

Collective Analysis of Pharmacy Inspection Observations Data Report Quarter 3 Year 2026

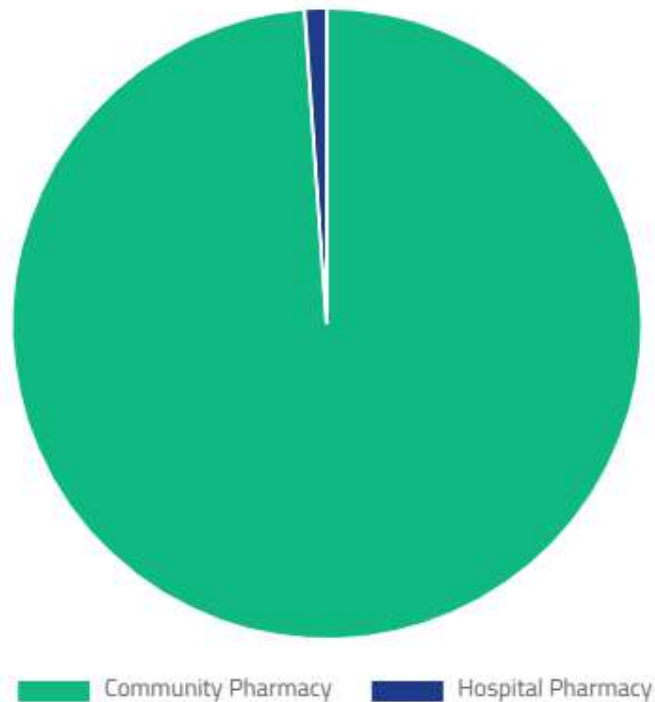
1. Executive Summary

Total No. of Pharmacy Inspections: **39,919 inspection**

Type of Pharmacy Establishment

- Community Pharmacy: **39,470 inspection**
- Hospital Pharmacy: **449 inspection**

Proportion and comparison of Community Pharmacies vs. Hospital Pharmacies for Q3



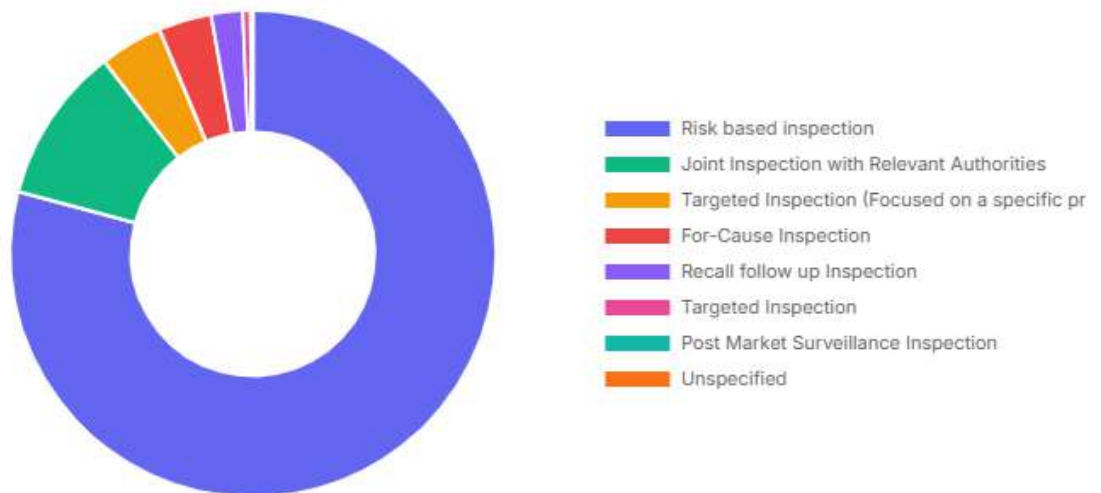
Note: Pharmacies may be inspected more than once during a quarter. For this analysis, only the most recent inspection result for each pharmacy is included, ensuring that each pharmacy is counted once and reducing the risk of duplicate or misleading results.

Type of Inspection

For Community pharmacies

- Targeted Inspection (Focused on a Specific Product): **1,657 inspection**
- Risk-Based Inspection: **31,232 inspection**
- Joint Inspection with Relevant Authorities: **4,101 inspection**

- Post-Market Surveillance Inspection: **36 inspection**
- For-Cause Inspection: **1,394 inspection**
- Follow-Up Inspection: **195 inspection**
- Recall Follow-Up Inspection: **826 inspection**



For Hospital pharmacies

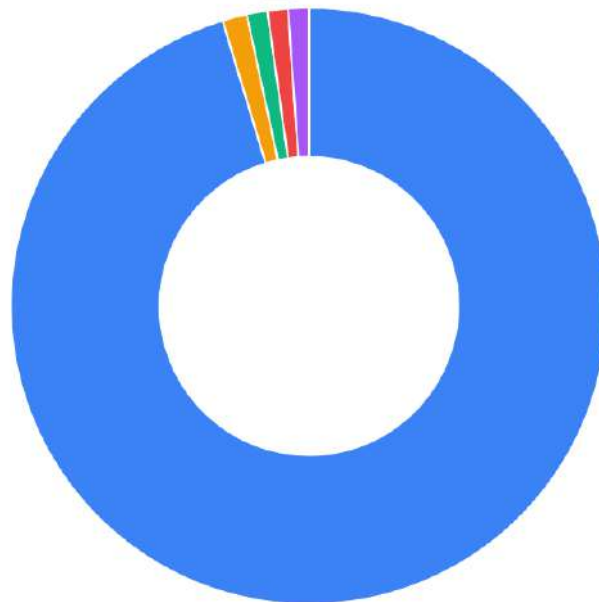
- Risk-Based Inspection: **429 inspection**
- Joint Inspection with Relevant Authorities: **5 inspection**
- For-Cause Inspection: **5 inspection**
- Recall Follow-Up Inspection: **6 inspection**
- Targeted Inspection (Focused on a Specific Product): **5 inspection**



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Risk-Based Inspection Recall Follow Up Joint Inspection Targeted Product For-Cause



2. Overview Section

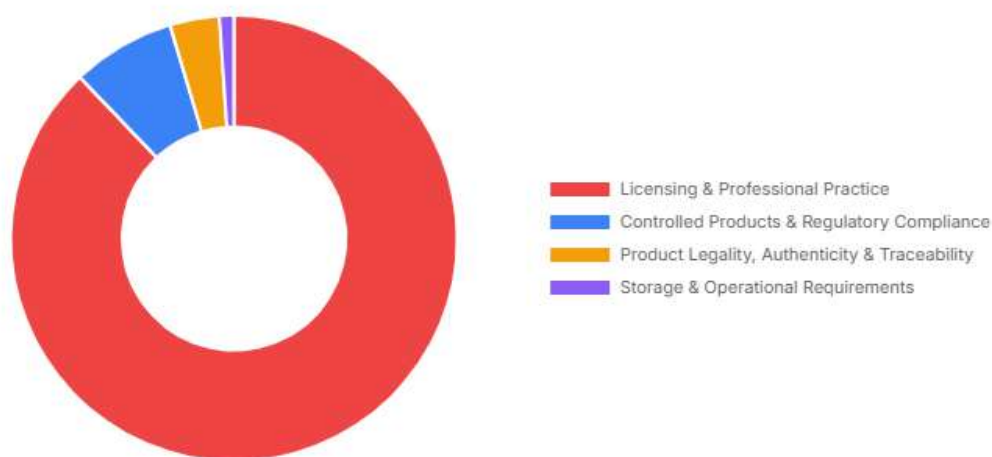
A) Total Number of Violations

For Community Pharmacies

Total No. of Violations: **6125 violation** (Note: The same violation may be recorded more than once for the same pharmacy.)

Violation Category	No.	%
Licensing & Professional Practice	5382	87.9%
Product Legality, Authenticity & Traceability	221	3.6%
Controlled Products & Regulatory Compliance	459	7.5%
Storage & Operational Requirements	63	1%

Share of each category among total recorded violations

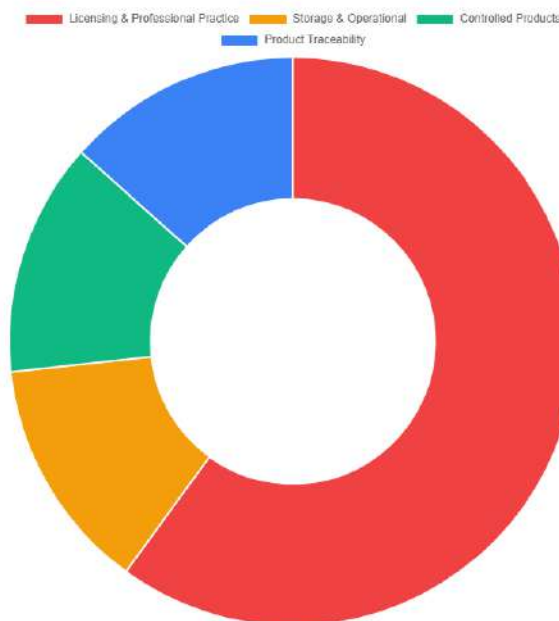


For

For Hospital Pharmacies

Total No. of Violations: **15 violation** (Note: The same violation may be recorded more than once for the same pharmacy.)

Violation Category	No.	%
Licensing & Professional Practice	9	60%
Product Legality, Authenticity & Traceability	2	13.3%
Controlled Products & Regulatory Compliance	2	13.3%
Storage & Operational Requirements	2	13.3%



B) Distribution of Violations by Type of Pharmacy Establishment

Total Community Pharmacy violations: **3026 violations**

Total Hospital Pharmacy violations: **15 violations**

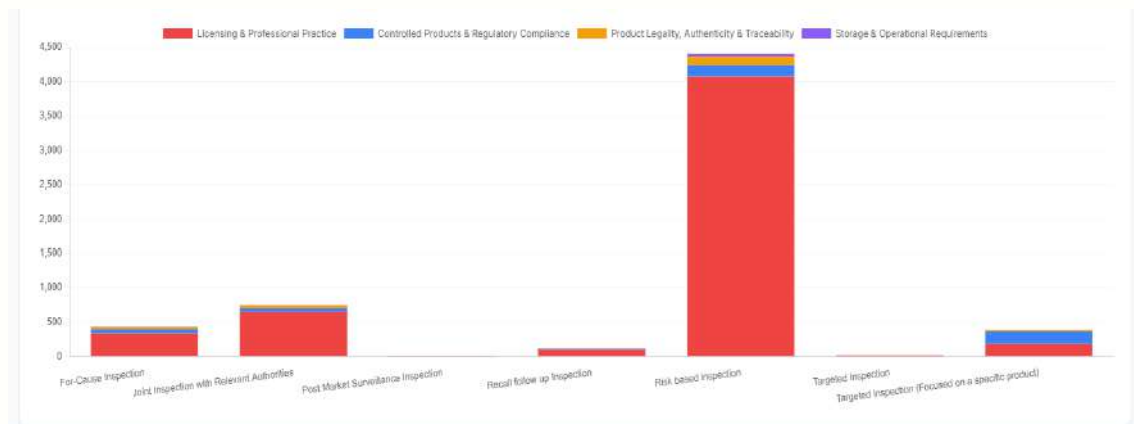
C) Distribution of Violations by Inspection Type For Community Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Targeted Inspection (Focused on a Specific Product)	1657	390	23.5%
Risk-Based Inspection	31232	4403	14.1%
Joint Inspection with Relevant Authorities	4101	748	18.2%
Post-Market Surveillance Inspection	36	3	8.3%
For-Cause Inspection	1394	440	31.6%
Follow-Up Inspection	195	19	9.7%
Recall Follow-Up Inspection	826	122	14.8%



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For Hospital Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Risk-Based Inspection	429	6	1.2%
Joint Inspection with Relevant Authorities	5	1	20%
Targeted Inspection (Focused on a Specific Product)	5	0	0%
For-Cause Inspection	5	2	40%
Recall Follow-Up Inspection	6	0	0%



D) Trend Analysis

• Most Frequent Violations For Community Pharmacies

1. Licensing & Professional Practice (5,382)
2. Controlled Products & Regulatory Compliance (459)
3. Product Legality, Authenticity & Traceability (221)

For Hospital Pharmacies



1. Licensing & Professional Practice (60%)
2. Storage & Operational Requirements (13.3%)
3. Controlled Products & Regulatory Compliance (13.3%)

• **Increasing Trends**

For Community Pharmacies

1. Joint Inspections with Relevant Authorities: Increased significantly from 1,613 in Q2 to 4,101 in Q3.
2. Recall Follow-Up Inspections: More than doubled, rising from 293 in Q2 to 826 in Q3.
3. Targeted Inspections (Focused on a Specific Product): Increased from 634 in Q2 to 1,657 in Q3.

For Hospital Pharmacies

1. Total Inspections Volume: Massive increase in inspection activity, jumping from 143 in Q2 to 449 in Q3 (a 214% increase).
2. Hospital Pharmacies with Violations: The absolute number of "Not Comply" findings doubled from 3 in Q2 to 6 in Q3.
3. Violation Category Diversity: In Q2, violations were limited mainly to Licensing (71.4%) and Traceability (28.6%). By Q3, violations expanded into four distinct categories, with new issues arising in Storage/Operational (13.3%) and Controlled Products (13.3%).

• **Recurring Violations**

For Community Pharmacies

1. Licensing & Professional Practice: Remains the dominant violation category across all quarters (5,382 in Q3), representing most of all findings.
2. Controlled Products & Regulatory Compliance: Consistently the second most frequent category of violations (459 in Q3).
3. Product Legality, Authenticity & Traceability: Persistently recurring (221 in Q3), often requiring escalated follow-up.

For Hospital Pharmacies

1. Licensing & Professional Practice: Remains the number one recurring violation across both quarters, though its share dropped slightly from 71.4% in Q2 to 60% in Q3 (as other violation types started being recorded).
2. Product Legality, Authenticity & Traceability: Consistently recurring across both quarters (28.6% in Q2, dropping to 13.4% in Q3).
3. Follow-up/Compliance issues: "Need Follow Up" cases increased from 1 in Q2 to 7 in Q3.

- **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.

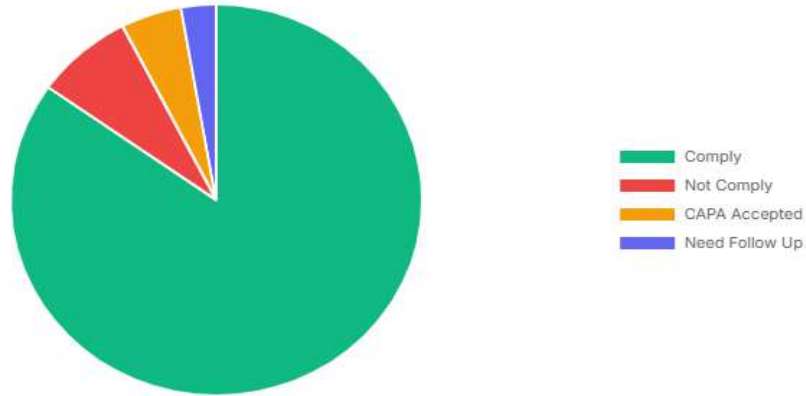
For Hospital Pharmacies

1. **Significant Increase in Non-Compliance:** The number of facilities failing to comply doubled from Q2 (3) to Q3 (6). While the compliance rate remains high overall (96.44%), the doubling of absolute failures requires attention.
2. **New Operational & Storage Violations:** Q3 recorded violations in "Storage & Operational Requirements" and "Controlled Products" which were not explicitly detailed in the Q2 breakdown. This indicates that as the inspection scope widened, new types of non-compliance were identified.
3. **Elevated "Not Comply" Rates in Specific Governorates:** While Q2 had isolated issues in Giza (1) and Monufia (2), Q3 shows acute non-compliance clusters requiring targeted intervention in **Gharbia** (3 "Not Comply" out of 28 inspections) and **Sharqia** (2 "Not Comply" out of 41 inspections).

E) Regulatory/Enforcement Actions

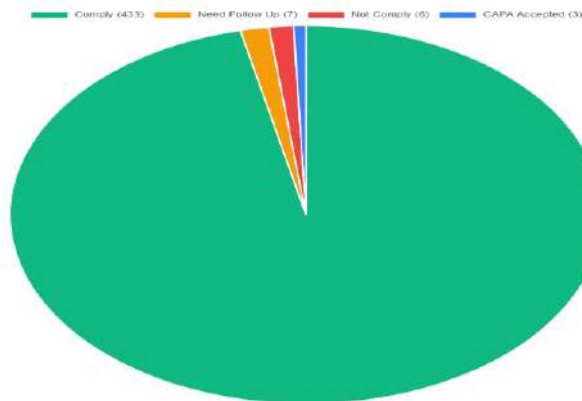
For Community Pharmacies

- No. of regulatory/enforcement actions: **3987**
- No. of follow-up inspections: **1091**
- No. of recall follow-up inspections: **826**
- No. of other applicable regulatory actions: **2233**



For Hospital Pharmacies

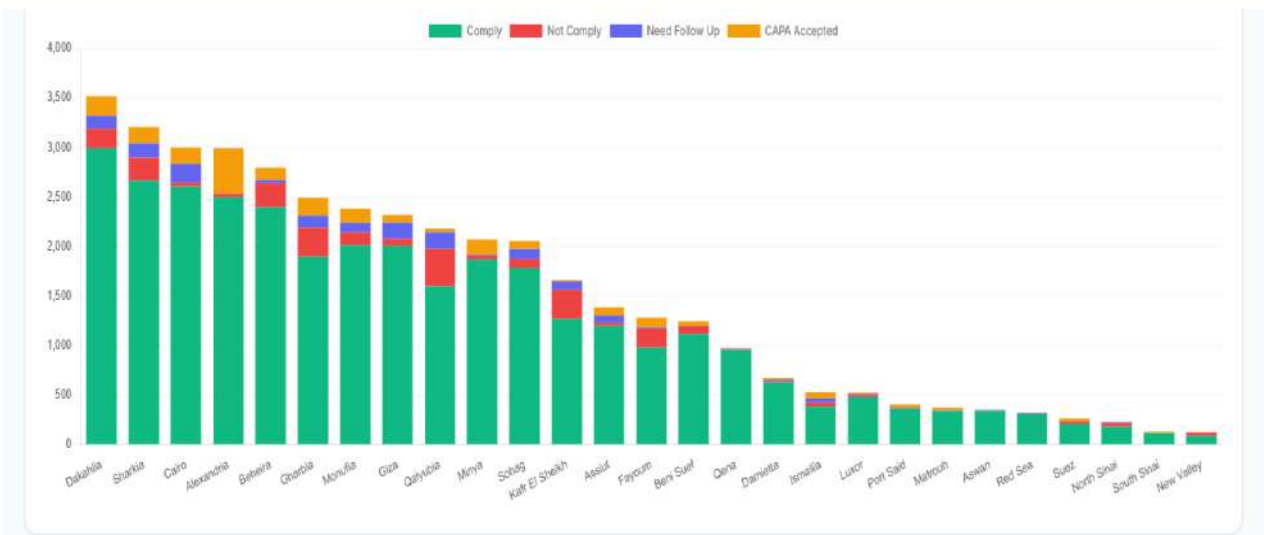
- No. of regulatory/enforcement actions: 6
- No. of follow-up inspections: 7
- No. of recall follow-up inspections: 6
- No. of other applicable regulatory actions: 3



3. Conclusion

For Community Pharmacies

- % of pharmacy inspections with no violations: **84.79%** (33,465 Comply / 39,470 Total)
- % of pharmacy inspections with violations: **15.21%** (3,026 Not Comply + 1,888 CAPA Accepted + 1,091 Need Follow Up = 6,005 / 39,470)
- % of pharmacy inspections requiring follow-up: **2.76%** (1,091 Need Follow Up / 39,470 Total)
- % of pharmacy inspections resulting in regulatory/enforcement actions: **10.1%** (3,987 resulting in regulatory/enforcement actions / 39,470 Total)
- Most frequent violation category: **Licensing & Professional Practice** (5,382 violations)
- Most frequent recurring violation: **Licensing & Professional Practice**
- Governorate/EDA Branch requiring increased attention: **Kafr El Sheikh** (Highest number of "Not Comply" at 503, representing 25.9% of its total inspections) and **Sharkia** (Highest absolute "Need Follow Up" at 233).



- 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).

