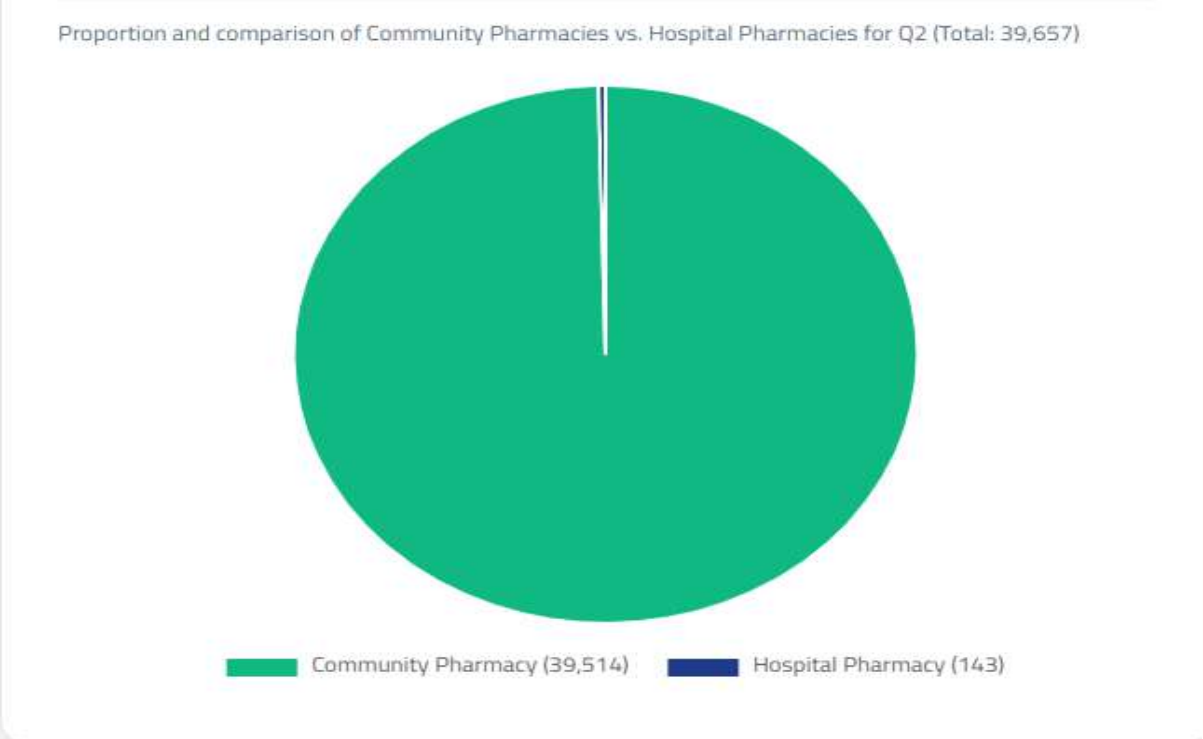
Collective Analysis of Pharmacy Inspection Observations Data Report
Quarter 2 Year 2026

1. Executive Summary

Total No. of Pharmacy Inspections: **39,657 inspection**

Type of Pharmacy Establishment

- Community Pharmacy: **39,514 inspection**
- Hospital Pharmacy: **143inspection**



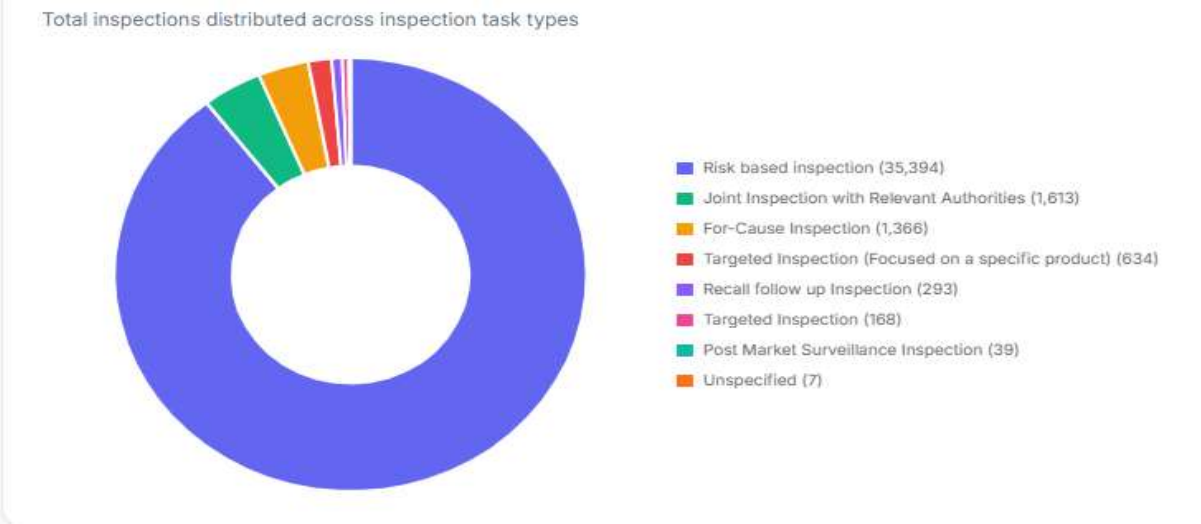
Note: Pharmacies may be inspected more than once during a quarter. For this analysis, only the most recent inspection result for each pharmacy is included, ensuring that each pharmacy is counted once and reducing the risk of duplicate or misleading results.

Type of Inspection

For Community pharmacies

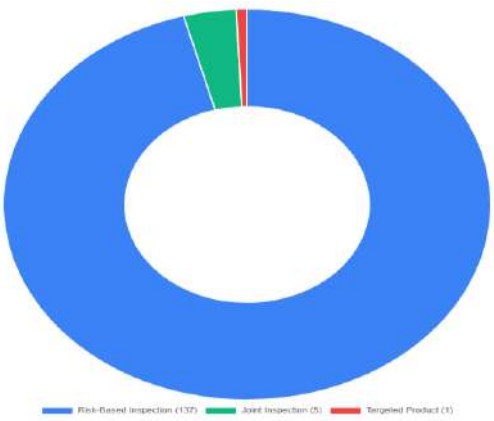
- Targeted Inspection (Focused on a Specific Product): **634 inspection**
- Risk-Based Inspection: **35,401 inspection**
- Joint Inspection with Relevant Authorities: **1,613 inspection**
- Post-Market Surveillance Inspection: **39 inspection**

- For-Cause Inspection: **1,366 inspection**
- **Targeted** Inspection: **168 inspection**
- Recall Follow-Up Inspection: **293 inspection**



For Hospital pharmacies

- Risk-Based Inspection: **137 inspection**
- Joint Inspection with Relevant Authorities: **5 inspection**
- Targeted Inspection (Focused on a Specific Product): **1 inspection**



2. Overview Section

A) Total Number of Violations

For Community Pharmacies

Total No. of Violations: **5,493 violation** (Note: The same violation may be recorded more than once for the same pharmacy.)

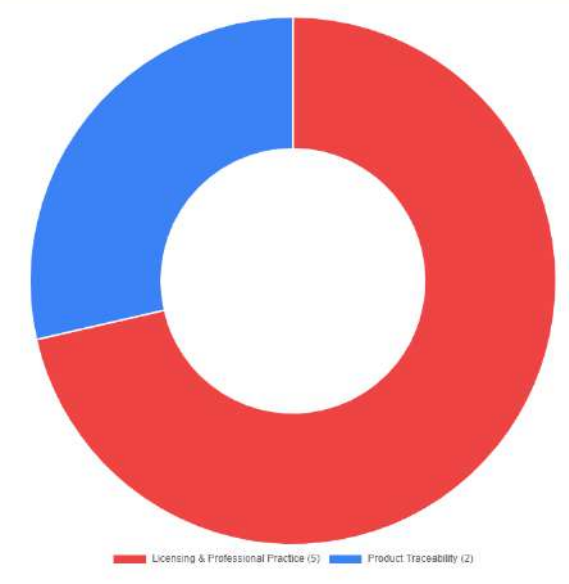
Violation Category	No.	%
Licensing & Professional Practice	**4,850**	**88.3%**
Product Legality, Authenticity & Traceability	**256**	**4.7%**
Controlled Products & Regulatory Compliance	**199**	**3.6%**
Storage & Operational Requirements	**188**	**3.4%**



For For Hospital Pharmacies

Total No. of Violations: **7 violation** (Note: The same violation may be recorded more than once for the same pharmacy.)

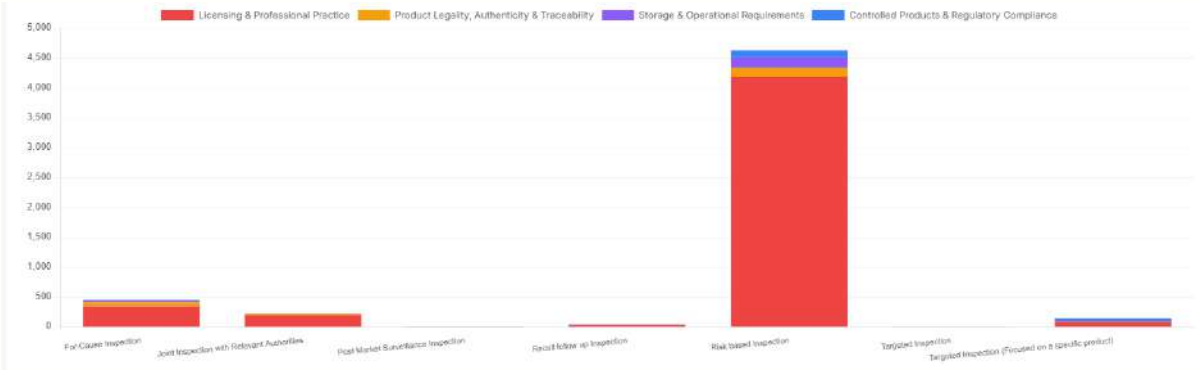
Violation Category	No.	%
Licensing & Professional Practice	5	71.4%
Product Legality, Authenticity & Traceability	2	28.6%



B) Distribution of Violations by Type of Pharmacy Establishment
Total Community Pharmacy violations: **5,493 violations**
Total Hospital Pharmacy violations: **7 violations**

C) Distribution of Violations by Inspection Type
For Community Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Targeted Inspection (Focused on a Specific Product)	1,613	227	14.1%
Risk-Based Inspection	35,401	4,625	13.1%
Joint Inspection with Relevant Authorities	1,613	227	14.1%
Post-Market Surveillance Inspection	39	2	5.1%
For-Cause Inspection	1,366	447	32.7%
Follow-Up Inspection	168	8	4.8%
Recall Follow-Up Inspection	293	43	14.7%



For Hospital Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Risk-Based Inspection	137	7	5.1%
Joint Inspection with Relevant Authorities	**5**	**0**	**0%**
Targeted Inspection (Focused on a Specific Product)	**1**	**0**	**0%**



D) Trend Analysis

- **<u>Most Frequent Violations</u>**

For Community Pharmacies

1. Licensing & Professional Practice (4,850)
2. Product Legality, Authenticity & Traceability (256)
3. Storage & Operational Requirements (199)

For Hospital Pharmacies

1 Licensing & Professional Practice (5)

2 Product Legality, Authenticity & Traceability (2)

- **Increasing Trends**

For Community Pharmacies

1. **Joint Inspections Remain Highly Effective**

Joint inspections consistently yield a high number of violations per operation (588 in Q1; 227 in Q2), proving their value in detecting complex, multi-authority issues.

2. **Rise in Controlled Products Violations**

Violations related to Controlled Products & Regulatory Compliance increased in Q2 (188) compared to Q1 (146), indicating a specific and growing compliance gap.

3. **Persistent Hotspots in Specific Governorates**

While Q1 saw high "Not Comply" volumes in Kafr El Sheikh (372) and Qalyubia (322), Q2 shows the highest local failure rates concentrating in Qalyubia (375 "Not Comply") and Kafr El Sheikh (296), indicating these specific regions require sustained, targeted regulatory intervention.

For Hospital Pharmacies

1. 1. Surge in Inspection Volume

   The total number of hospital inspections more than doubled from 65 in Q1 to 143 in Q2 (a 120% increase), reflecting a significant expansion in hospital audit activity.

2. Emergence of Licensing Violations

   In Q1, the only recorded violation was Product Legality/Traceability (1 instance). By Q2, Licensing & Professional Practice emerged as the dominant violation (5 instances), alongside an increase in Traceability issues (2 instances).

3. Spike in Localized Non-Compliance

   In Q1, only one "Not Comply" case was recorded in a single governorate. In Q2, non-compliance spread, with Monufia emerging as a hotspot (2 "Not Comply" out of 8 inspections) and Giza recording 1.

- **Recurring Violations**

For Community Pharmacies

1. Licensing & Professional Practice (Accounts for 88.3% of all violations)
2. Product Legality & Traceability
3. Storage & Operational Requirements

For Hospital Pharmacies

1. Licensing & Professional Practice (Dominates the violation categories at 71.4%)
2. Product Legality & Traceability (28.6%)

- **Emerging Areas of Concern**

For Community Pharmacies

1. Surge in Violations via Joint Inspections: Q3 saw a massive spike in violations found during Joint Inspections (748 violations compared to 227 in Q2), indicating a need to evaluate the focus or effectiveness of these multi-authority operations.
2. Elevated "Not Comply" Rates in Specific Governorates: While overall compliance remains stable, specific areas like Kafr El Sheikh (503 Not Comply) and Gharbia (470 Not Comply) show acute regulatory gaps requiring targeted intervention.
3. High Yield of For-Cause Inspections: For-Cause inspections in Q3 had the highest violation hit rate (31.6%). This suggests that intelligence/risk signals prompting these inspections are highly accurate, and resources may need to shift toward more intelligence-led targeting.

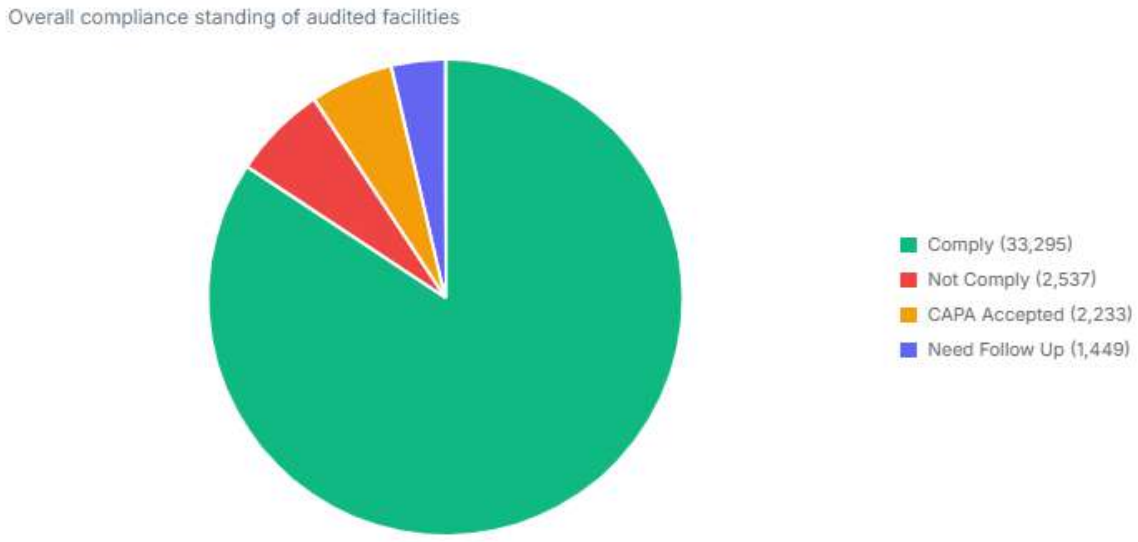
For Hospital Pharmacies

1. Monufia shows a concerning localized trend with 2 "Not Comply" out of only 8 inspections (25% failure rate).
2. Follow-up actions are required in Dakahlia (1 case).
3. All violations identified in Q2 were found during Risk-Based Inspections, suggesting a need to diversify inspection triggers or verify the low activity of For-Cause/Targeted inspections in hospitals.

E) Regulatory/Enforcement Actions

For Community Pharmacies

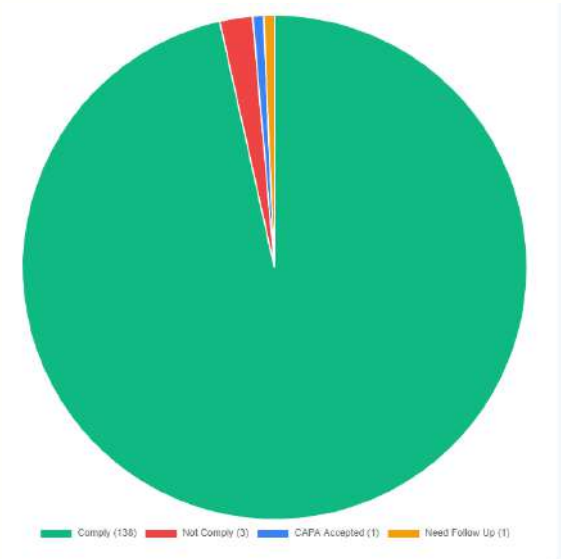
- No. of regulatory/enforcement actions: **2,537**
- No. of follow-up inspections: **1,449**
- No. of recall follow-up inspections: **293**
- No. of other applicable regulatory actions: **2,233**



For Hospital Pharmacies

- No. of regulatory/enforcement actions: **3**

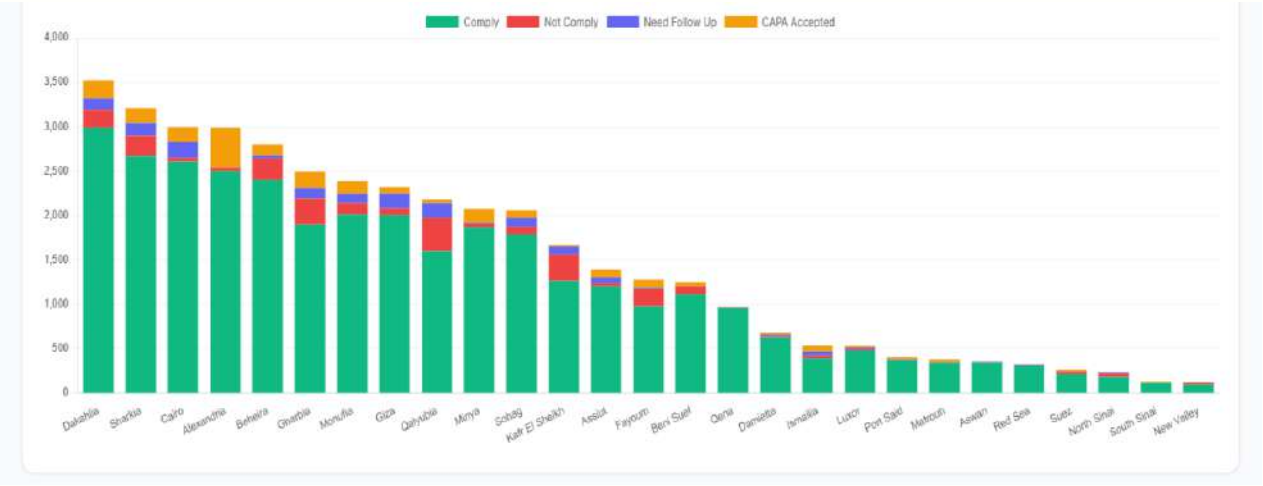
- No. of follow-up inspections: **1**
- No. of recall follow-up inspections: **0**
- No. of other applicable regulatory actions: **1**



3. Conclusion

For Community Pharmacies

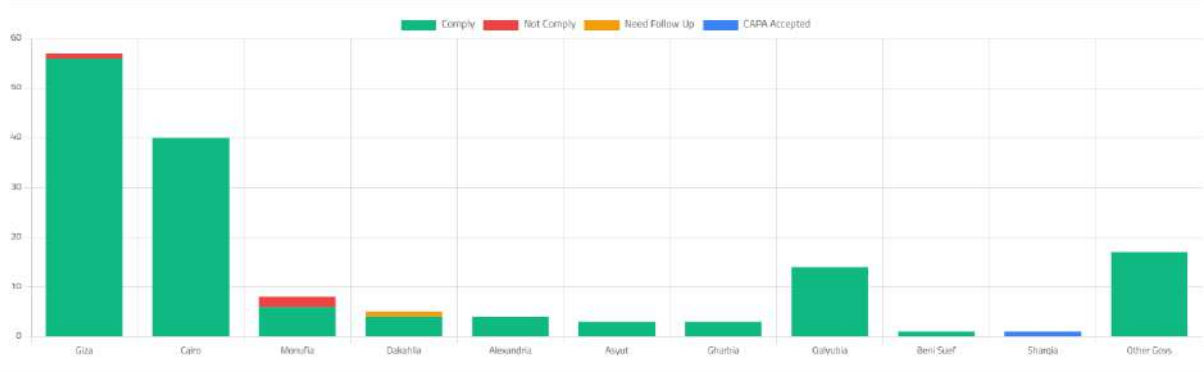
- % of pharmacy inspections with no violations: **84.26%** (33,295 Comply / 39,514 Total)
- % of pharmacy inspections with violations: **15.74%** (2,537 Not Comply + 1,449 Need Follow Up + 2,233 CAPA Accepted = 6,219 / 39,514 Total)
- % of pharmacy inspections requiring follow-up: **3.67%** (1,449 Need Follow Up / 39,514 Total)
- % of pharmacy inspections resulting in regulatory/enforcement actions: **6.42%** (2,537 Not Comply / 39,514 Total)
- Most frequent violation category: **Licensing & Professional Practice** (4,850 violations)
- Most frequent recurring violation: **Licensing & Professional Practice**
- **Governorate/EDA Branch requires increased attention: Qalyubia** (Highest number of "Not Comply" at 375 , representing 17 % of its total 2,181 inspections) and **Kafr El Sheikh** (296 "Not Comply"). ***Note: Gharbia*** also has a high absolute number (293).



- Inspection type requiring adjustment/increase: **For-Cause Inspection** (Has the highest percentage of violations found at 32.7%, indicating a high yield for finding issues).

For Hospital Pharmacies

- **% of pharmacy inspections with no violations: 96.50%** (138 Comply / 143 Total)
- **% of pharmacy inspections with violations: 3.50%** (3 Not Comply + 1 Need Follow Up + 1 CAPA Accepted = 5 / 143 Total)
- **% of pharmacy inspections requiring follow-up: 0.70%** (1 Need Follow Up / 143 Total)
- **% of pharmacy inspections resulting in regulatory/enforcement actions: 2.10%** (3 Not Comply / 143 Total)
- **Most frequent violation category:** Licensing & Professional Practice (71.4 %)
- **Most frequent recurring violation:** Licensing & Professional Practice
- **Governorate/EDA Branch requiring increased attention: Monufia** (Highest failure rate: 2 "Not Comply" out of 8 inspections, equating to a 25% failure rate in that governorate).



- **Inspection type requiring adjustment/increase: Risk-Based Inspection** (Currently carrying 100% of the detection load for violations; **Targeted or For-Cause** inspections may need to be increased in hospitals).