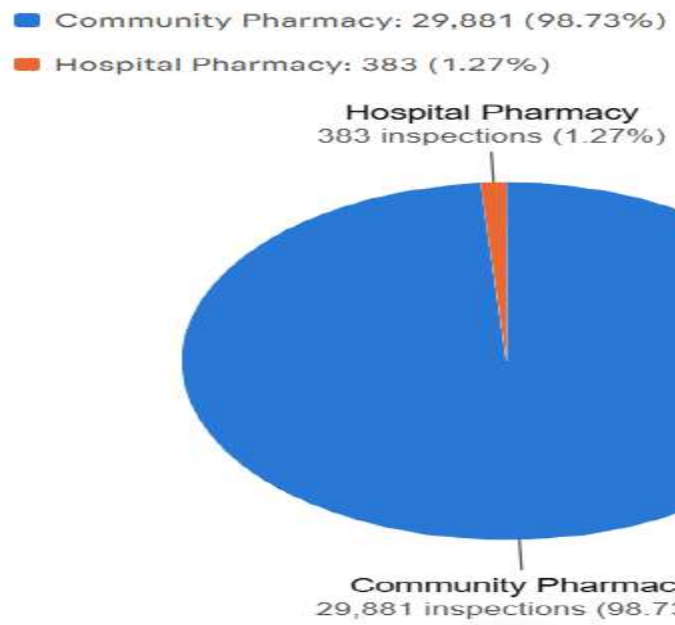
Collective Analysis of Pharmacy Inspection Observations Data Report
Quarter 4 Year 2024

1. Executive Summary

Total No. of Pharmacy Inspections: **30,264 inspections**

Type of Pharmacy Establishment

- Community Pharmacy:**29,881**
  Hospital Pharmacy:**383**

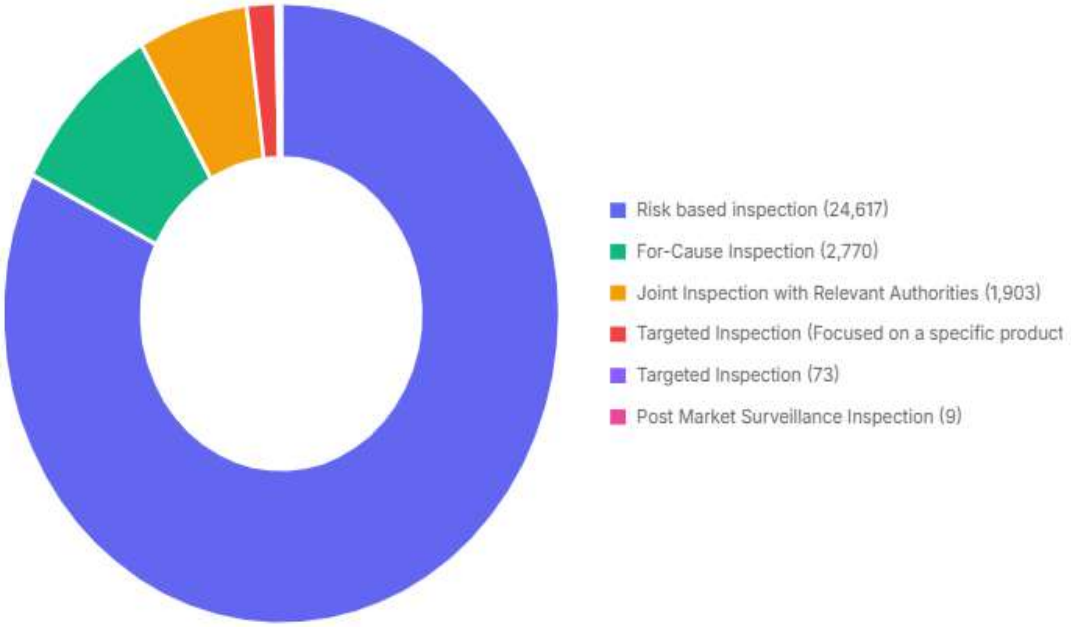


Note: Pharmacies may be inspected more than once during a quarter. For this analysis, only the most recent inspection result for each pharmacy is included, ensuring that each pharmacy is counted once and reducing the risk of duplicate or misleading results.

Type of Inspection

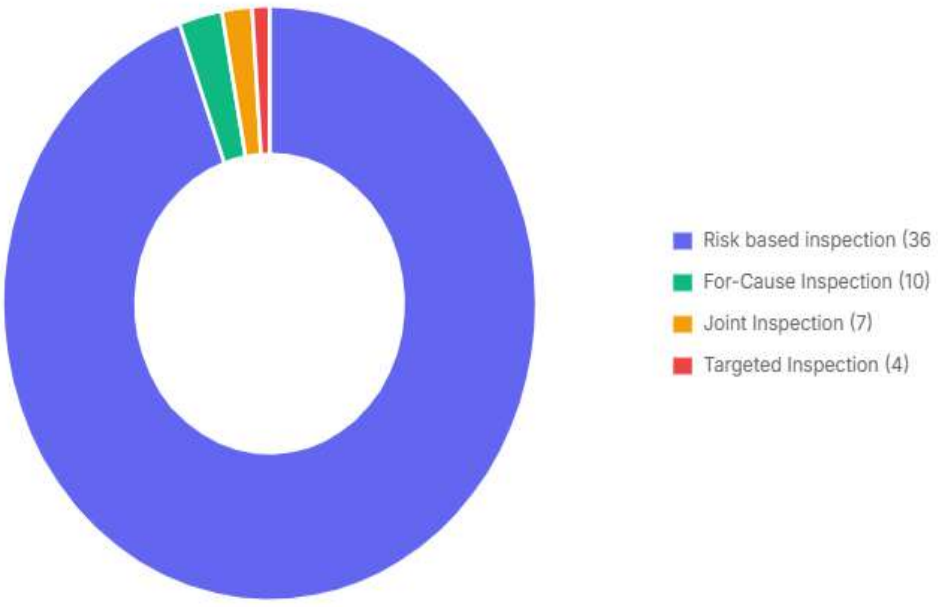
For Community pharmacies

- Risk-Based Inspection (incl. Unspecified merged):**24,617**
- For-Cause Inspection:**2,770**
- Joint Inspection with Relevant Authorities:**1,903**
- Targeted Inspection (Focused on a Specific Product):**509**
- Targeted Inspection:**73**
- Post-Market Surveillance Inspection:**9**
- Total:**29,881**



For Hospital Pharmacies

- Risk-Based Inspection:**362**
- For-Cause Inspection:**10**
- Joint Inspection:**7**
- Targeted Inspection:**4**
- Total:**383**



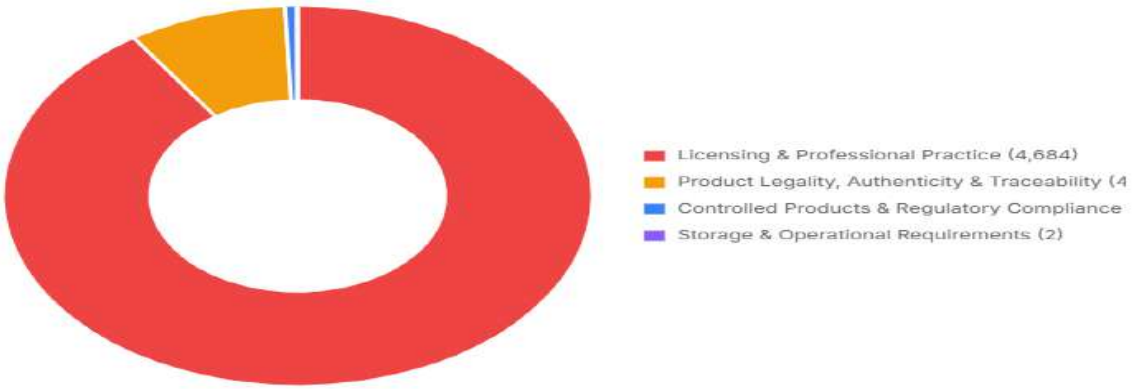
2. Overview Section

A) Total Number of Violations

For Community Pharmacies

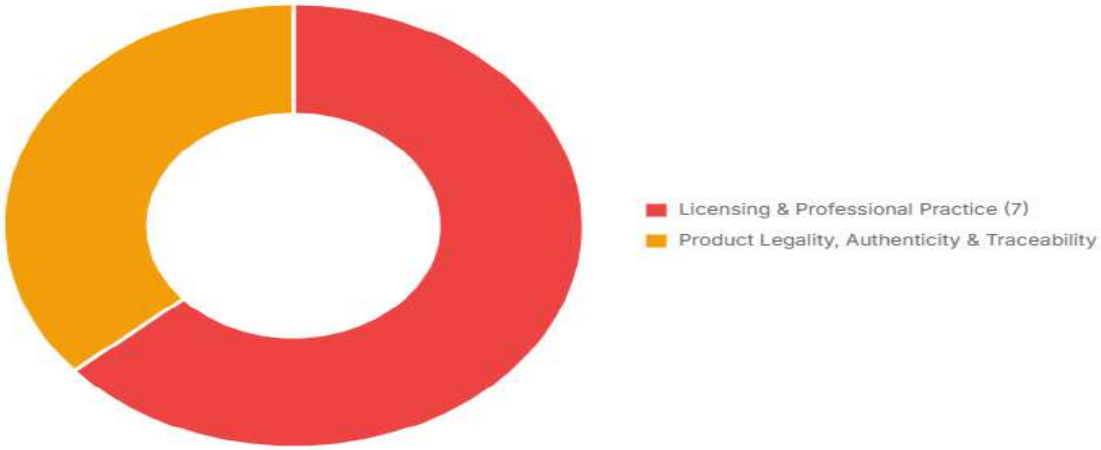
Total No. of Violations: **5,170 violations** (Note: Different violations can be recorded to the same institute.)

Violation Category	No.	%
Licensing & Professional Practice	4,684	90.60%
Product Legality, Authenticity & Traceability	450	8.70%
Controlled Products & Regulatory Compliance	34	0.66%
Storage & Operational Requirements	2	0.04%



for hospital pharmacies : 11 Violations

Violation Category	No.	%
Licensing & Professional Practice	7	63.64%
Product Legality, Authenticity & Traceability	4	36.36%



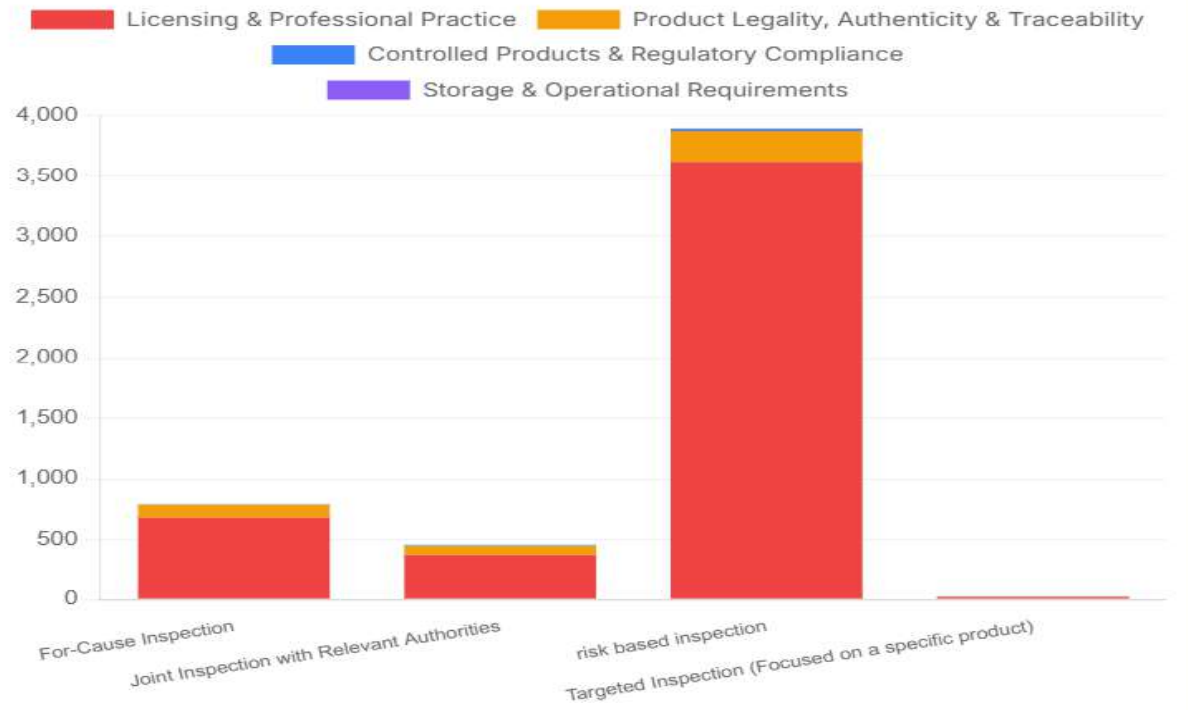
B) Distribution of Violations by Type of Pharmacy Establishment

- Community Pharmacy:**5,170**
- Hospital Pharmacy:**11**
- Total:**5,181**

C) Distribution of Violations by Inspection Type

For Community Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
For-Cause Inspection	**2,770**	**792**	**28.59%**
Joint Inspection with Relevant Authorities	**1,903**	**458**	**24.07%**
Risk-Based Inspection (incl. Unspecified merged)	**24,617**	**3,860**	**15.68%**
Targeted Inspection (Focused on a Specific Product)	**509**	**25**	**4.91%**
Targeted Inspection	**73**	**0**	**0.00%**
Post-Market Surveillance Inspection	**9**	**0**	**0.00%**



For hospital pharmacies:

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Risk-Based Inspection	**362**	**6**	**1.66%**
For-Cause Inspection	**10**	**1**	**10.00%**
Joint Inspection	**7**	**4**	**57.14%**
Targeted Inspection	**4**	**0**	**0.00%**
Risk-Based Inspection	**362**	**6**	**1.66%**



D) Trend Analysis

- **Most Frequent Violations**

For Community Pharmacies

1 Licensing & Professional Practice:**4,684**
2 Product Legality, Authenticity & Traceability:**450**
3 Controlled Products & Regulatory Compliance:**34**

For Hospital Pharmacies

1 Licensing & Professional Practice:**7**
2 Product Legality, Authenticity & Traceability:**4**

- **Trending**

For Community Pharmacies

1- Inspection Volume Grew by 13.2%

Total inspections rose from **26,402 (Q3)** to **29,881 (Q4)**. Risk-Based Inspections drove this growth (20,615 → 24,617), while For-Cause Inspections also increased (2,214 → 2,770). Post-Market Surveillance, however, dropped from 9 to 9 (flat), and Targeted-Specific fell from 2,516 to 509.

2. Governorate Non-Compliance Shifted Slightly (Governorate Trend)
While overall "Not Comply" counts rose (4,374 → 4,921), **Gharbia (613 → 616)** and **Dakahlia (491 → 597)** remained the highest non-compliance clusters. **Qalyubia (442 → 565)** worsened notably, while **Alexandria (98 → 71)** and **Beheira (270 → 299)** showed mixed results. **Bani Suef** continued to show an unusually high Need Follow Up count (51 → 148), indicating a persistent localized backlog.

3. Violations Increased, Led by Licensing & Product Legality
Total violations rose from **4,897 (Q3)** to **5,170 (Q4)**. **Licensing & Professional Practice** increased from 4,292 to 4,684, and **Product Legality** rose from 557 to 450. **Controlled Products** declined from 48 to 34, while **Storage & Operational Requirements** emerged from 0 to 2 — indicating a slight broadening of violation types in Q4.

For hospital pharmacies:

1**. Inspection Volume More Than Doubled**:
Total hospital pharmacy inspections surged from 146 (Q3) to 383 (Q4) — a 162% increase. Risk-Based Inspections drove the growth (132 → 362), while Joint Inspections rose from 1 to 7 and For-Cause Inspections increased from 6 to 10. Targeted Inspections fell slightly from 7 to 4.

2**. Governorate Coverage Concentrated in Alexandria & Cairo (Governorate Trend)**
Q3 covered 12 governorates, while Q4 narrowed to 10 governorates with inspections heavily concentrated in Alexandria (85) and Cairo (70) together accounting for 40% of all hospital inspections. Gharbia (30) and Sharqia (26) followed. Non-compliance spread from 4 governorates in Q3 to 4 in Q4, with Gharbia (4 Not Comply) and Sharqia (3) showing the highest clusters, followed by Alexandria (2) and Cairo (1).

3. **Violations Rose Slightly, Led by Licensing**
Total violations increased from 9 (Q3) to 11 (Q4), a 22% increase. Licensing & Professional Practice remained stable at 7, while Product Legality, Authenticity & Traceability doubled from 2 to 4. Not Comply findings rose from 10 to 14, and CAPA Accepted increased from 4 to 7 — indicating both broader detection and more corrective actions in Q4.

- **<u>Recurring Violations</u>**

For Community Pharmacies

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

For Hospital Pharmacies

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

Emerging Areas of Concern

For Community Pharmacies

1. **For-Cause Inspection Yield:** 792 violations found across 2,770 For-Cause Inspections (28.59% yield) — the highest violation hit rate among all inspection types, indicating strong intelligence-led targeting effectiveness**.**
2. **Governorate Non-Compliance Concentrated in Gharbia & Dakahlia:** الغربية (616 Not Comply) and الدقهلية (597 Not Comply) were the highest absolute non-compliance clusters, followed by القليوبية (565) and البحيرة (299).
3. **Bani Suef Follow-Up Spike**: بنى سويف recorded 148 Need Follow Up cases — significantly higher than any other governorate, indicating a localized follow-up backlog requiring attention.
4. **Storage & Operational Requirements: 2 violations recorded — the category remains nearly absent, emerging only in Risk-Based Inspections.**

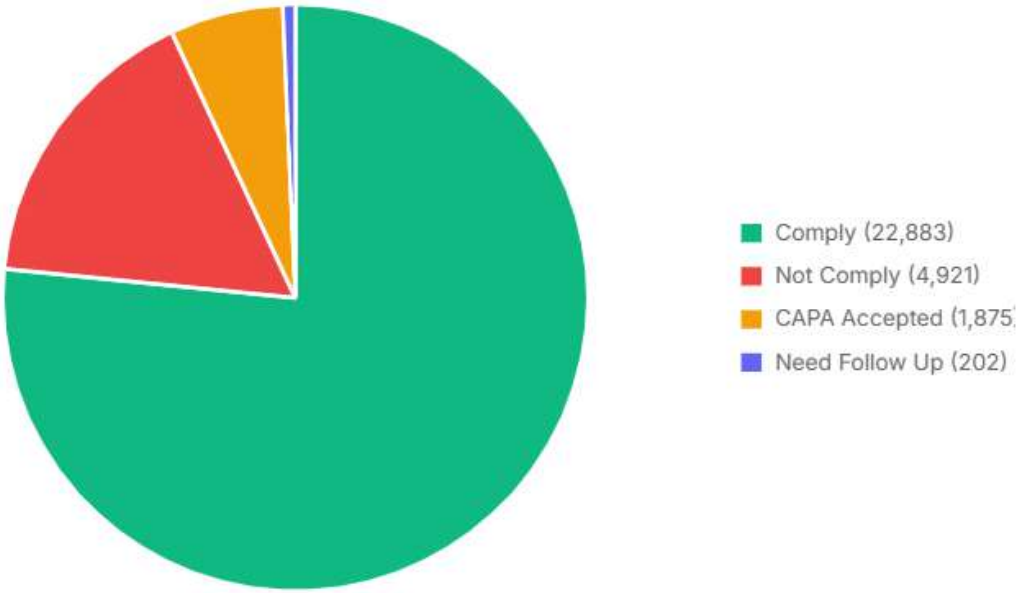
For Hospital Pharmacies

1. **Joint Inspection Yield:** 4 violations found across 7 Joint Inspections (57.14% yield) — the highest violation hit rate among all inspection types, indicating multi-authority operations were highly effective at identifying violations**.**
2. **Governorate Non-Compliance Concentrated in Gharbia & Sharqia:** الغربية (4 Not Comply) and الشرقية (3 Not Comply) were the highest absolute non-compliance clusters, followed by الإسكندرية (2) and القاهرة (1).
3. **No Follow-Up Recorded:** 0 Need Follow Up across all 383 hospital inspections — all non-compliance was either remedied via CAPA (7) or left as Not Comply (14).

- **Regulatory/Enforcement Actions**

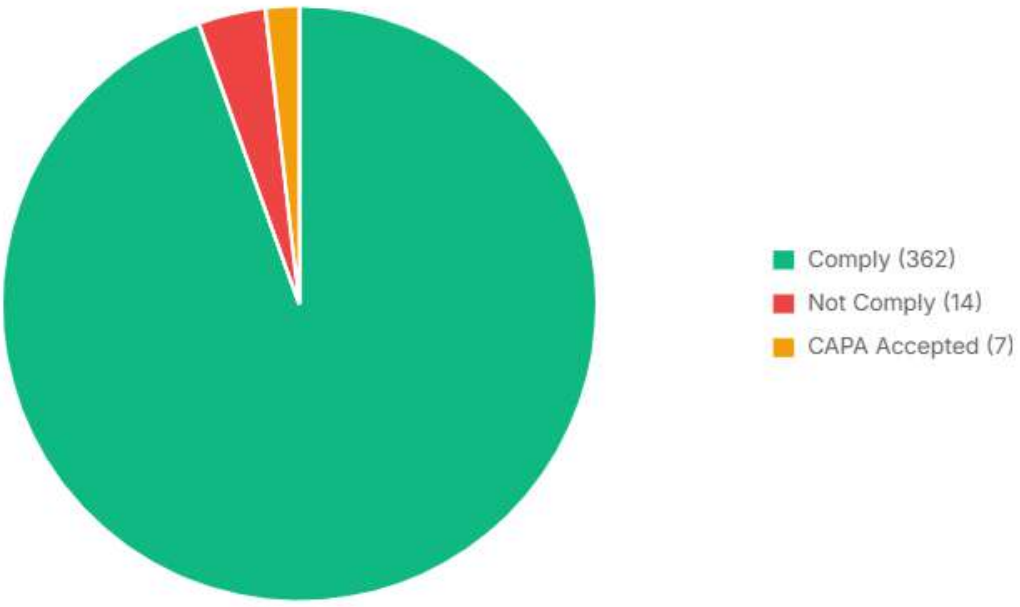
For Community Pharmacies

- No. of regulatory/enforcement actions 4,921
- No. of follow-up inspections 202
- No. of recall follow-up inspections 0
- No. of other applicable regulatory actions 1,875



For Hospital Pharmacies

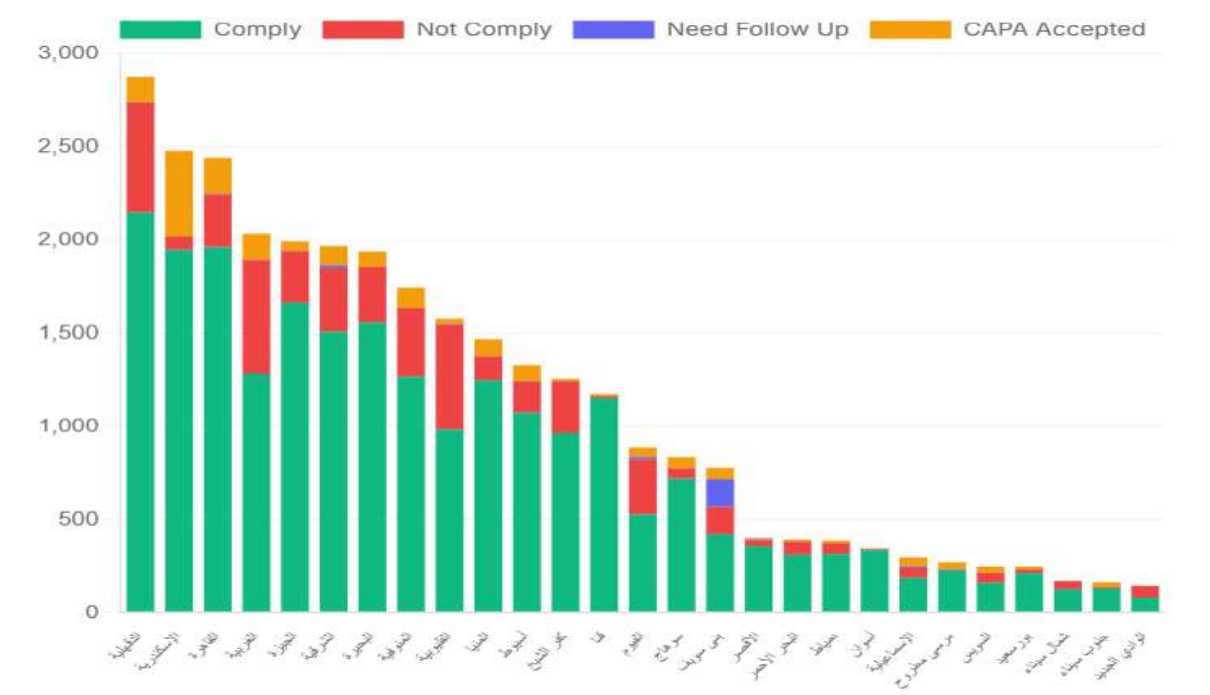
- No. of regulatory/enforcement actions 14
- No. of follow-up inspections 0
- No. of recall follow-up inspections 0
- No. of other applicable regulatory actions 7



3- Conclusion

For Community Pharmacies

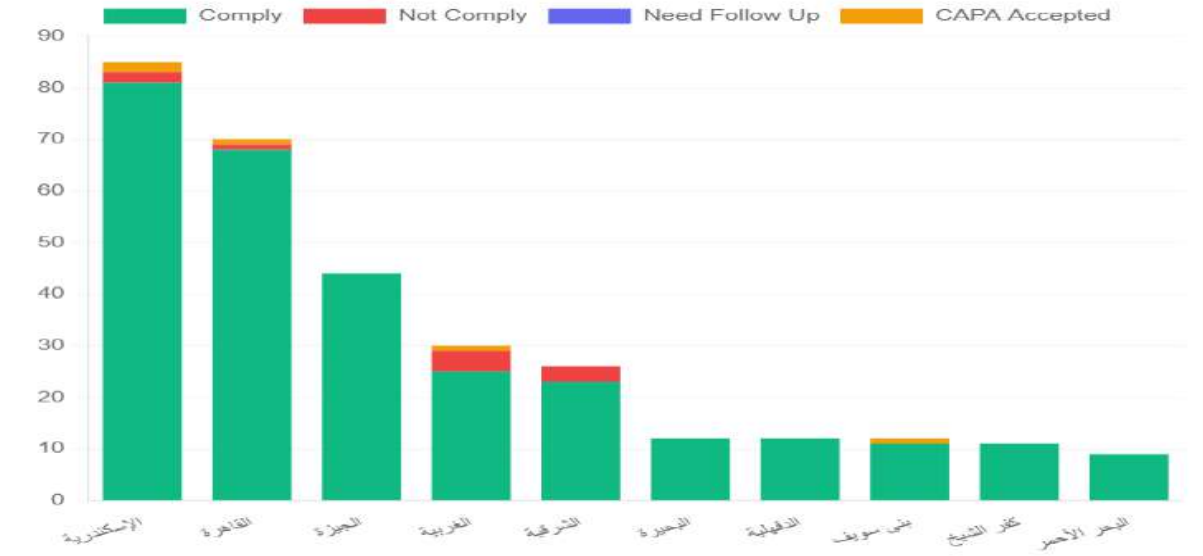
- **% of pharmacy inspections with no violations: 76.58% (22,883 Comply / 29,881)**
- **% of pharmacy inspections with violations: 23.42% (4,921 Not Comply + 1,875 CAPA Accepted + 202 Need Follow Up = 6,998 / 29,881)**
- **% of pharmacy inspections requiring follow-up: 0.68% (202 Need Follow Up / 29,881)**
- **% of pharmacy inspections resulting in regulatory/enforcement actions: 16.47% (4,921 Not Comply / 29,881)**
- **Most frequent violation category: Licensing & Professional Practice (4,684 violations; 90.60%)**
- **Most frequent recurring violation: Licensing & Professional Practice**
- **Governorate requiring increased attention: الغربية (highest Not Comply = 616; 30.24% of its 2,037 inspections) and الدقهلية (597 Not Comply; 20.74% of 2,879)**
- **Inspection type requiring adjustment/increase: For-Cause Inspection (highest violation yield at 28.59%) and Joint Inspection (24.07%)**



For Hospital Pharmacies :

- **% of hospital inspections with no violations**: 94.52% (362 Comply / 383)
- **% of hospital inspections with violations**: 5.48% (14 Not Comply + 7 CAPA Accepted = 21 / 383)

- **% of hospital inspections requiring follow-up:** 0.00% (0 Need Follow Up / 383)
- **% of hospital inspections resulting in regulatory/enforcement actions**: 3.66% (14 Not Comply / 383)
- **Most frequent violation category**: Licensing & Professional Practice (7 violations; 63.64%)
- **Most frequent recurring violation**: Licensing & Professional Practice
- **Governorate requiring increased attention**: الغربية (4 Not Comply), الشرقية (3), and الإسكندرية (2)
- **Inspection type requiring adjustment/increase**: Joint Inspection (highest violation yield at 57.14%) and For-Cause Inspection (10.00%)



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