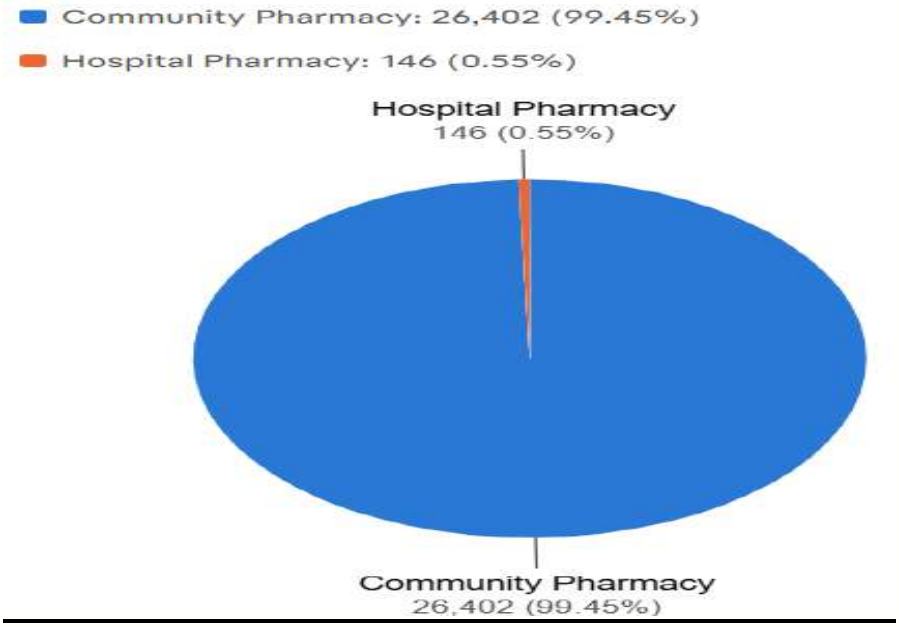
Collective Analysis of Pharmacy Inspection Observations Data Report
Quarter 3 Year 2024

1. Executive Summary

Total No. of Pharmacy Inspections: **26,548 inspections**

Type of Pharmacy Establishment

- Community Pharmacy:**26,402**
- Hospital Pharmacy:**146**
- Total:**26,548**

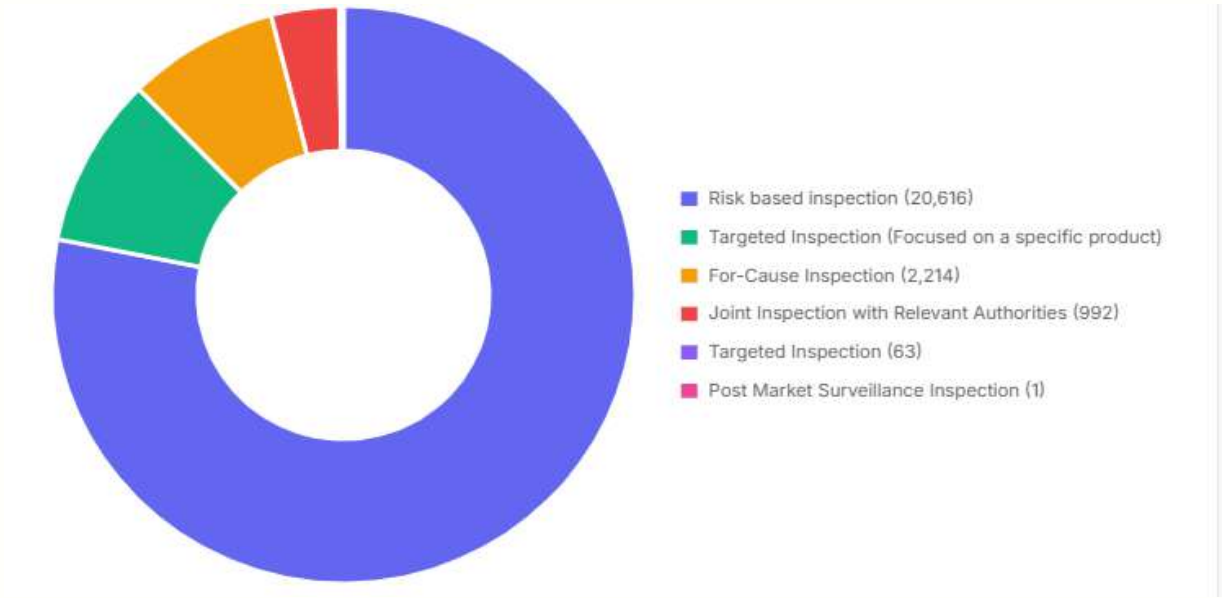


Note: Pharmacies may be inspected more than once during a quarter. For this analysis, only the most recent inspection result for each pharmacy is included, ensuring that each pharmacy is counted once and reducing the risk of duplicate or misleading results.

Type of Inspection

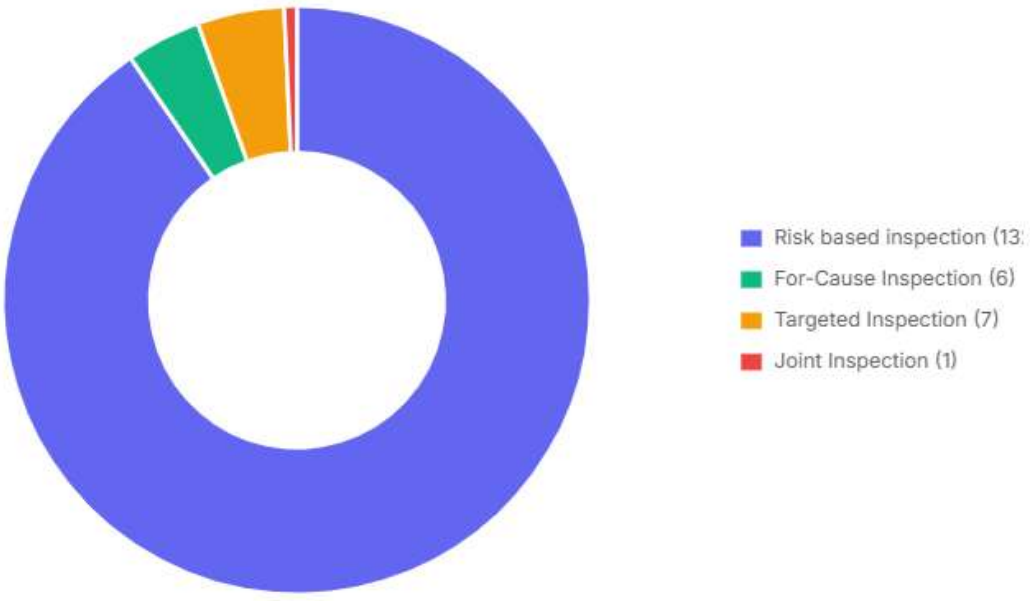
For Community pharmacies

- Risk-Based Inspection (incl. Unspecified & N.A. merged):**20,616**
- Targeted Inspection (Focused on a Specific Product):**2,516**
- For-Cause Inspection:**2,214**
- Joint Inspection with Relevant Authorities:**992**
- Targeted Inspection:**63**
- Post-Market Surveillance Inspection:**1**
- Total:**26,402**



For Hospital Pharmacies

- Risk-Based Inspection:**132**
- Targeted Inspection:**7**
- For-Cause Inspection:**6**
- Joint Inspection with Relevant Authorities:**1**
- Total:**146**



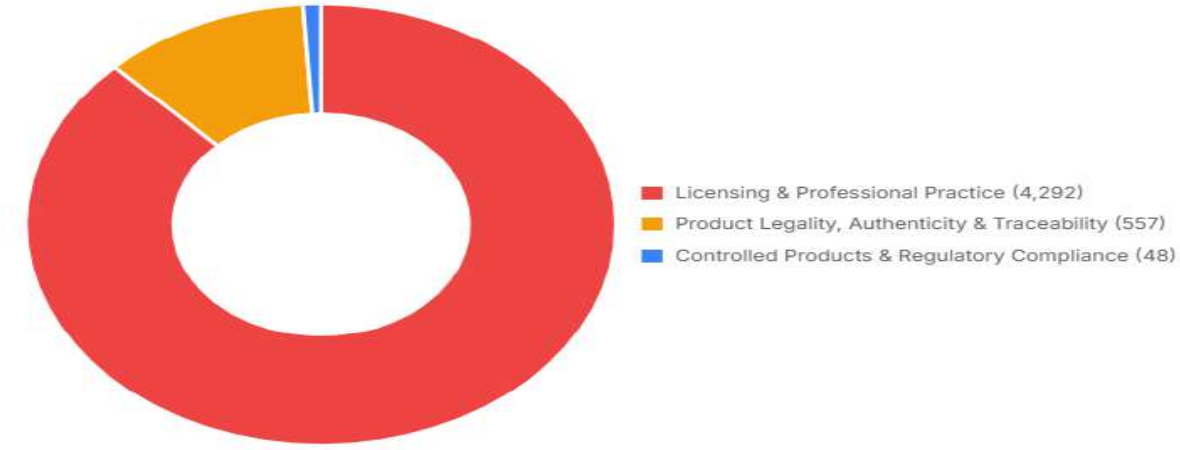
2. Overview Section

A) Total Number of Violations

For Community Pharmacies

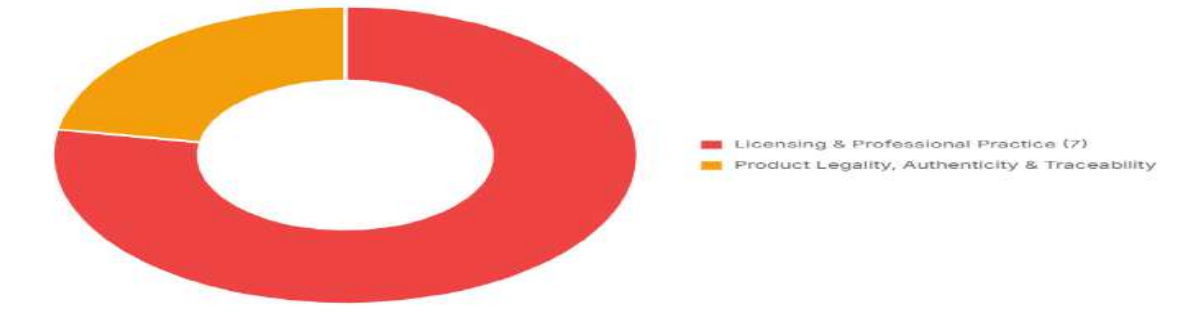
Total No. of Violations: **4,897 violations** (Note: Different violations can be recorded to the same institute.)

Violation Category	No.	%
Licensing & Professional Practice	**4,292**	**87.65%**
Product Legality, Authenticity & Traceability	**557**	**11.37%**
Controlled Products & Regulatory Compliance	**48**	**0.98%**
Storage & Operational Requirements	**0**	**0.00%**



- ***Hospital Pharmacies: 9 Violations***

Violation Category	No.	%
Licensing & Professional Practice	**7**	**77.78%**
Product Legality, Authenticity & Traceability	**2**	**22.22%**



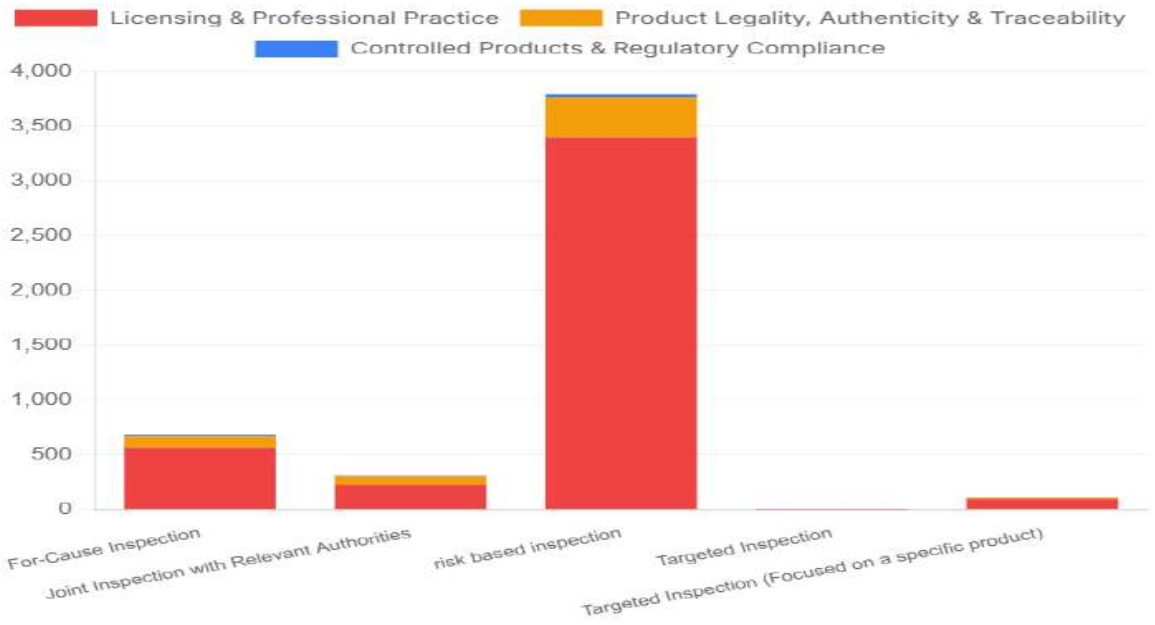
B) Distribution of Violations by Type of Pharmacy Establishment

- Community Pharmacy:**4,897 Violations**
- Hospital Pharmacy:**9 Violations**
- Total:**4,906 Violations**

C) Distribution of Violations by Inspection Type

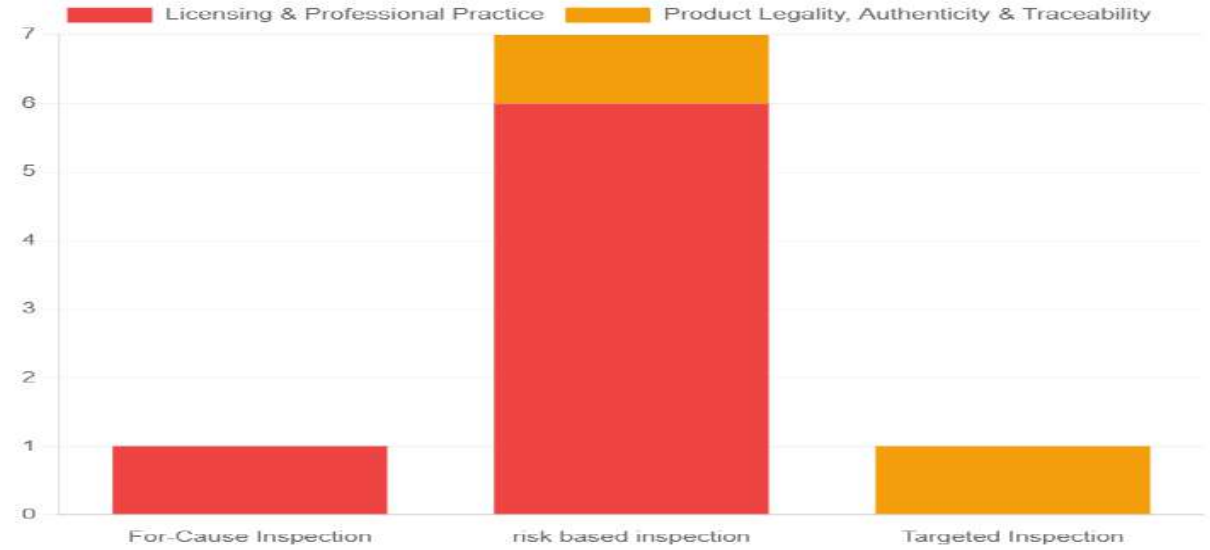
- **For Community Pharmacies**

Inspection Type	No. of Inspections	No. with Violations	% with Violations
For-Cause Inspection	2,214	680	30.71%
Joint Inspection with Relevant Authorities	992	315	31.75%
Risk-Based Inspection (incl. Unspecified merged)	20,615	3,785	18.36%
Targeted Inspection (Focused on a Specific Product)	2,516	109	4.33%
Targeted Inspection	63	2	3.17%
Post-Market Surveillance Inspection	1	0	0.00%



For Hospital Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
For-Cause Inspection	**6**	**1**	**16.67%**
Risk-Based Inspection	**132**	**7**	**5.30%**
Targeted Inspection	**7**	**1**	**14.29%**
Joint Inspection with Relevant Authorities	**1**	**0**	**0.00%**



D) Trend Analysis

- **Most Frequent Violations**

For Community Pharmacies

1 Licensing & Professional Practice:**4,292**
2 Product Legality, Authenticity & Traceability:**557**
3 Controlled Products & Regulatory Compliance:**48**

For hospital pharmacies

1 Licensing & Professional Practice:**7**
2 Product Legality, Authenticity & Traceability**:2**

Trending

For Community Pharmacies

1. Inspection Volume Surged by 48%

Total inspections jumped from **17,839 (Q2)** to **26,402 (Q3)**. Risk-Based Inspections grew from 16,320 to 20,615, while Targeted-Specific Inspections

spiked massively from 18 to 2,516 and Joint Inspections rose from 280 to 992 — indicating a major expansion in inspection scope and activity.

2. Governorate Non-Compliance Shifted (Governorate Trend)
While overall "Not Comply" counts rose (3,091 → 4,374), **Gharbia (449 → 613)** and **Dakahlia (400 → 491)** remained the highest non-compliance clusters. **Qalyubia (531 → 442)** improved slightly, but **Menoufia (279 → 375)** and **Kafr El Sheikh (190 → 336)** worsened notably. **Bani Suef** saw a sharp rise in Need Follow Up (0 → 51), indicating a new localized backlog.

3. Violations Rose Sharply, Led by Licensing
Total violations increased from **3,018 (Q2)** to **4,897 (Q3)** — a **62% surge**. **Licensing & Professional Practice** jumped from 2,728 to 4,292, and **Product Legality** rose from 264 to 557. **Controlled Products** nearly doubled from 26 to 48, while **Storage & Operational Requirements** remained at 0 — confirming a consistent absence of storage-related findings.

For hospital pharmacies:
1. Inspection Volume Nearly Doubled: Total hospital pharmacy inspections surged from 76 (Q2) to 146 (Q3) — a 92.1% increase. Risk-Based Inspections drove the growth (73 → 132), while For-Cause Inspections rose from 2 to 6 and Targeted Inspections jumped from 1 to 7. A new Joint Inspection category appeared (1).

2. Governorate Coverage Expanded Significantly (Governorate Trend) : Q2 covered only 8 governorates with inspections concentrated in Cairo (27) and Giza (21). Q3 expanded to 12 governorates, with Cairo (37) and Alexandria (27) leading. New governorates — Beheira, Port Said, Red Sea, Qena, and Sohag — entered the dataset. Non-compliance spread from 3 governorates (Cairo, Sharqia, Damietta) in Q2 to 5 governorates in Q3, with Sharqia (3) and Cairo (3) showing the highest clusters, followed by Giza (2).

3. Violations Tripled, Led by Licensing : Total violations rose from 3 (Q2) to 9 (Q3) — a 200% increase. Licensing & Professional Practice grew from 3 to 7, and Product Legality, Authenticity & Traceability emerged from 0 to 2. Not Comply findings jumped from 3 to 10, while CAPA Accepted rose from 1 to 4 — indicating both broader detection and more corrective actions in Q3.

- **Recurring Violations**

For Community Pharmacies

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

Hospital Pharmacies

1. Licensing & Professional Practice
2. Product Legality, Authenticity & Traceability

Emerging Areas of Concern

For Community Pharmacies

1. **For-Cause Inspection and joint inspection Yield:**
   680 violations found across 2,214 For-Cause Inspections (30.71% yield) — the highest violation hit rate among all inspection types, confirming intelligence-led targeting effectiveness.
   315 violations found across 992 Joint Inspections (31.75% yield) — the highest percentage yield overall, indicating multi-authority operations were highly effective at identifying violations.

2. **Governorate non-compliance:**
   Concentrated in Gharbia & Dakahlia: الغربية (613 Not Comply) and الدقهلية (491 Not Comply) were the highest absolute non-compliance clusters, followed by القليوبية (442) and المنوفية (375).
   Bani Suef Follow-Up Spike: بنى سويف recorded 51 Need Follow Up cases — notably higher than any other governorate, indicating a localized follow-up backlog requiring attention.

3. Storage & Operational Requirements Absent: 0 violations recorded — the category was completely absent in Q3 2024.

- **For hospital pharmacies**
  1. **Non-Compliance Concentrated in Cairo, Sharqia, and Giza**: القاهرة (3 Not Comply), الشرقية (3), and الجيزة (2) accounted for 8 of the 10 Not Comply findings across 146 inspections.

  2. **For-Cause and Targeted Inspection Yield:** For-Cause Inspection (1 violation / 6 inspections = 16.67%) and Targeted Inspection (1 / 7 = 14.29%)

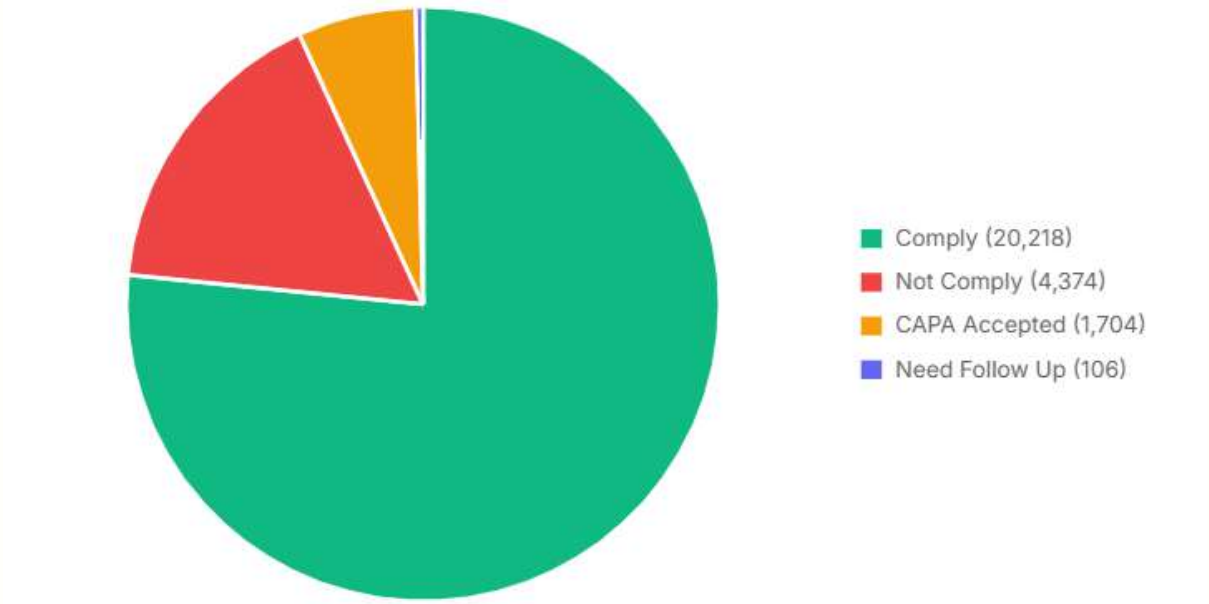
showed the highest violation rates, while Risk-Based Inspection had 7 violations across 132 inspections (5.30%).

3. **No Follow-Up Recorded:** 0 Need Follow Up across all 146 hospital inspections — all non-compliance was either remedied via CAPA (4) or left as Not Comply (10).

- **Regulatory/Enforcement Actions**

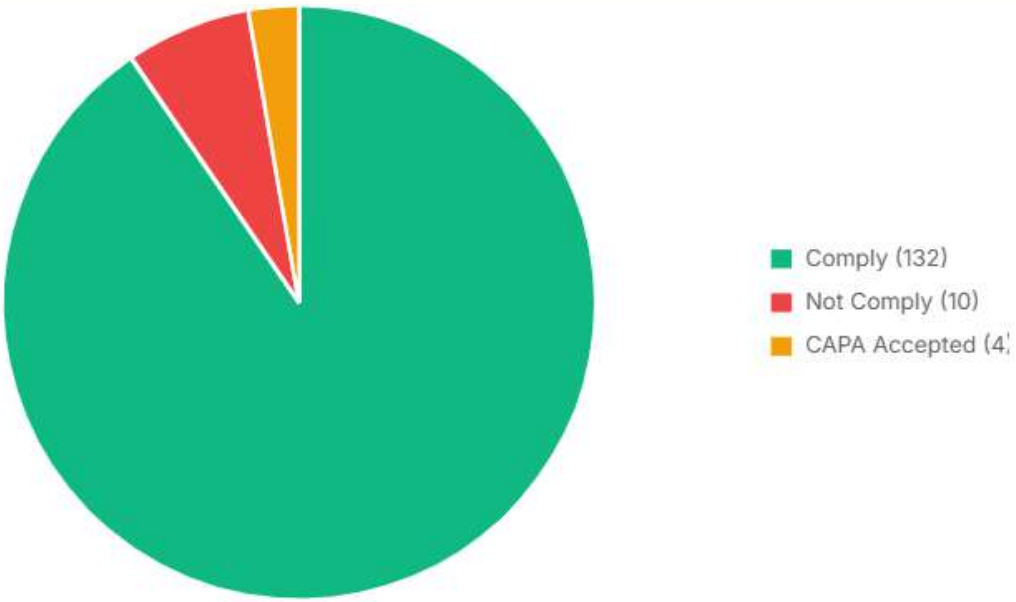
For Community Pharmacies

- No. of regulatory/enforcement actions:**4,374**
- No. of follow-up inspections:**106**
- No. of recall follow-up inspections:**0**
- No. of other applicable regulatory actions:**1,704**



For hospital pharmacies

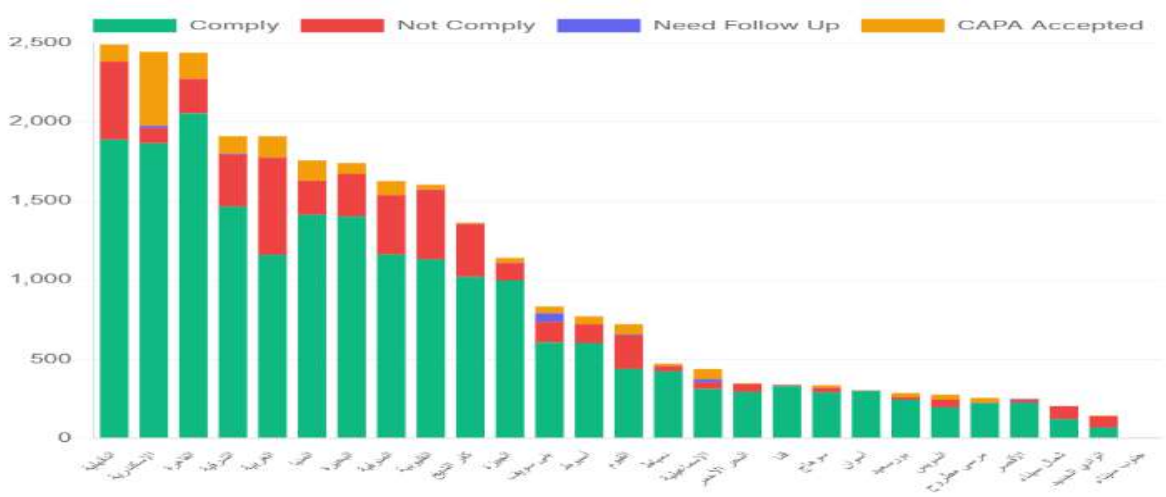
- No. of regulatory/enforcement actions:**10**
- No. of follow-up inspections:**0**
- No. of recall follow-up inspections:**0**
- No. of other applicable regulatory actions:**4**


Comply (132)
Not Comply (10)
CAPA Accepted (4

3. Conclusion

For Community Pharmacies

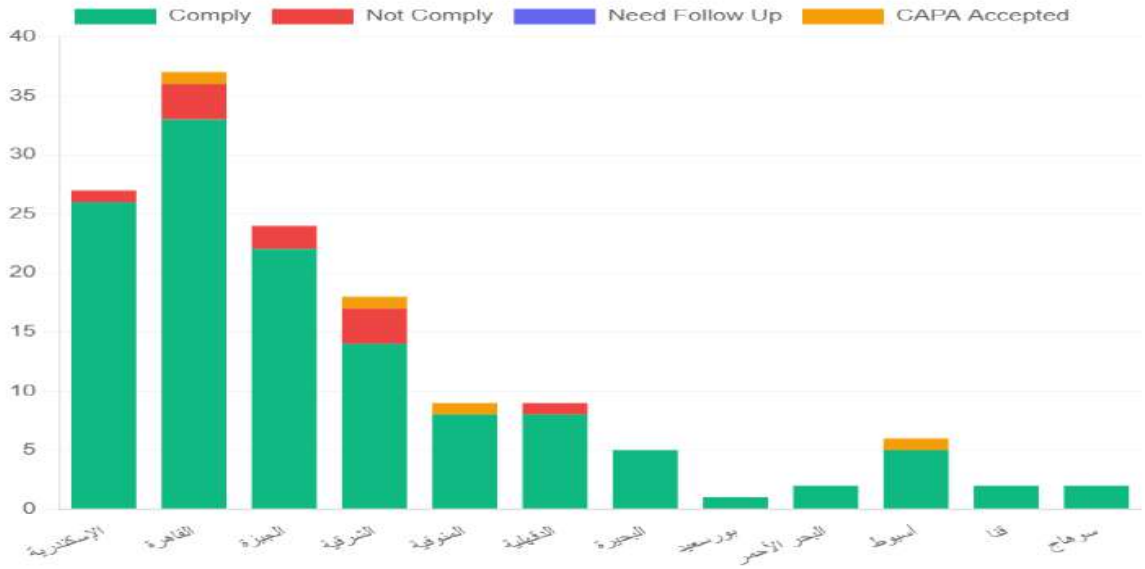
- **% of pharmacy inspections with no violations:** 76.58% (20,218 Comply / 26,402)
- **% of pharmacy inspections with violations:** 23.42% (4,374 Not Comply + 1,704 CAPA Accepted + 106 Need Follow Up = 6,184 / 26,402)
- **% of pharmacy inspections requiring follow-up:** 0.40% (106 Need Follow Up / 26,402)
- **% of pharmacy inspections resulting in regulatory/enforcement actions:** 16.57% (4,374 Not Comply / 26,402)
- **Most frequent violation category:** Licensing & Professional Practice (4,292 violations; 87.65%)
- **Most frequent recurring violation:** Licensing & Professional Practice
- **Governorate requiring increased attention:** الغربية (highest Not Comply = 613; 32.08% of its 1,911 inspections) and الدقهلية (491 Not Comply; 19.71% of 2,491)
- **Inspection type requiring adjustment/increase:** Joint Inspection with Relevant Authorities (highest violation yield at 31.75%) and For-Cause Inspection (30.71%)



For Hospital Pharmacies

- **% of hospital inspections with no violations**: 90.41% (132 Comply / 146)
- **% of hospital inspections with violations**: 9.59% (10 Not Comply + 4 CAPA Accepted = 14 / 146)

- **% of hospital inspections requiring follow-up**: 0.00% (0 Need Follow Up / 146)
- **% of hospital inspections resulting in regulatory/enforcement actions**: 6.85% (10 Not Comply / 146)
- **Most frequent violation category:** Licensing & Professional Practice (7 violations; 77.78%)
- **Most frequent recurring violation**: Licensing & Professional Practice
- **Governorate requiring increased attention**: القاهرة and الشرقية (3 Not Comply each), followed by الجيزة (2)
- **Inspection type requiring adjustment/increase**: For-Cause Inspection (16.67% yield) and Targeted Inspection (14.29% yield)



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