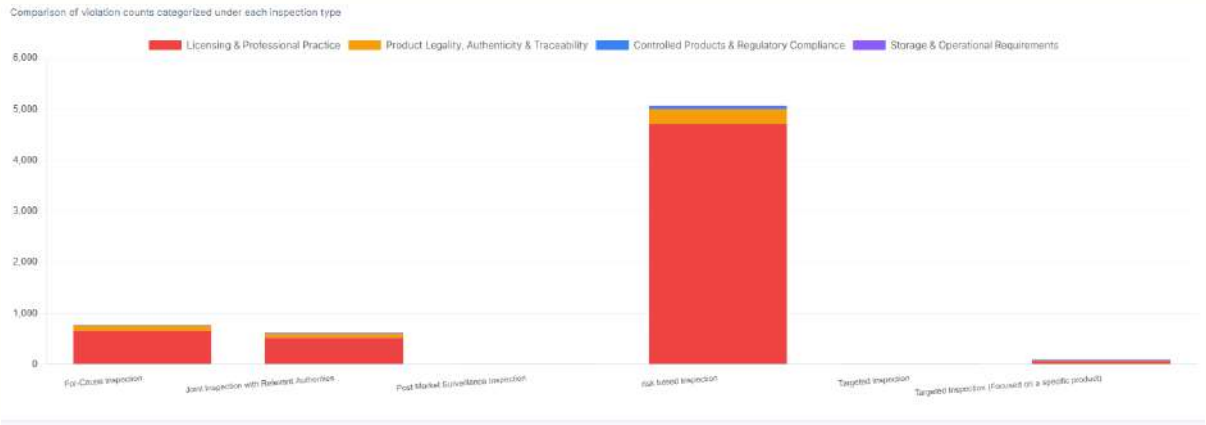
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B) Distribution of Violations by Type of Pharmacy Establishment
Total Community Pharmacy violations: **6,586 violations**
Total Hospital Pharmacy violations: **2 violations**

C) Distribution of Violations by Inspection Type
For Community Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Risk-Based Inspection	**32,723**	**5,031**	**15.4%**
For-Cause Inspection	**2,724**	**774**	**28.4%**
Joint Inspection with Authorities	**2,849**	**630**	**22.1%**
Targeted (Specific Product)	**663**	**103**	**15.5%**
Follow-Up Inspection	**206**	**6**	**2.9%**
Post-Market Surveillance	**67**	**6**	**9.0%**
Recall Follow-Up Inspection	**0**	**0**	**0.0%**



For Hospital Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Risk-Based Inspection	**50**	**2**	**4.0%**
Joint Inspection with Authorities	**5**	**0**	**0.0%**
Targeted (Specific Product)	**1**	**0**	**0.0%**
Recall Follow-Up Inspection	**6**	**0**	**0%**



D) Trend Analysis

- **<u>Most Frequent Violations</u>**

For Community Pharmacies

1. Licensing & Professional Practice (5,961)
2. Product Legality, Authenticity & Traceability (493)
3. Controlled Products & Regulatory Compliance (98)

For Hospital Pharmacies

1. Licensing & Professional Practice (2%)

- **Increasing Trends**

For Community Pharmacies

1. Sharp Increase in Total Inspections and Non-Compliance

Inspection volume surged by 19.4% (from 32,860 in Q2 to 39,232 in Q3). Alongside this, absolute "Not Comply" findings increased from 5,274 to 6,129. This indicates that while the authority expanded its reach, a higher volume of pharmacies were found in violation.

2. Shift in Dominant Violation Types

While Licensing & Professional Practice remains the top violation (increasing from 4,964 to 5,961), Product Legality, Authenticity & Traceability violations rose from 430 in Q2 to 493 in Q3.

3. Emerging Geographic Hotspots (Governorates)

The concentration of non-compliance shifted significantly. While Q2 saw high "Not Comply" numbers in Qalyubia (654) and Gharbia (549), Q3 shows these same two governorates spiking further, with Gharbia jumping to 787 and Qalyubia to 757. These regions are emerging as acute, persistent hotspots requiring prioritized regulatory intervention.

For Hospital Pharmacies

1. **Emergence of non-compliance**

The hospital sector shifted from zero recorded violations in Q2 (65 inspections) to 2 "Not Comply" findings in Q3 (56 inspections), indicating either increased inspection rigor or new compliance gaps.

2. **Introduction of Joint Inspections**

While Q2 relied entirely on Risk-Based and Targeted audits, Q3 introduced 5 Joint Inspections with Relevant Authorities, reflecting a strategic shift toward multi-agency enforcement.

3. **Localized Regional Failures**

Q2 showed zero failures across all governorates, but Q3 saw new non-compliance hotspots emerge specifically in Gharbia and Qalyubia (1 "Not Comply" finding each).

- **Recurring Violations**

For Community Pharmacies

1. Licensing & Professional Practice (Accounts for 90.5% of all violations)
2. Product Legality, Authenticity & Traceability
3. Controlled Products & Regulatory Compliance

For Hospital Pharmacies

1. Licensing & Professional Practice (100% of recorded violations)

- **Emerging Areas of Concern**

For Community Pharmacies

1. High absolute numbers of "Not Comply" findings in Gharbia (787) and Qalyubia (757).

While overall Q3 compliance was 78.41%, specific governorates showed acute localized gaps. Gharbia and Qalyubia each recorded roughly 28-29% of their total inspections as "Not Comply." These figures are disproportionately high compared to major hubs, indicating a need for targeted local enforcement and reallocation of inspection resources to these regions.

2. High volume of violations found during Risk-Based inspections (5,031), indicating widespread systemic issues.

Risk-Based inspections made up the vast majority of the Q3 workload (32,723 audits) and yielded 5,031 violations. This high hit rate (15.4%) from routine, broad-coverage audits suggests that non-compliance is not isolated to a few bad actors, but is widespread across the general community pharmacy sector, highlighting a need for reinforced baseline training and compliance standards.

3. For-Cause inspections yielded a high hit rate (28.4%), validating the intelligence triggers.

Out of 2,724 For-Cause inspections, 774 resulted in violations. This hit rate is nearly double that of routine Risk-Based inspections (15.4%). It confirms that intelligence-led triggers (such as public complaints or suspicious data) are highly accurate at identifying severe non-compliance and should remain a top priority for resource allocation.

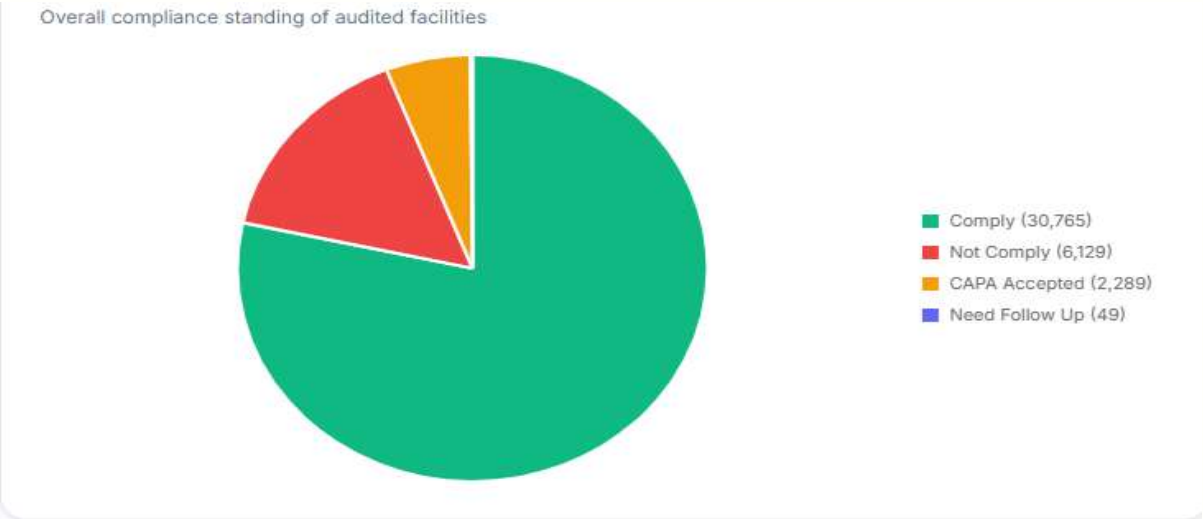
For Hospital Pharmacies

1. **Overall compliance is very high (91.07%), with only 2 violations recorded.**
2. **Failures were recorded in Gharbia and Qalyubia (1 "Not Comply" each).**
3. **3 CAPA accepted cases (Cairo, Suez, Minya).**

E) Regulatory/Enforcement Actions

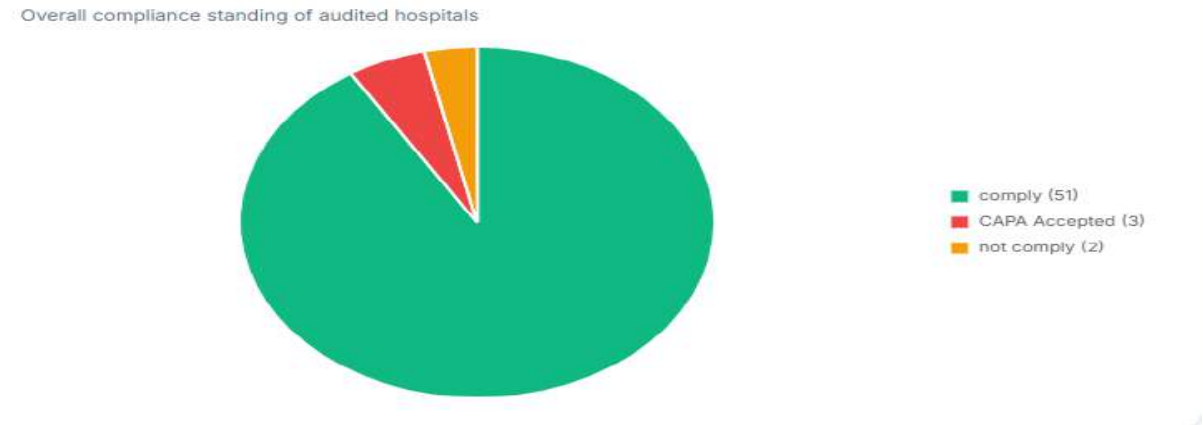
For Community Pharmacies

- No. of regulatory/enforcement actions: **6,129**
- No. of follow-up inspections: **49**
- No. of recall follow-up inspections: **0**
- No. of other applicable regulatory actions: **2,289**



For Hospital Pharmacies

- No. of regulatory/enforcement actions: **2**
- No. of follow-up inspections: **0**
- No. of recall follow-up inspections: **0**
- No. of other applicable regulatory actions: **3**



3. Conclusion

For Community Pharmacies

- % of pharmacy inspections with no violations: **78.41%** (30,765 Comply / 39,232 Total)
- % of pharmacy inspections with violations: **21.59%** (8,467 Total Violations / 39,232 Total)
- % of pharmacy inspections requiring follow-up: **0.12%** (49 Need Follow Up / 39,232 Total)
- % of pharmacy inspections resulting in regulatory/enforcement actions: **15.62%** (6,129 Not Comply / 39,232 Total)
- Most frequent violation category: **Licensing & Professional Practice** (90.5%)
- Most frequent recurring violation: **Licensing & Professional Practice**
- Governorate/EDA Branch requiring increased attention: **Gharbia** (787) and **Qalyubia** (757)

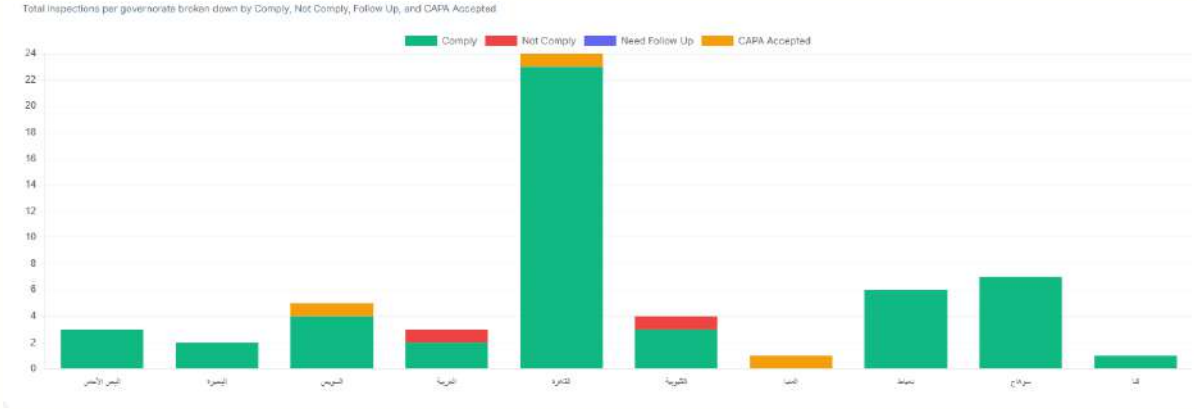


- Inspection type requiring adjustment/increase: **For-Cause Inspection** (Has the highest percentage of violations found at 28.4%, indicating a high yield for finding issues).

For Hospital Pharmacies

- % of pharmacy inspections with no violations: **91.07%** (51 Comply / 56 Total)
- % of pharmacy inspections with violations: **8.93%** (5 Total / 56 Total)

- % of pharmacy inspections requiring follow-up: **0.00%** (0 Need Follow Up / 56 Total)
- % of pharmacy inspections resulting in regulatory/enforcement actions: **3.57%** (2 Not Comply / 56 Total)
- Most frequent violation category: **Licensing & Professional Practice** (100%)
- Most frequent recurring violation: **Licensing & Professional Practice**
- Governorate/EDA Branch requiring increased attention: **Gharbia** and **Qalyubia** (1 each)



- Inspection type requiring adjustment/increase: **Risk-Based Inspection** (Currently finding all hospital violations)