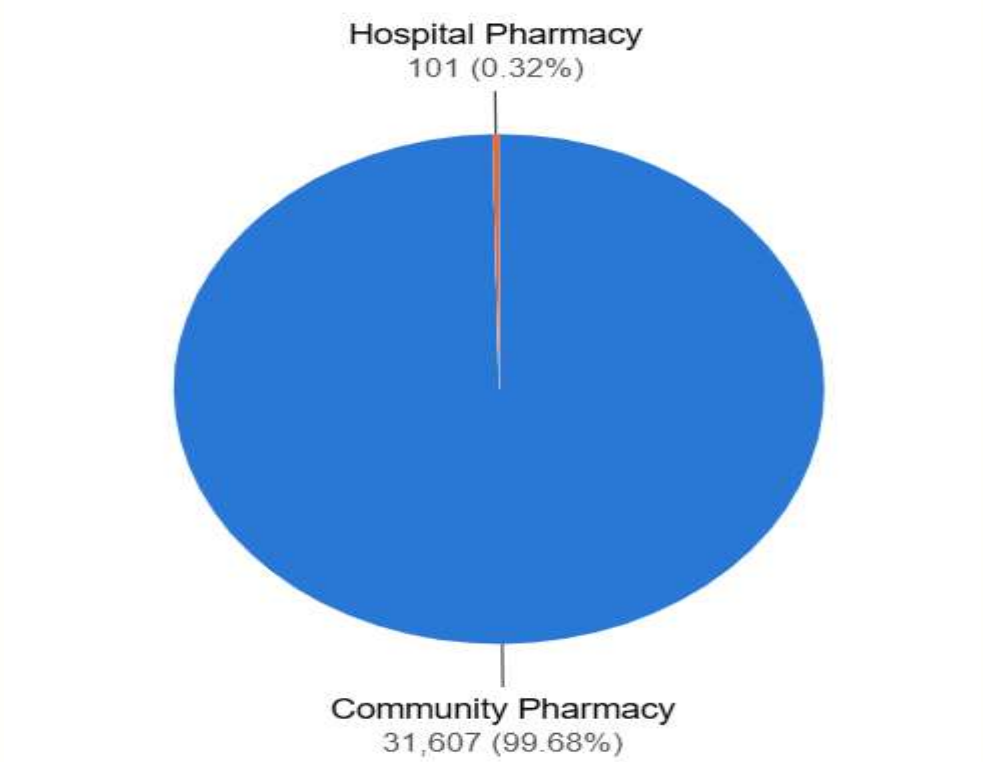
Collective Analysis of Pharmacy Inspection Observations Data Report
Quarter 1 Year 2025

1. Executive Summary

Total No. of Pharmacy Inspections: **31,708 inspection**

Type of Pharmacy Establishment

- Community Pharmacy:**31,607**
- Hospital Pharmacy:**101**



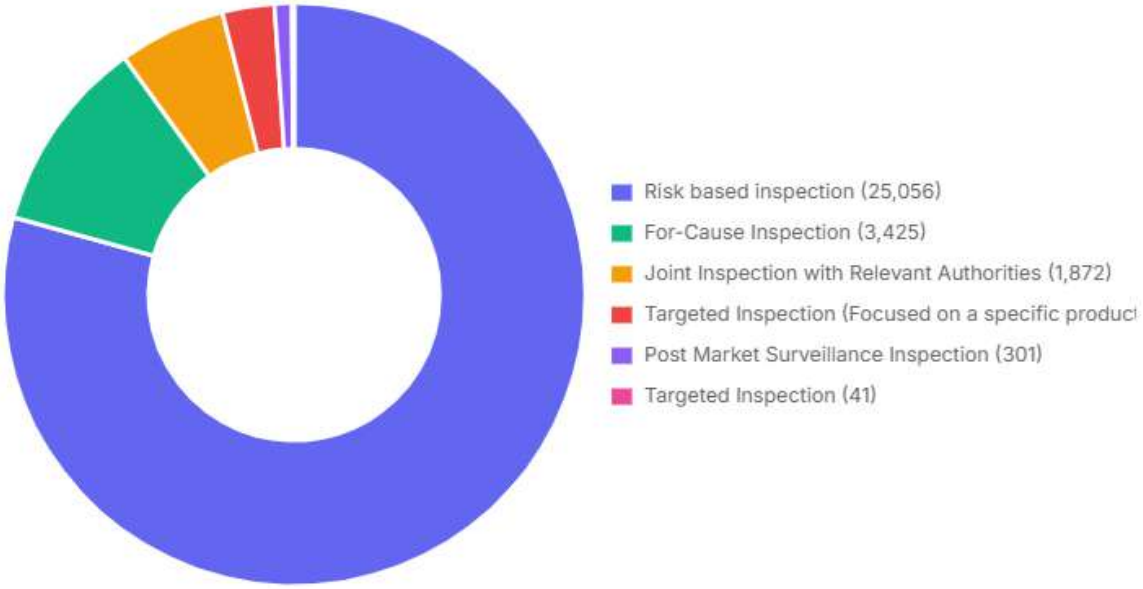
Note: Pharmacies may be inspected more than once during a quarter. For this analysis, only the most recent inspection result for each pharmacy is included, ensuring that each pharmacy is counted once and reducing the risk of duplicate or misleading results.

Type of Inspection

For Community pharmacies

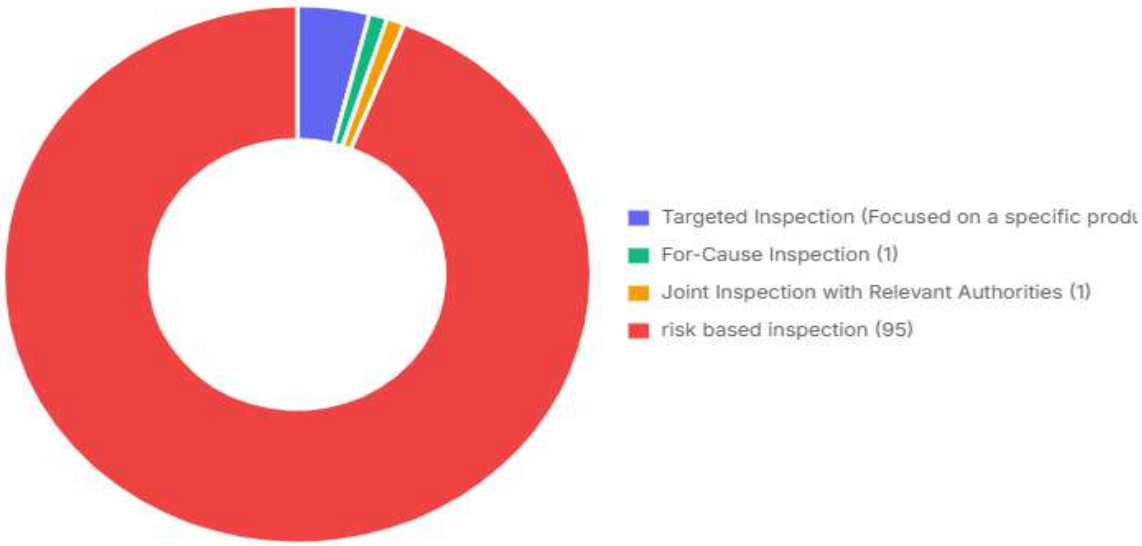
- Risk-Based Inspection (incl. Unspecified merged):**25,056**
- For-Cause Inspection:**3,425**
- Joint Inspection with Relevant Authorities:**1,872**
- Targeted Inspection (Focused on a Specific Product):**912**
- Post-Market Surveillance Inspection:**301**

- Targeted Inspection:**41**



For Hospital pharmacies

- Risk-Based Inspection (incl. Unspecified merged):**95**
- Targeted Inspection (Focused on a Specific Product):**4**
- For-Cause Inspection:**1**
- Joint Inspection with Relevant Authorities:**1**



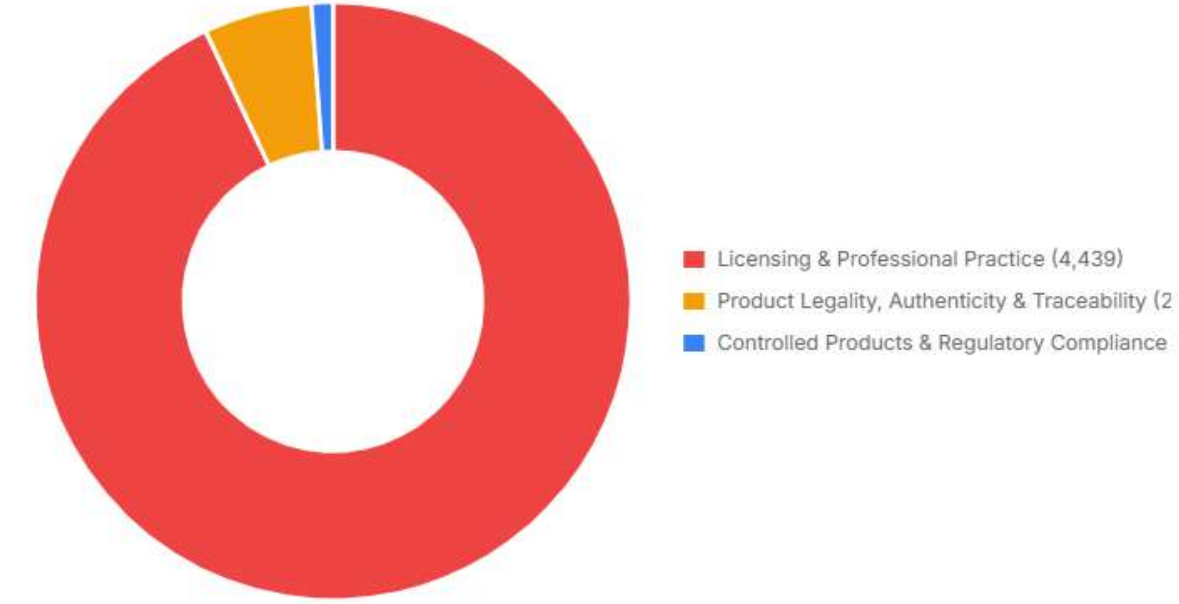
2. Overview Section

A) Total Number of Violations

For Community Pharmacies

Total No. of Violations: **4,774 violations** (Note: Different violations can be recorded to the same institute).

Violation Category	No.	%
Licensing & Professional Practice	4,439	92.98%
Product Legality, Authenticity & Traceability	280	5.87%
Controlled Products & Regulatory Compliance	55	1.15%
Storage & Operational Requirements	0	0.00%



For Hospital Pharmacies

Total No. of Violations: **1 violation** (Note: The same violation may be recorded more than once for the same pharmacy)

Violation Category	No.	%
Licensing & Professional Practice	1	100%

.

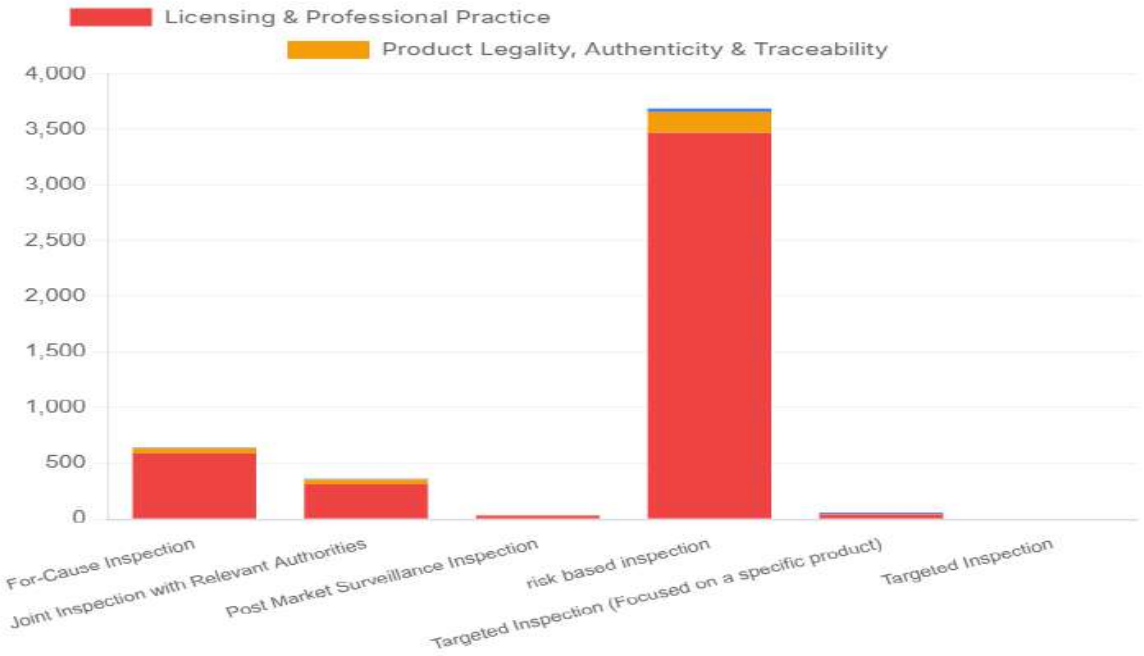
B) Distribution of Violations by Type of Pharmacy Establishment

Total Community Pharmacy violations**: 4,774 violations**

Total Hospital Pharmacy violations: **1 violations**

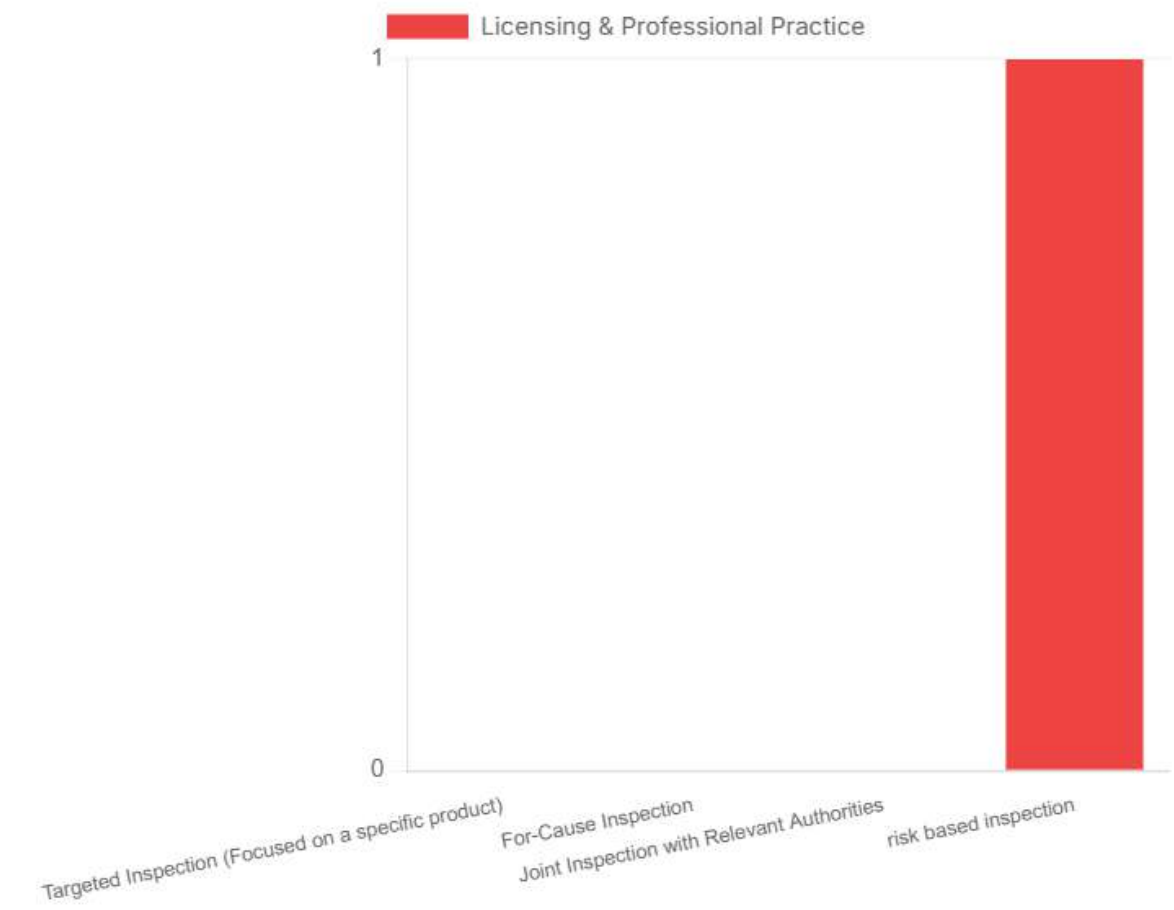
C) Distribution of Violations by Inspection Type
For Community Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
For-Cause Inspection	**3,425**	**637**	**18.60%**
Joint Inspection with Relevant Authorities	**1,872**	**357**	**19.07%**
Post-Market Surveillance Inspection	**301**	**34**	**11.30%**
Risk-Based Inspection (incl. Unspecified merged)	**25,056**	**3,682**	**14.70%**
Targeted Inspection (Focused on a Specific Product)	**912**	**56**	**6.14%**
Targeted Inspection	**41**	**0**	**0.00%**



For Hospital Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Risk-Based Inspection (incl. Unspecified merged)	**95**	**1**	**1.05%**
Joint Inspection with Relevant Authorities	**1**	**0**	**0.00%**
Targeted Inspection (Focused on a Specific Product)	**4**	**0**	**0.00%**
For-Cause Inspection	**1**	**0**	**0.00%**



D) Trend Analysis

- **Most Frequent Violations**

For Community Pharmacies

1. Licensing & Professional Practice (4,439)
2. Product Legality, Authenticity & Traceability (280)
3. Controlled Products & Regulatory Compliance (55)

For Hospital Pharmacies

1. Licensing & Professional Practice (100%)

- **Recurring Violations**

For Community Pharmacies

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

For Hospital Pharmacies

1. Licensing & Professional Practice

- **Increasing Trends**

For Community Pharmacies

1- Overall Inspection Volume Grew, Driven by Risk-Based Activity

Total active inspections rose from 29,881 in Q4 2024 to 31,607 in Q1 2025 (a 5.8% increase).
Risk-Based inspections grew from 24,617 to 25,056.
For-Cause inspections jumped significantly from 2,770 to 3,425.

2- Violations Eased Slightly, but "Not Comply" Volume Remained High

Total recorded violations decreased from 5,170 (Q4 2024) to 4,774 (Q1 2025).
The absolute number of "Not Comply" facilities dropped from 4,921 to 4,679 (a 4.9% decrease).
"Comply" cases increased from 22,883 to 24,905.
The "Need Follow Up" burden eased significantly from 202 down to 78.

3- Licensing Violations Remain Dominant; Storage Issues Nearly Vanish

"Licensing & Professional Practice" remained the overwhelming violation category, dropping slightly from 4,684 (Q4 2024) to 4,439 (Q1 2025).
"Storage & Operational Requirements" plummeted from 2 violations in Q4 2024 to 0 in Q1 2025.

4- Non-Compliance Hotspots Shifted to Qalyubia and Gharbia

Gharbia maintained its position as a major non-compliance hotspot, recording 616 "Not Comply" in Q4 2024 and 555 in Q1 2025.

Qalyubia remained highly problematic, with 565 in Q4 2024 and 524 in Q1 2025. Dakahlia improved significantly, dropping from 597 to 488.

For Hospital Pharmacies

1- Drastic Drop in Total Inspection Volume

Total hospital inspections plummeted from 383 in Q4 2024 to 101 in Q1 2025 (a 73.6% decrease). This drop was driven almost entirely by a massive reduction in Risk-Based inspections, which fell from 362 to 95. Joint Inspections also decreased from 7 to 1.

2. Violations Dropped Significantly, Aligning with Lower Volume

Total recorded violations decreased from 11 (7 Licensing & 4 Product Legality) in Q4 2024 to just 1 (Licensing) in Q1 2025.

3. Geographic Concentration Tightened Around Giza and Cairo

In Q4 2024, inspections were spread across 10 governorates, with Alexandria leading (81 inspections) followed by Cairo (68) and Giza (44). In Q1 2025, the geographic focus tightened dramatically, concentrating heavily on Giza (60 inspections) and Cairo (28 inspections), while Alexandria dropped to just 6 inspections.

<u>Emerging Areas of Concern</u>

For Community Pharmacies

1. **Low Inspection Volume, High Yield in For-Cause Inspections:**
   3,425 For-Cause Inspections (10.8% of volume) produced 637 violations (18.60% yield) — intelligence-led targeting was effective even at lower inspection volumes.
2. **Governorate Non-Compliance Concentrated in Gharbia & Qalyubia:**
   الغربية (555 Not Comply) and القليوبية (524 Not Comply) were the highest absolute non-compliance clusters, followed by الدقهلية (488) and البحيرة (339).
3. **Licensing Violations Dominated;**
   Storage & Operational Absent: Licensing & Professional Practice accounted for 4,439 violations (92.98%), while Storage & Operational Requirements recorded 0 violations — a category that later emerged in Q3 and Q4.

For Hospital Pharmacies

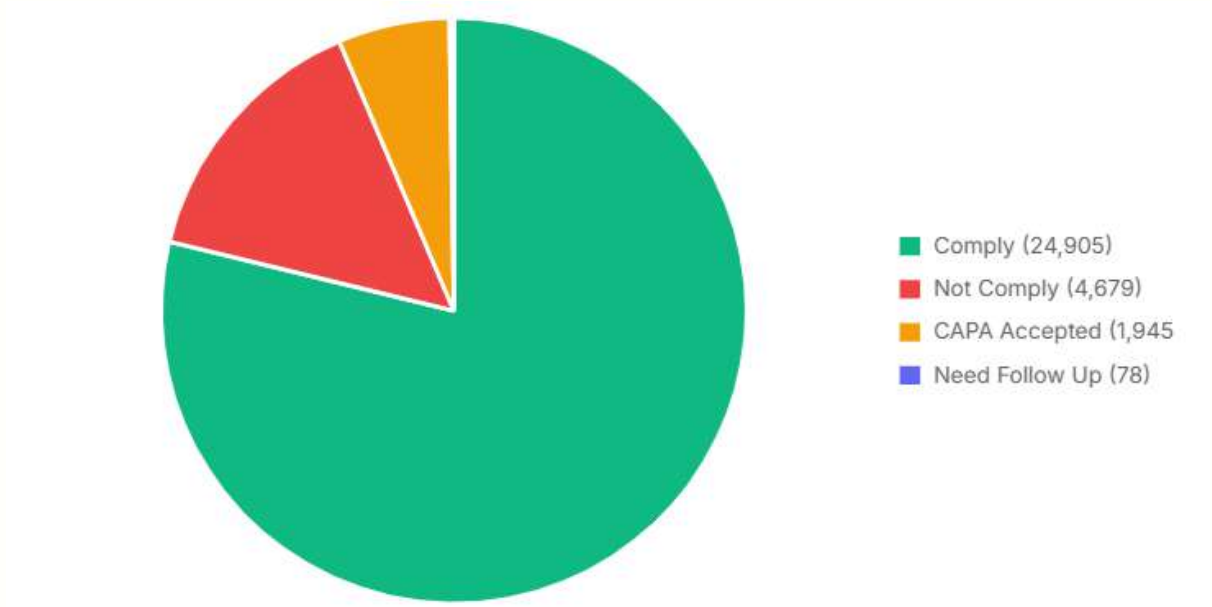
1. **High Inspection Volume, Driven by Risk-Based:**
   101 hospital inspections. Risk-Based Inspections accounted for 95 (94.1%), indicating an early-year push focused on routine risk-based auditing.
2. **Minimal Violations :**
   Only 1 Licensing Finding: Only 1 violation recorded across 101 inspections — a single Licensing & Professional Practice finding under Risk-Based Inspection (0.99% violation rate).
3. **Compliance Near-Perfect;**
   CAPA Accepted Outpaced Not Comply: 98 Comply, 2 CAPA Accepted, 1 Not Comply — a 97.03% no-violation rate. CAPA Accepted (2) exceeded Not Comply

(1), indicating a cooperative compliance posture early in the year.

E) Regulatory/Enforcement Actions

For Community Pharmacies

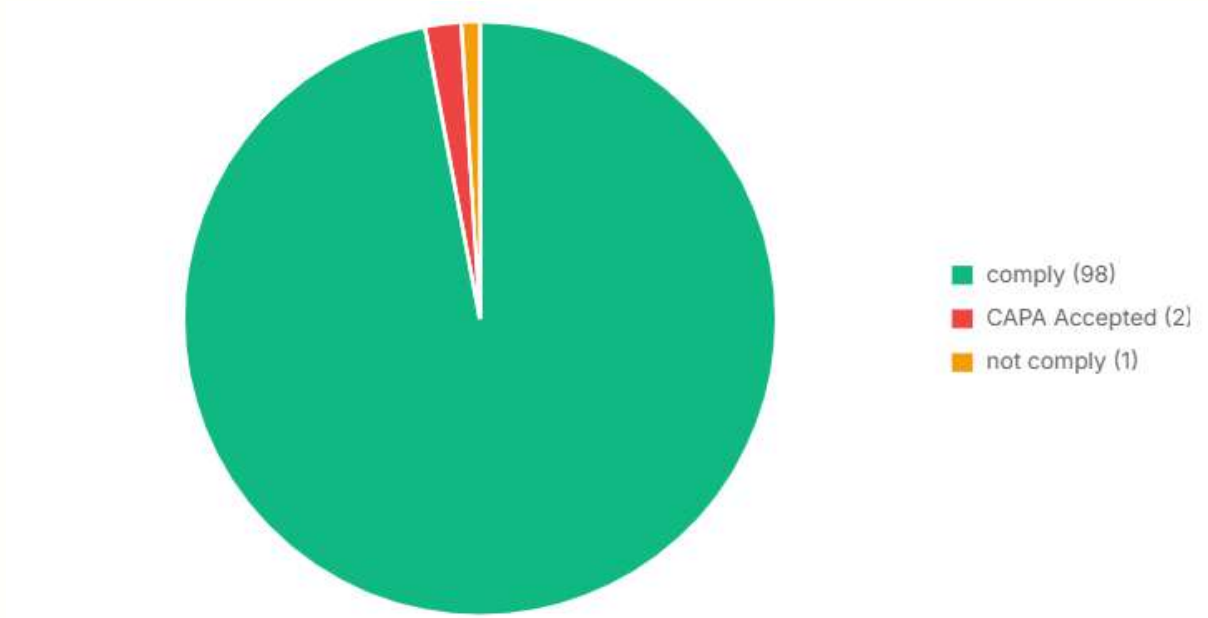
- No. of regulatory/enforcement actions 4,679
- No. of follow-up inspections 78
- No. of recall follow-up inspections 0
- No. of other applicable regulatory actions 1,945



For Hospital Pharmacies

- No. of regulatory/enforcement actions 1
- No. of follow-up inspections 0
- No. of recall follow-up inspections 0

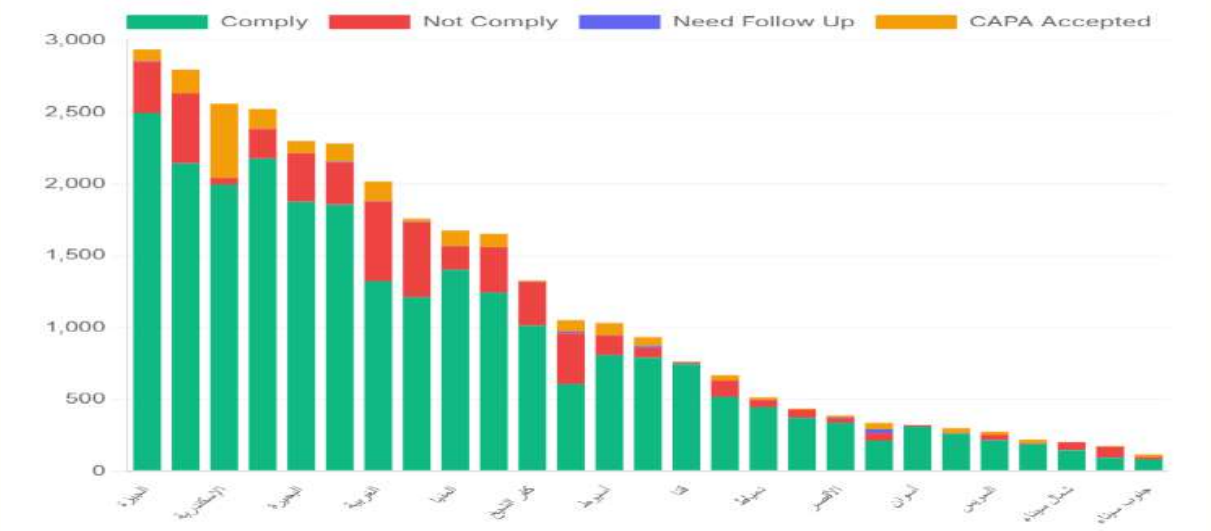
- No. of other applicable regulatory actions 2



3-Conclusion

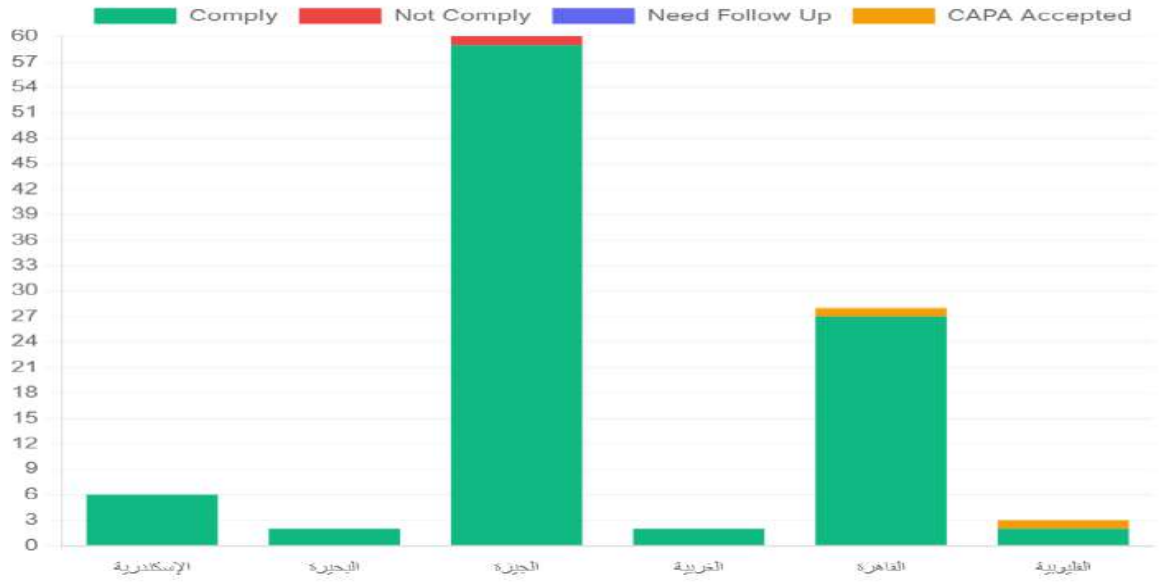
For Community Pharmacies

- % of pharmacy inspections with no violations: **78.80%** (24,905 Comply / 31,607
- % of pharmacy inspections with violations: **21.20%** (4,679 Not Comply + 1,945 CAPA Accepted + 78 Need Follow Up = 6,702 / 31,607)
- % of pharmacy inspections requiring follow-up: **0.25%** (78 Need Follow Up / 31,607)
- % of pharmacy inspections resulting in regulatory/enforcement actions: **14.80%** (4,679 Not Comply / 31,607)
- Most frequent violation category: **Licensing & Professional Practice** (4,439 violations; 92.98%)
- Most frequent recurring violation: **Licensing & Professional Practice**
- Governorate requiring increased attention: **Gharbia** (highest Not Comply = 555; 27.5% of its 2,020 inspections) and **Qalyuobia** (524 Not Comply; 29.8% of 1,760)
- Inspection type requiring adjustment/increase: **Joint Inspection with Relevant Authorities** (highest violation yield at 19.07%) **and For-Cause Inspection** (18.60%)



For Hospital Pharmacies

- % of hospital inspections with no violations: **97.03%** (98 Comply / 101)
- % of hospital inspections with violations: **2.97%** (1 Not Comply + 2 CAPA Accepted = 3 / 101)
- % of hospital inspections requiring follow-up: **0.00%** (0 Need Follow Up / 101)
- % of hospital inspections resulting in regulatory/enforcement actions: **0.99%** (1 Not Comply / 101)
- Most frequent violation category: **Licensing & Professional Practice** (1 violation, 100%)
- Most frequent recurring violation: **Licensing & Professional Practice**
- Governorate requiring increased attention: **Giza** (1 Not Comply of 60; 1.7%)
- Inspection type requiring adjustment/increase: **Risk-Based Inspection** (1 of 101 violations; 1.05% yield)



Prepared by:
Manager of EDA Branches Follow-up
Name:
Sign./ date:

Reviewed by
General Manager of Market Control
Name:
Sign./date:

Reviewed by:
General Manager of Governmental Institutes Inspection
Name:
Sign./date:

Approved by:
Head of Central Administration of CIP
Name:
Sign./date: