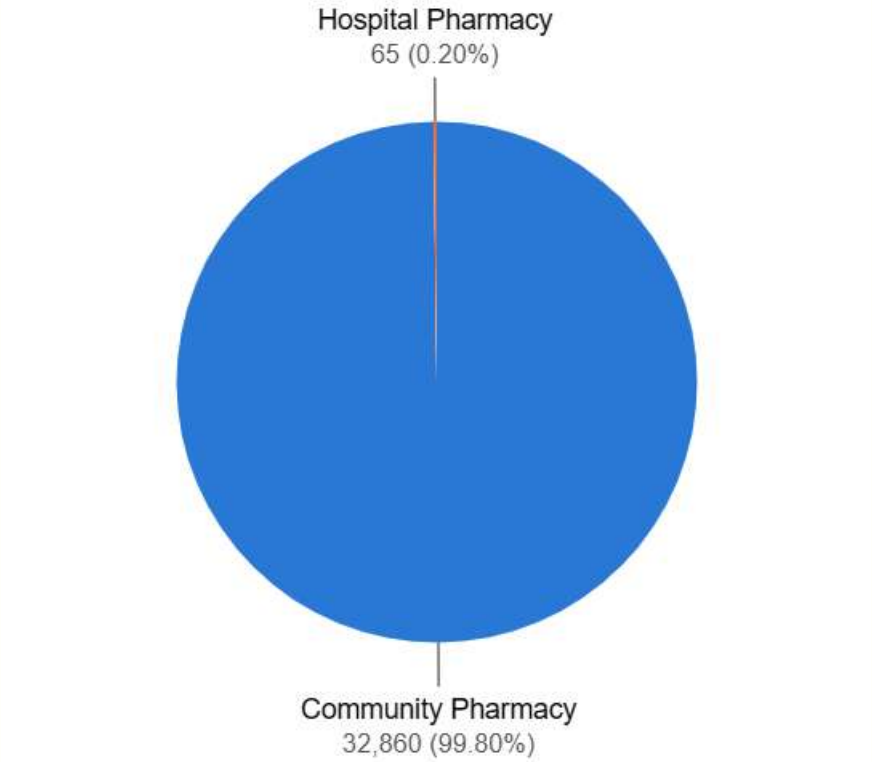
Collective Analysis of Pharmacy Inspection Observations Data Report
Quarter 2 Year 2025

1. Executive Summary

Total No. of Pharmacy Inspections:**32,925 inspections**

Type of Pharmacy Establishment

- Community Pharmacy:**32,860**
- Hospital Pharmacy:**65**



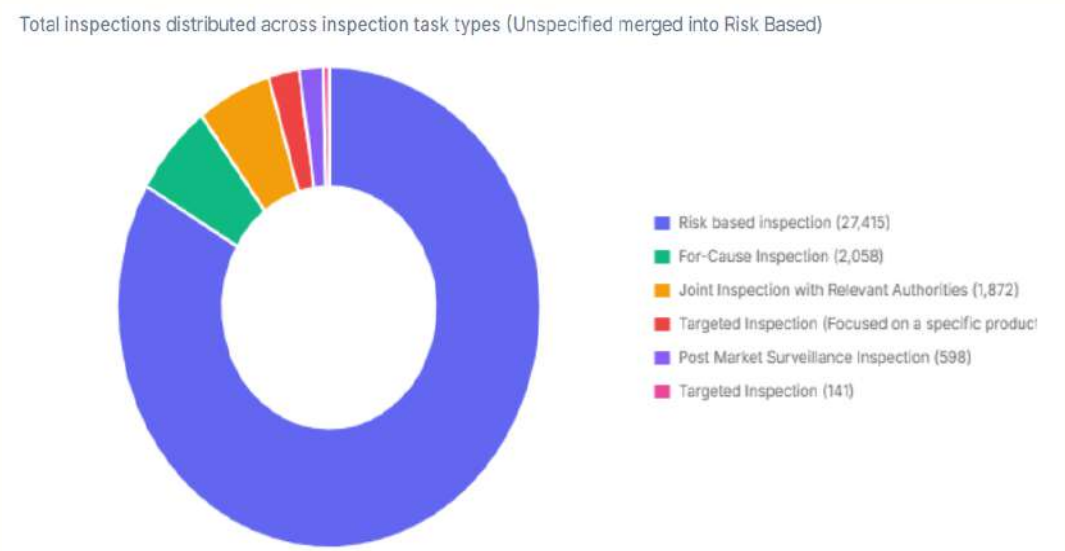
Note: Pharmacies may be inspected more than once during a quarter. For this analysis, only the most recent inspection result for each pharmacy is included, ensuring that each pharmacy is counted once and reducing the risk of duplicate or misleading results.

Type of Inspection

For Community pharmacies

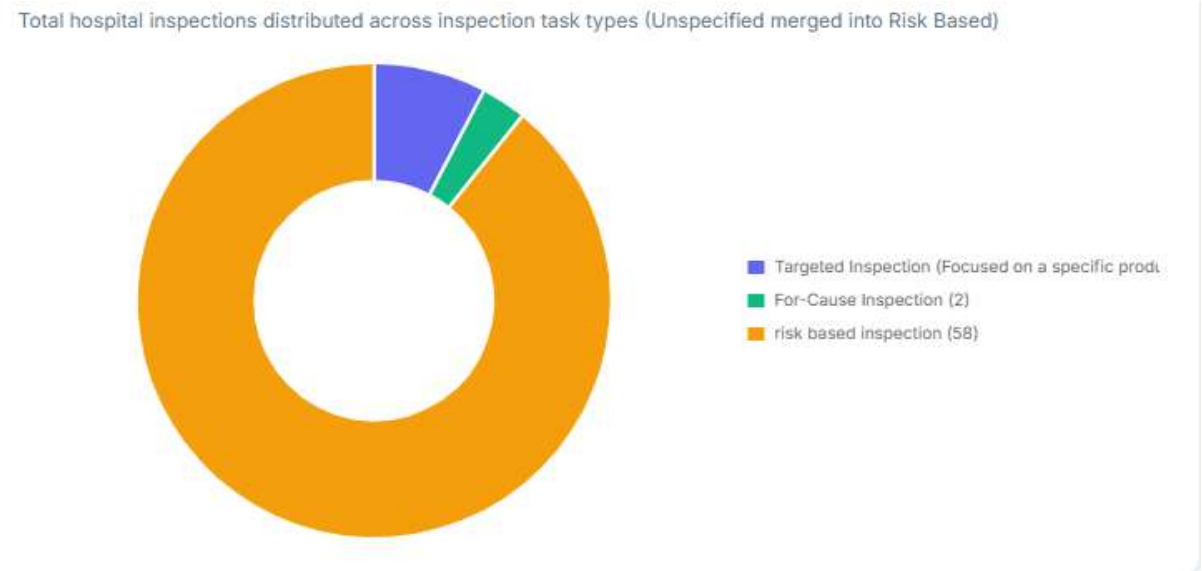
- Risk-Based Inspection (incl. Unspecified merged):**27,415**
- For-Cause Inspection:**2,058**
- Joint Inspection with Relevant Authorities:**1,872**

- Targeted Inspection (Focused on a Specific Product):**776**
- Post-Market Surveillance Inspection:**598**
- Targeted Inspection:**141**



For Hospital pharmacies

- Risk-Based Inspection (incl. Unspecified merged):**58**
- Targeted Inspection (Focused on a Specific Product):**5**
- For-Cause Inspection:**2**



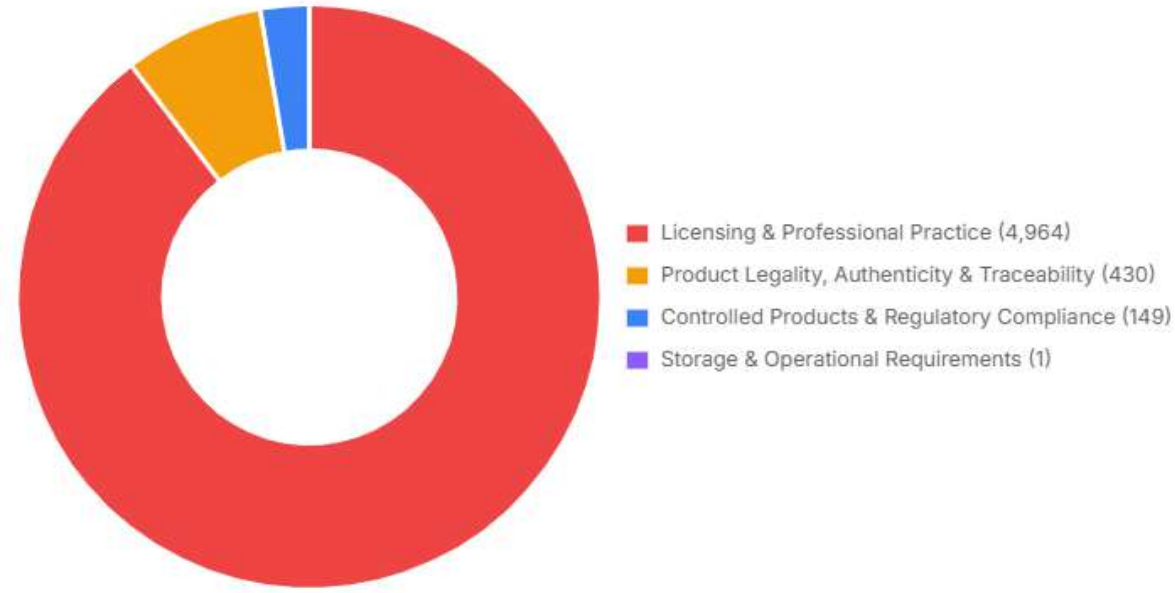
2. Overview Section

A) Total Number of Violations

For Community Pharmacies

Total No. of Violations: **5,544 violations** (Note: Different violations can be recorded in the same institute.)

Violation Category	No.	%
Licensing & Professional Practice	4,964	89.54%
Product Legality, Authenticity & Traceability	430	7.76%
Controlled Products & Regulatory Compliance	149	2.69%
Storage & Operational Requirements	1	0.02%



For Hospital Pharmacies

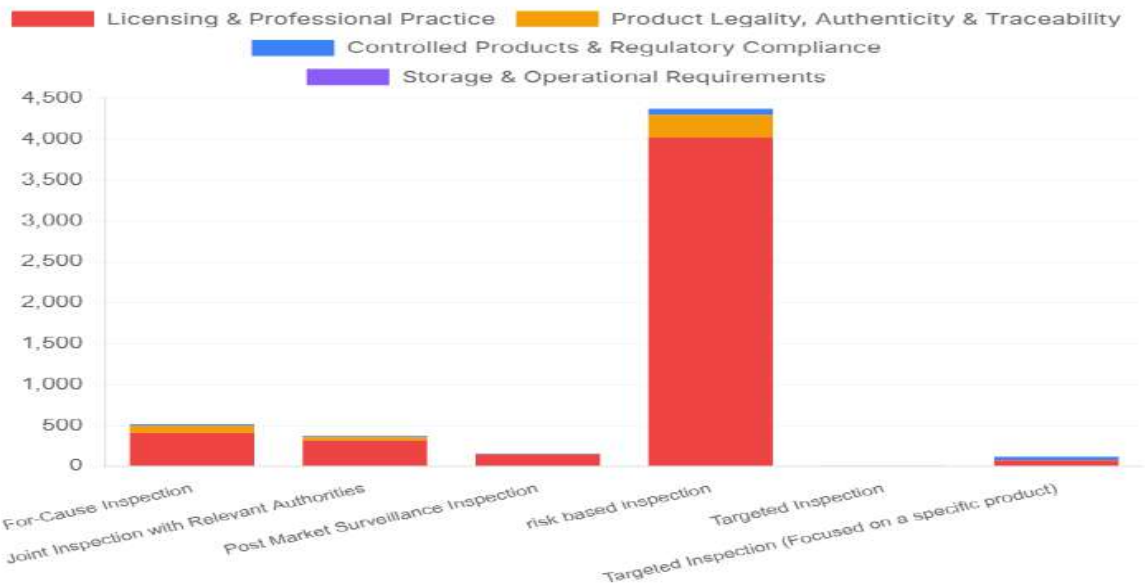
Total No. of Violations: **0 violation** (Note: The same violation may be recorded more than once for the same pharmacy.)

Violation Category	No.	%
No Violations Recorded	0	0.00%

B) Distribution of Violations by Type of Pharmacy Establishment
Community Pharmacy:**5,544 Violations**
Hospital Pharmacy:**0 Violations**

C) Distribution of Violations by Inspection Type
For Community Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
For-Cause Inspection	**2,058**	**519**	**25.22%**
Joint Inspection with Relevant Authorities	**1,872**	**374**	**19.98%**
Post-Market Surveillance Inspection	**598**	**159**	**26.59%**
Risk-Based Inspection (incl. Unspecified merged)	**27,415**	**4,366**	**15.93%**
Targeted Inspection (Focused on a Specific Product)	**776**	**118**	**15.21%**
Targeted Inspection	**141**	**7**	**4.96%**



For Hospital Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Risk-Based Inspection (incl. Unspecified merged)	**58**	**0**	**0.00%**
Joint Inspection with Relevant Authorities	**0**	**0**	**0.00%**
Targeted Inspection (Focused on a Specific Product)	**5**	**0**	**0.00%**
For-Cause Inspection	**2**	**0**	**0.00%**

D) Trend Analysis

- **Most Frequent Violations**

For Community Pharmacies

1 Licensing & Professional Practice (**4,964**)
2 Product Legality, Authenticity & Traceability (**430**)
3 Controlled Products & Regulatory Compliance (**149**)

For Hospital Pharmacies

1 No Violations Recorded (**0**)

- **Increasing Trends**

For Community Pharmacies

1. **Decline in Inspection Volume, But Sharper Focus**

Total inspections dropped from 31,607 in Q1 to 32,860 in Q2 (a slight increase in volume), but the mix shifted: For-Cause inspections fell from 3,425 to 2,058, while Risk-Based inspections rose to 27,415. This indicates a move away from reactive, intelligence-led inspections toward broader routine coverage.

2. Not Comply Rate Rose Sharply

The number of "Not Comply" findings increased from 4,679 in Q1 to 5,274 in Q2, while Comply cases rose from 24,905 to 25,567. This suggests that despite stable inspection volume, non-compliance is becoming more concentrated and detectable—particularly in Licensing & Professional Practice, which grew from 4,439 to 4,964 violations.

3. For-Cause and Post-Market Yield Remained High

For-Cause inspections yielded 519 violations in Q2 (25.22% yield). Although For-Cause volume dropped from Q1, the high yield confirms that intelligence-led targeting remains highly effective and should not be scaled back.

For Hospital Pharmacies

1. Inspection Volume Declined Sharply

Total hospital inspections fell from 101 in Q1 to 65 in Q2 (a 35.6% decrease). Risk-Based inspections dropped from 95 to 58, while Targeted (Specific Product) inspections rose slightly from 4 to 5. This suggests reduced inspection coverage or a deliberate pullback in hospital oversight.

2. Violations Dropped to Zero

Q1 recorded 1 violation (Licensing & Professional Practice, found during a Risk-Based inspection) and 1 "Not Comply" outcome. By Q2, violations fell to 0, with 63 Comply and 2 CAPA Accepted—a 100% no-violation rate. This indicates either strong compliance improvement or limited inspection depth in Q2.

3. Geographic Concentration Intensified

Q1 hospital inspections were spread across 6 governorates (Giza: 60, Cairo: 28, Alexandria: 6, Beheira: 2, Gharbia: 2, Qalyubia: 3). By Q2, inspections concentrated further into just 10 governorates, with Giza (28) and Cairo (21) dominating. This geographic narrowing may create blind spots in other regions.

- **Recurring Violations**

For Community Pharmacies

1. Licensing & Professional Practice
2. Product Legality, Authenticity & Traceability
3. Controlled Products & Regulatory Compliance

For Hospital Pharmacies

No recurring violations recorded in Q2 2025

- **Emerging Areas of Concern**

For Community Pharmacies

1. **High Yield of For-Cause Inspections**
   For-Cause inspections yielded 519 violations out of 2,058 inspections (25.22% yield), confirming that intelligence-led targeting remains highly effective.
2. **Geographic Concentration of Non-Compliance in Qalyubia & Gharbia**
   Qalyubia (654 Not Comply) and Gharbia (549 Not Comply) recorded the highest absolute clusters of non-compliance, followed by Dakahlia (531) and Beheira (446).
3. **Strategic Significance of Risk-Based Inspections Despite Lower Yield**
   Although Risk-Based inspections did not yield the highest violation rate, their massive volume makes them highly significant. They account for most total inspections and uncover the highest absolute number of violations (especially Licensing & Professional Practice), proving to be the foundational mechanism for capturing the largest overall bulk of non-compliance.

For Hospital Pharmacies

1. **Zero Violations Recorded:** 0 violations across 65 inspections — a 100% no-violation rate. This is the lowest violation count of any quarter in 2025, suggesting strong baseline compliance or limited inspection depth.
2. **Near-Perfect Compliance:** 63 Comply, 2 CAPA Accepted, 0 Not Comply, 0 Need Follow Up — a 96.92% no-violation rate. CAPA Accepted (2) was the only non-comply outcome, indicating a cooperative compliance posture.
3. **Risk-Based Inspections Dominated:** 58 of 65 inspections (89.2%) were Risk-Based, with no violations found across any inspection type.

E) Regulatory/Enforcement Actions

For Community Pharmacies

- No. of regulatory/enforcement actions:**5,274**
- No. of follow-up inspections:**67**
- No. of recall follow-up inspections:**0**
- No. of other applicable regulatory actions:**1,952**



For Hospital Pharmacies

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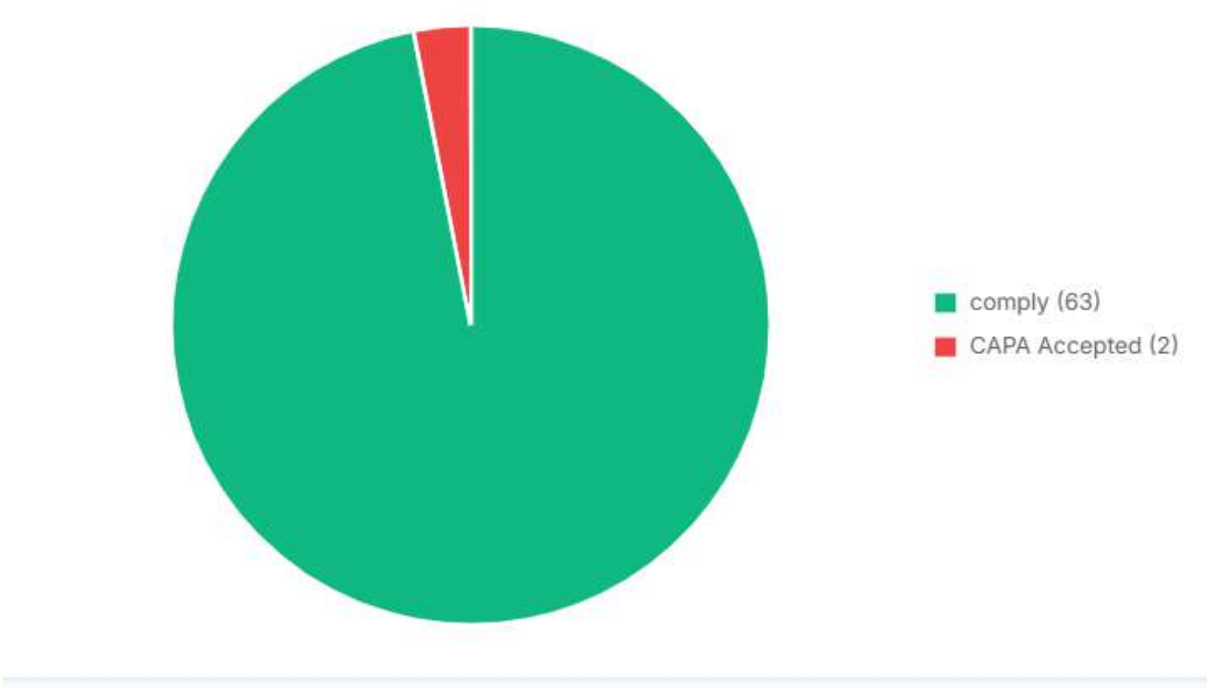
- No. of other applicable regulatory actions 2

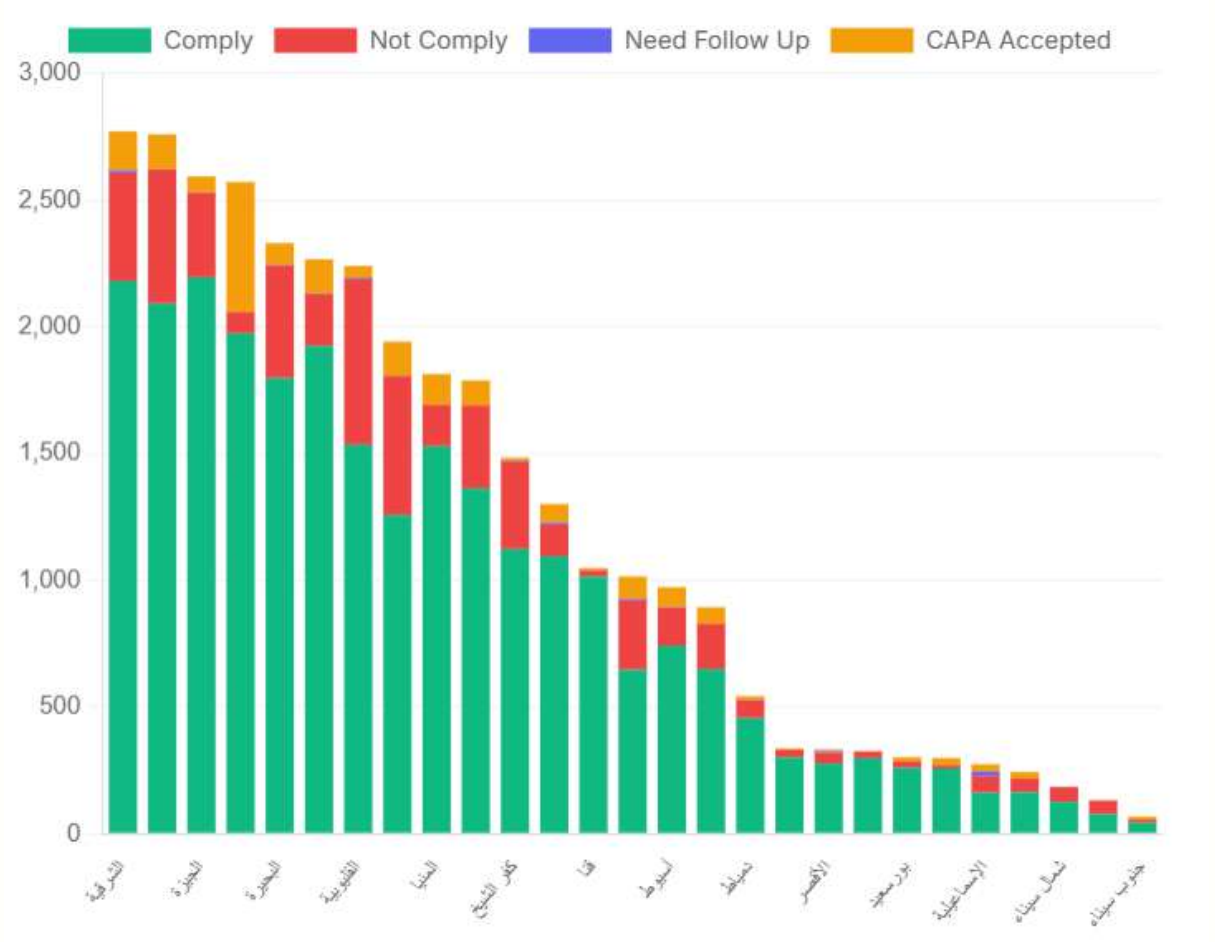


4. Conclusion

For Community Pharmacies

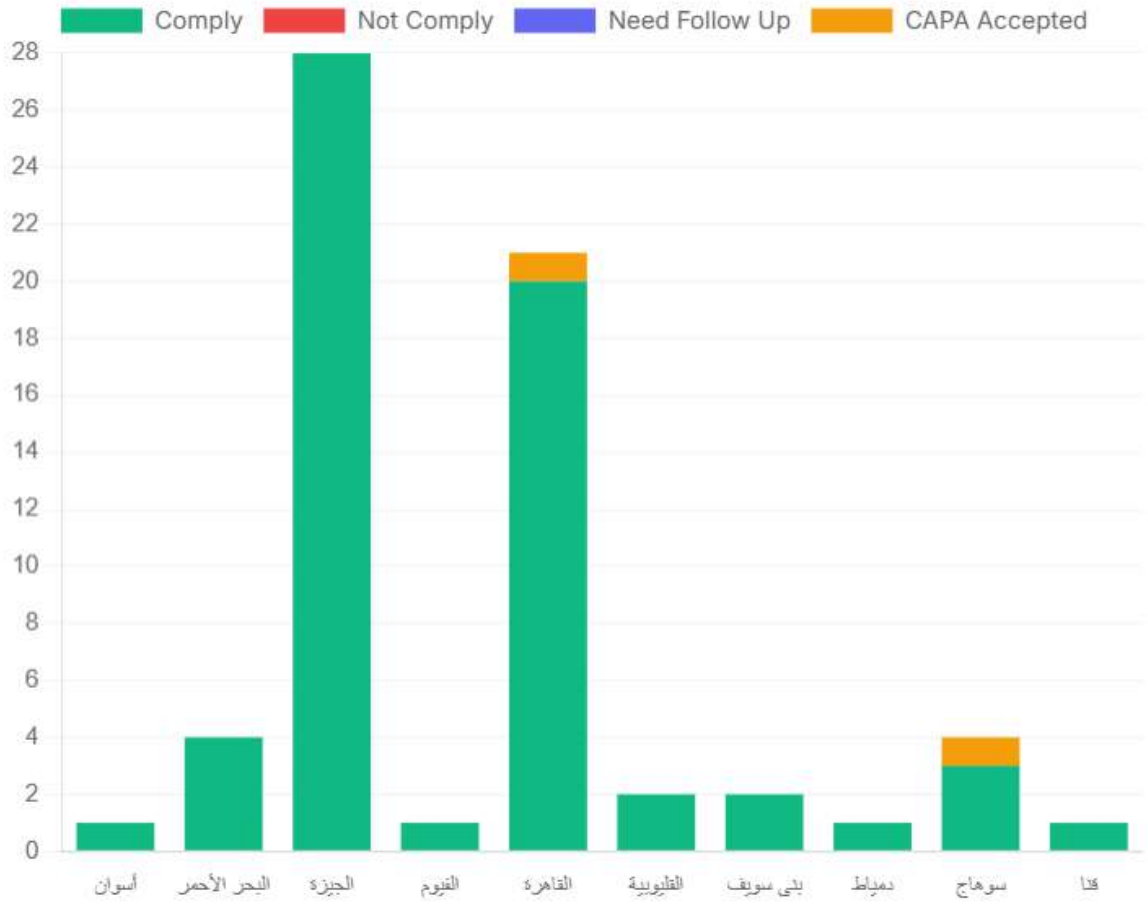
- % of pharmacy inspections with no violations: **77.80%** (25,567 Comply / 32,860)
- % of pharmacy inspections with violations: **22.20%** (5,274 Not Comply + 1,952 CAPA Accepted + 67 Need Follow Up = 7,293 / 32,860)
- % of pharmacy inspections requiring follow-up: **0.20%** (67 Need Follow Up / 32,860)

- % of pharmacy inspections resulting in regulatory/enforcement actions: **16.05%** (5,274 Not Comply / 32,860)
- Most frequent violation category: **Licensing & Professional Practice** (4,964 violations; 89.54%)
- Most frequent recurring violation: **Licensing & Professional Practice**
- Governorate requiring increased attention: **Qalyubia** (highest Not Comply = 654; 29.18% of its 2,241 inspections) and **Gharbia** (549 Not Comply; 28.27% of 1,942)
- Inspection type requiring adjustment/increase: **For-Cause Inspection** (25.22%) and **Joint Inspection with Relevant Authorities** (19.98%)



For Hospital Pharmacies

- % of hospital inspections with no violations: **100.00%** (63 Comply + 2 CAPA Accepted = 65 / 65)
- % of hospital inspections with violations: **0.00%** (0 Not Comply + 0 Need Follow Up = 0 / 65)
- % of hospital inspections requiring follow-up: **0.00%** (0 Need Follow Up / 65)
- % of hospital inspections resulting in regulatory/enforcement actions: **0.00%** (0 Not Comply / 65)
- Most frequent violation category: **No violations recorded**
- Most frequent recurring violation: **No violations recorded**
- Governorate requiring increased attention: **No** non-compliance clusters identified (0 Not Comply across all 10 governorates)
- Inspection type requiring adjustment/increase: **None** — all inspection types yielded 0 violations



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