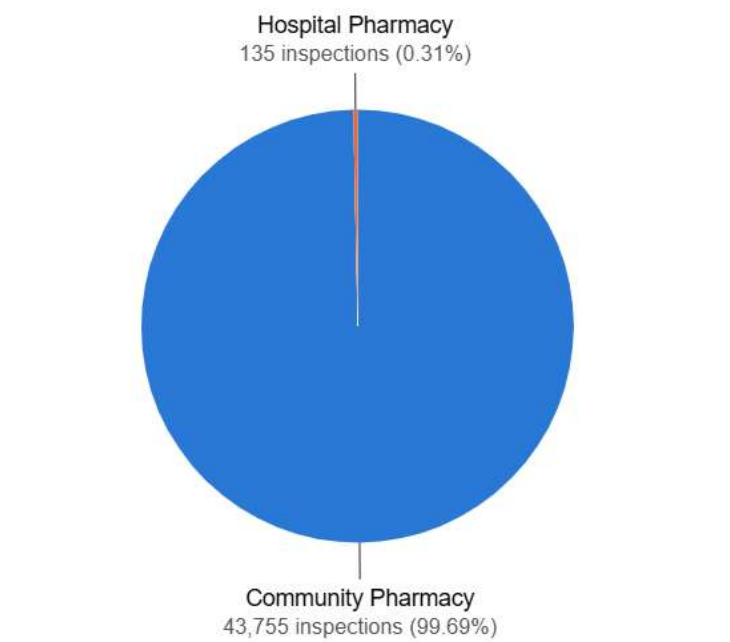
Collective Analysis of Pharmacy Inspection Observations Data Report
Quarter 4 Year 2025

1. Executive Summary

Total No. of Pharmacy Inspections: **43,890 inspection**

Type of Pharmacy Establishment

- Community Pharmacy: **43,755 inspection**
- Hospital Pharmacy: **135 inspection**

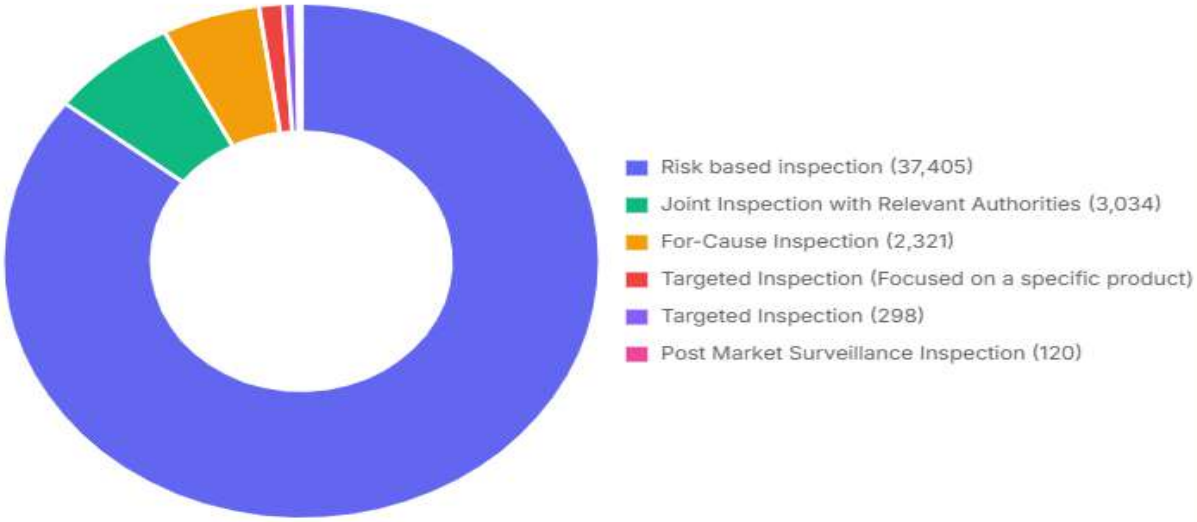


Note: Pharmacies may be inspected more than once during a quarter. For this analysis, only the most recent inspection result for each pharmacy is included, ensuring that each pharmacy is counted once and reducing the risk of duplicate or misleading results.

Type of Inspection

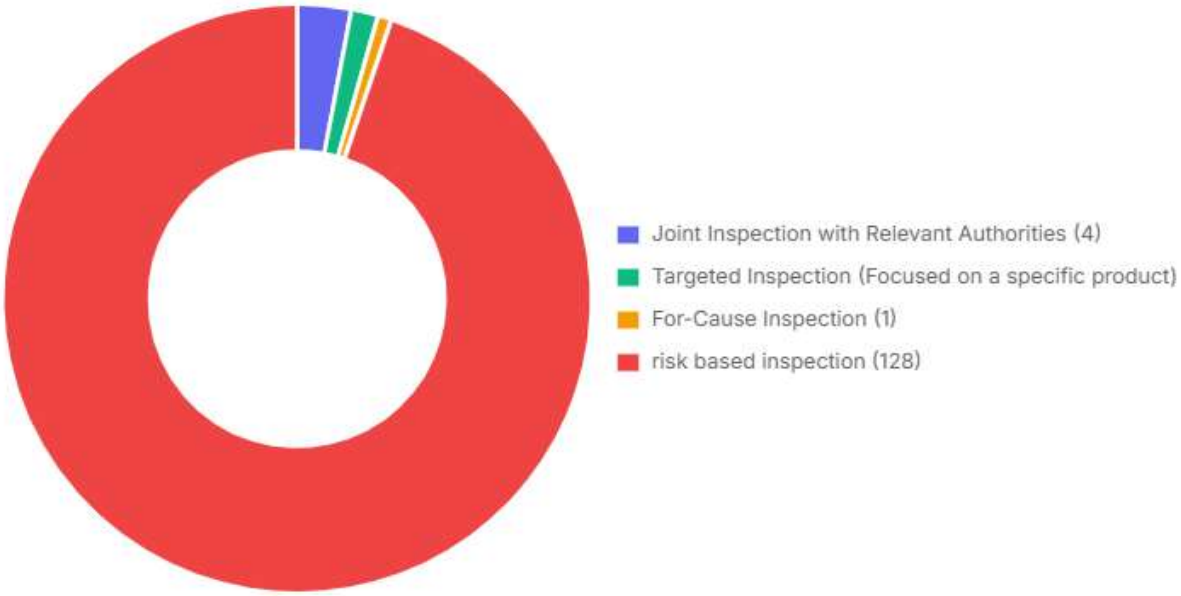
For Community pharmacies

- Risk-Based Inspection :**37,405**
- Joint Inspection with Relevant Authorities:**3,034**
- For-Cause Inspection:**2,321**
- Targeted Inspection (Focused on a Specific Product):**577**
- Targeted Inspection:**298**
- Post-Market Surveillance Inspection:**120**



For Hospital pharmacies

- Risk-Based Inspection :**128**
- Joint Inspection with Relevant Authorities:**4**
- Targeted Inspection (Focused on a Specific Product):**2**
- For-Cause Inspection:**1**



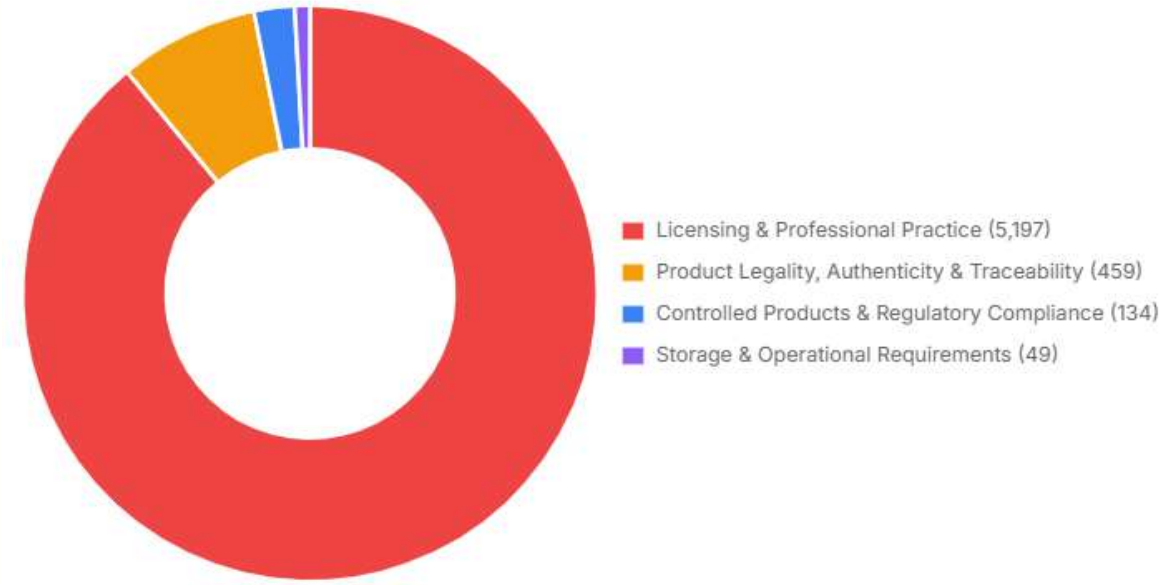
2. Overview Section

A) Total Number of Violations

For Community Pharmacies

Total No. of Violations: **5839 violation** (Note: The same violation may be recorded more than once for the same pharmacy.)

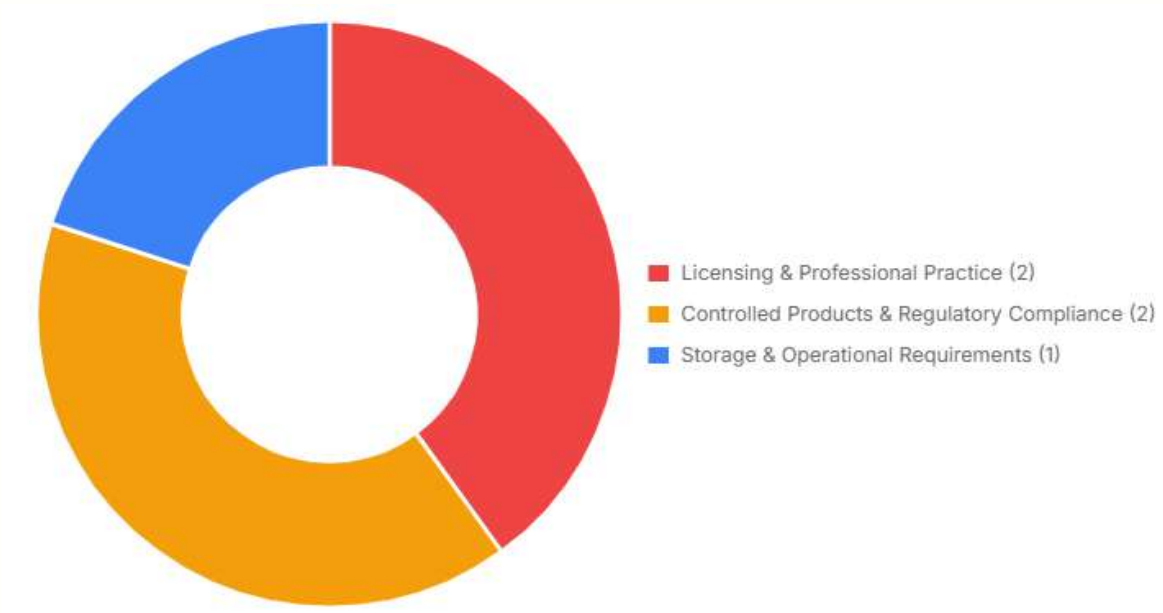
• **Violation Category**	**No.**	**%**
• Licensing & Professional Practice	5,197	89.01%
• Product Legality, Authenticity & Traceability	459	7.86%
• Controlled Products & Regulatory Compliance	134	2.29%
• Storage & Operational Requirements	49	0.84%



For Hospital Pharmacies

Total No. of Violations: **5 violations** (Note: The same violation may be recorded more than once for the same pharmacy.)

Violation Category	No.	%
Licensing & Professional Practice	2	40.0%
Controlled Products & Regulatory Compliance	2	40.0%
Storage & Operational Requirements	1	20.0%

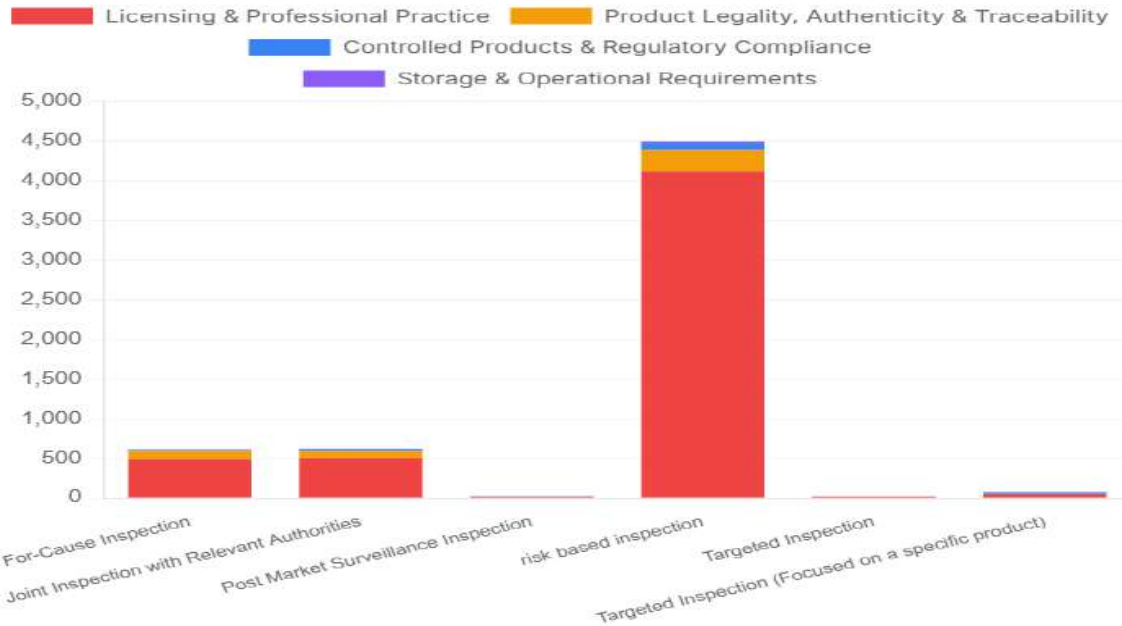


B) Distribution of Violations by Type of Pharmacy Establishment

Establishment Type	Violations
Community Pharmacy	5,839
Hospital Pharmacy	5
Total	**5,844**

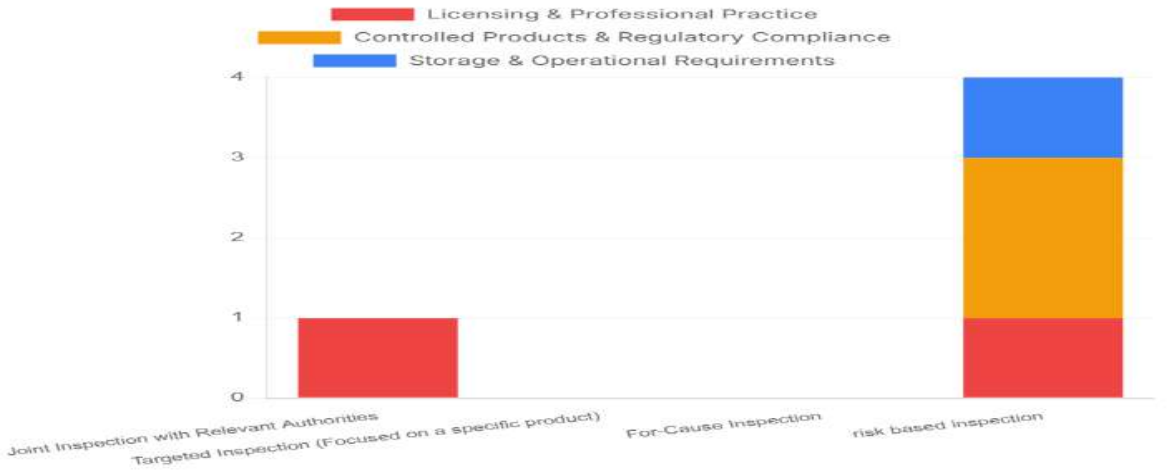
C) Distribution of Violations by Inspection Type
For Community Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
• Risk-Based Inspection	37,405	4,501	12.03%
• Joint Inspection with Relevant Authorities	3,034	615	20.27%
• For-Cause Inspection	2,321	606	26.11%
• Targeted Inspection (Focused on a Specific Product)	577	71	12.31%
• Targeted Inspection	298	22	7.38%
• Post-Market Surveillance Inspection	120	24	20.00%



For Hospital Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Risk-Based Inspection	128	4	3.13%
Joint Inspection with Relevant Authorities	4	1	25.00%
Targeted Inspection (Focused on a Specific Product)	2	0	0.00%
For-Cause Inspection	1	0	0.00%



D) Trend Analysis

- **Most Frequent Violations**

For Community Pharmacies

Rank	Violation Category	No.
1	Licensing & Professional Practice	5,197
2	Product Legality, Authenticity & Traceability	459
3	Controlled Products & Regulatory Compliance	134

For Hospital Pharmacies

Rank	Violation Category	No.
1	Licensing & Professional Practice	2
2	Controlled Products & Regulatory Compliance	2
3	Storage & Operational Requirements	1

- **Increasing Trends**

For Community Pharmacies

1. Inspection Volume Grew by 11.5%

Total inspections rose from 39,232 (Q3) to 43,755 (Q4), driven mainly by a surge in Risk-Based Inspections (32,723 → 37,405).

2. Governorate Non-Compliance Shifted

While overall "Not Comply" counts dropped (6,129 → 5,163), “Qalyubia (707)” and “Gharbia (619)” remain the highest non-compliance clusters. Cairo saw a significant improvement (334 → 217), but Monufia (414 → 395) and Sharqia (416 → 291) still require targeted attention.

3. Violation Categories Mostly Declined (Except Controlled Products)

Most violation counts fell (Licensing: 5,961 → 5,197; Traceability: 493 → 459; Storage: 34 → 49). The only category to increase was “Controlled Products” (98 → 134), indicating a new emerging risk area despite overall compliance improvements.

For Hospital Pharmacies

1. **Inspection Volume Surged:**
   Total inspections more than doubled from 56 to 135 (+141%), driven mainly by Risk-Based Inspections (50 to 128).
2. **Violations increased and diversified:**
   Total violations rose from 2 to 5. Q3 had only Licensing violations, while Q4 expanded into three categories (Licensing, Controlled Products, and Storage/Operational).
3. **Rising "Not Comply" Rate:**
   "Not Comply" findings increased from 2 to 5. The relative non-compliance rate rose slightly from 3.57% to 3.70%, while "CAPA Accepted" dropped significantly from 5.35% to 0.74%.

- **Recurring Violations**

For Community Pharmacies

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

For Hospital Pharmacies

4. Licensing & Professional Practice
5. Controlled Products & Regulatory Compliance
6. Storage & Operational Requirements

- **Emerging Areas of Concern**

For Community Pharmacies

1. **For-Cause Inspection Yield:** 606 violations found across 2,321 For-Cause inspections (26.11% yield) — the highest violation hit rate among all inspection types, indicating highly accurate intelligence/risk signals
2. **Elevated "Not Comply" Rates in Specific Governorates:** القليوبية (707 Not Comply), الدقهلية, (520) البحيرة, (619) الغربية (496) — acute regulatory gaps requiring targeted intervention.
3. **Product Legality/Traceability Violations:** 459 violations recorded — second-highest category, often requiring escalated follow-up.
4. **Joint Inspection Violation Load:** 615 violations found via Joint Inspections with Relevant Authorities (20.27% yield) — multi-authority operations remain high-yield.

For Hospital Pharmacies

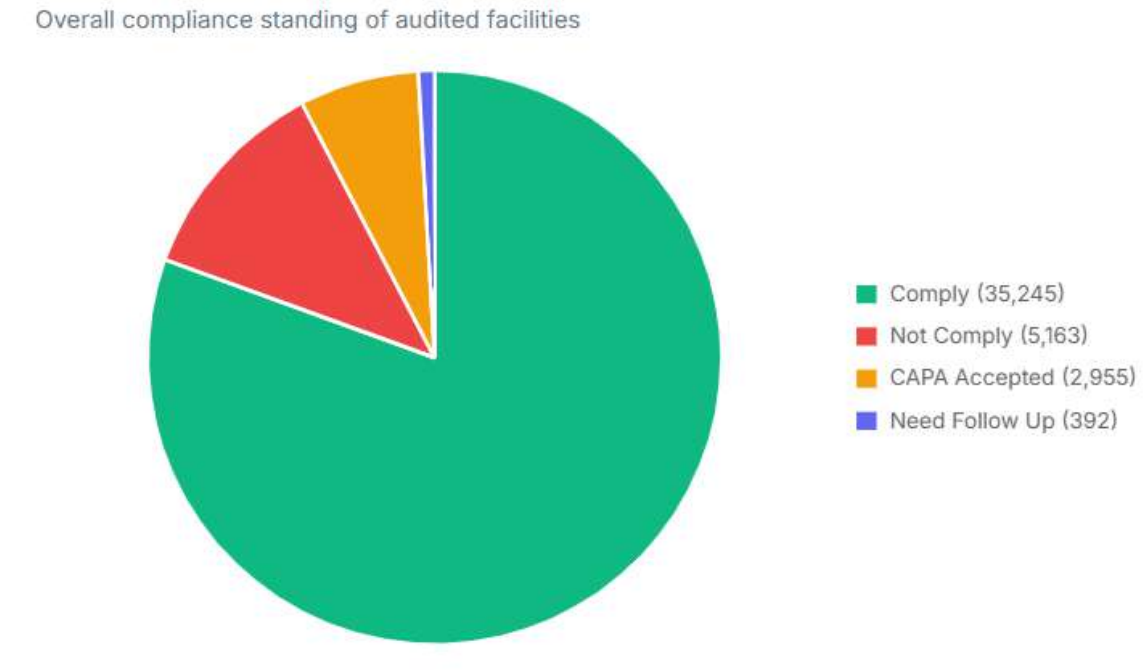
1. **Relative Non-Compliance:** 5 Not Comply findings across 135 inspections (3.70%) — concentrated in السويس, القليوبية, الغربية, البحيرة, and سوهاج.

2. **Storage & Operational Violations:** 1 violation recorded — indicating widened inspection scope identified new non-compliance types.
3. **Governorate Non-Compliance Clusters:** البحيرة (1 of 18; 5.6%), الغربية (1 of 16; 6.3%), القليوبية (1 of 12; 8.3%), السويس (1 of 2; 50%), سوهاج (1 of 3; 33.3%) — requiring targeted intervention.

E) Regulatory/Enforcement Actions

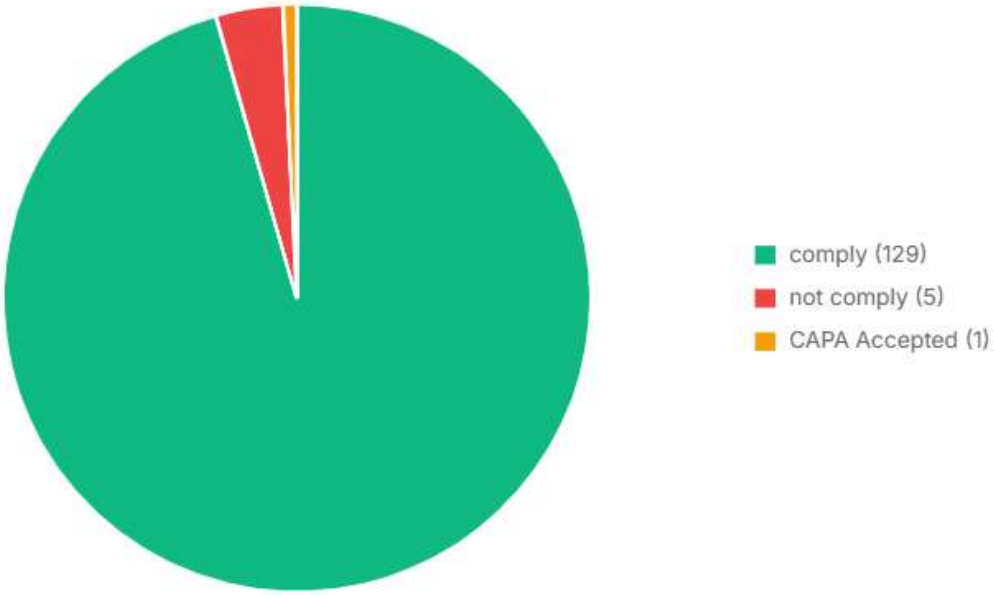
For Community Pharmacies

Action Type	Count
No. of regulatory/enforcement actions	5,163
No. of follow-up inspections	392
No. of recall follow-up inspections	0
No. of other applicable regulatory actions	2,955



For Hospital Pharmacies

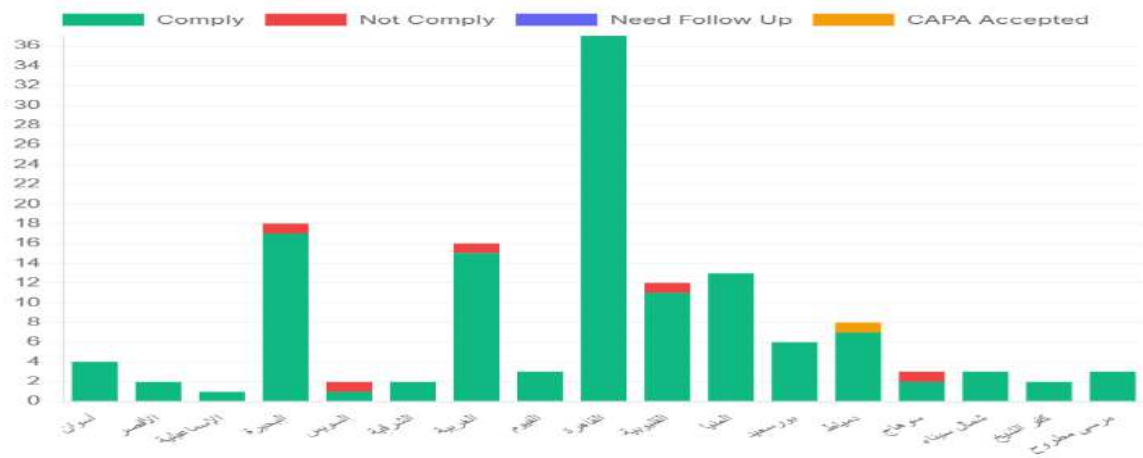
Action Type	Count
No. of regulatory/enforcement actions	**5**
No. of follow-up inspections	**0**
No. of recall follow-up inspections	**0**
No. of other applicable regulatory actions	**1**



3. Conclusion

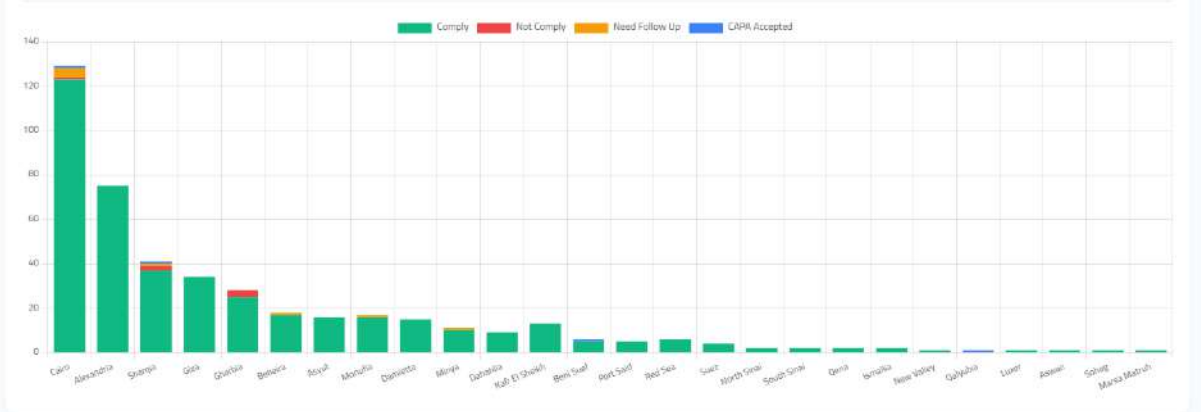
For Community Pharmacies (n = 43,755)

- **% of pharmacy inspections with no violations:** 80.55% (35,245 Comply / 43,755)
- **% of pharmacy inspections with violations:** 19.45% (5,163 Not Comply + 2,955 CAPA Accepted + 392 Need Follow Up = 8,510 / 43,755)
- **% of pharmacy inspections requiring follow-up:** 0.90% (392 Need Follow Up / 43,755)
- **% of pharmacy inspections resulting in regulatory/enforcement actions:** 11.80% (5,163 Not Comply / 43,755)
- **Most frequent violation category:** Licensing & Professional Practice (5,197 violations; 89.01%)
- **Most frequent recurring violation:** Licensing & Professional Practice
- **Governorate requiring increased attention:** القليوبية (highest Not Comply = 707; 24.7% of its 2,864 inspections) and الغربية (619 Not Comply; 22.5% of 2,749)
- **Inspection type requiring adjustment/increase:** For-Cause Inspection (highest violation yield at 26.11%)



- Inspection type requiring adjustment/increase: **For-Cause Inspection** (Has the highest percentage of violations found at 31.6%, indicating a high yield for finding issues).

For Hospital Pharmacies (n = 135)

- **% of hospital inspections with no violations:** 95.56% (129 Comply / 135)
- **% of hospital inspections with violations:** 4.44% (5 Not Comply + 1 CAPA Accepted = 6 / 135)
- **% of hospital inspections requiring follow-up:** 0.74% (1 CAPA Accepted / 135)
- **% of hospital inspections resulting in regulatory/enforcement actions:** 3.70% (5 Not Comply / 135)
- **Most frequent violation category:** Licensing & Professional Practice (2 violations, 40.0%) and Controlled Products & Regulatory Compliance (2, 40.0%) — tied
- **Most frequent recurring violation:** Licensing & Professional Practice
- **Governorate requiring increased attention:** البحيرة (1 Not Comply of 18; 5.6%) and الغربية (1 of 16; 6.3%); السويس (1 of 2; 50%) and سوهاج (1 of 3; 33.3%) as small-denominator clusters
- **Inspection type requiring adjustment/increase:** Risk-Based Inspection (4 of 5 violations; 3.13% yield)
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- **Inspection type requiring adjustment/increase: For-Cause Inspection** (Had the highest hit rate with 40% finding a violation).