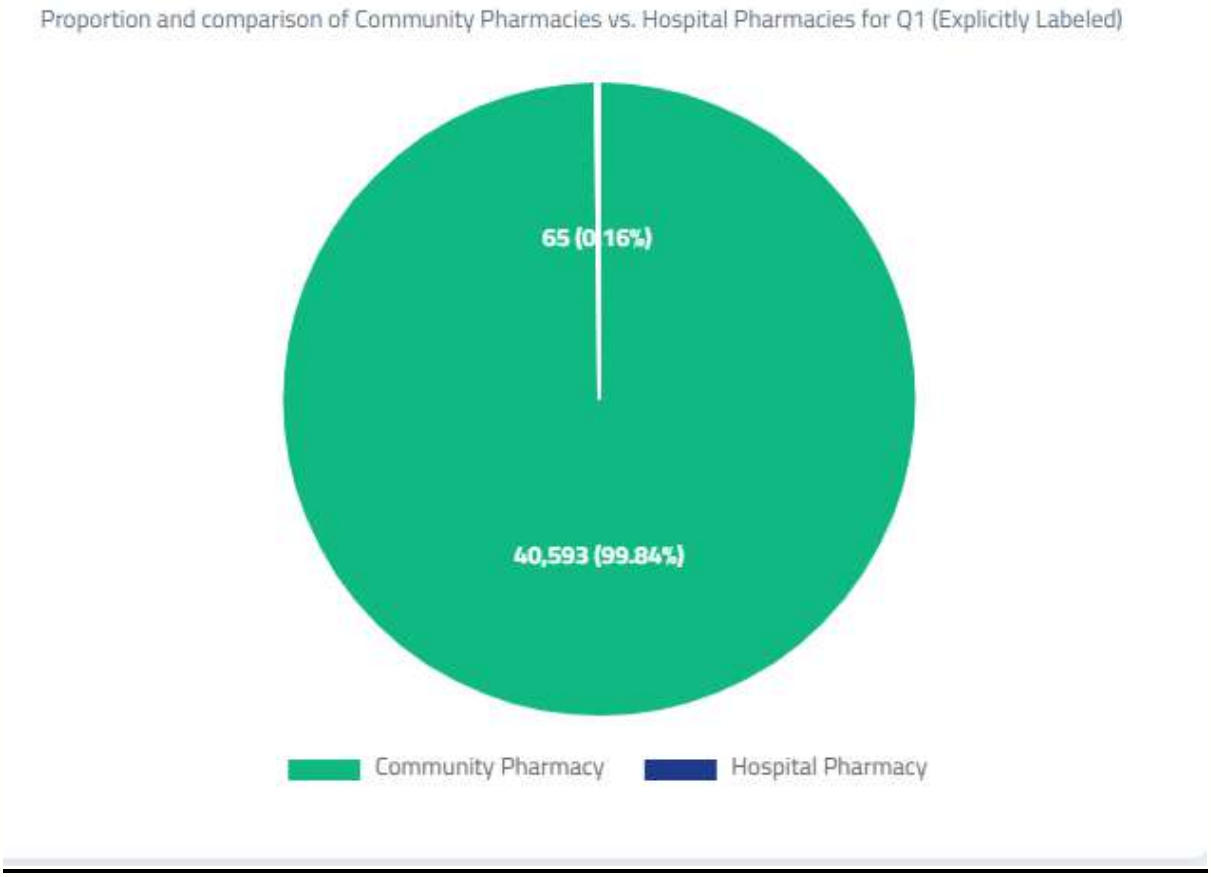
Collective Analysis of Pharmacy Inspection Observations Data Report
Quarter 1 Year 2026

1. Executive Summary

Total No. of Pharmacy Inspections: **40,658 inspection**

Type of Pharmacy Establishment

- Community Pharmacy: **40,593 inspection**
- Hospital Pharmacy: **65 inspection**



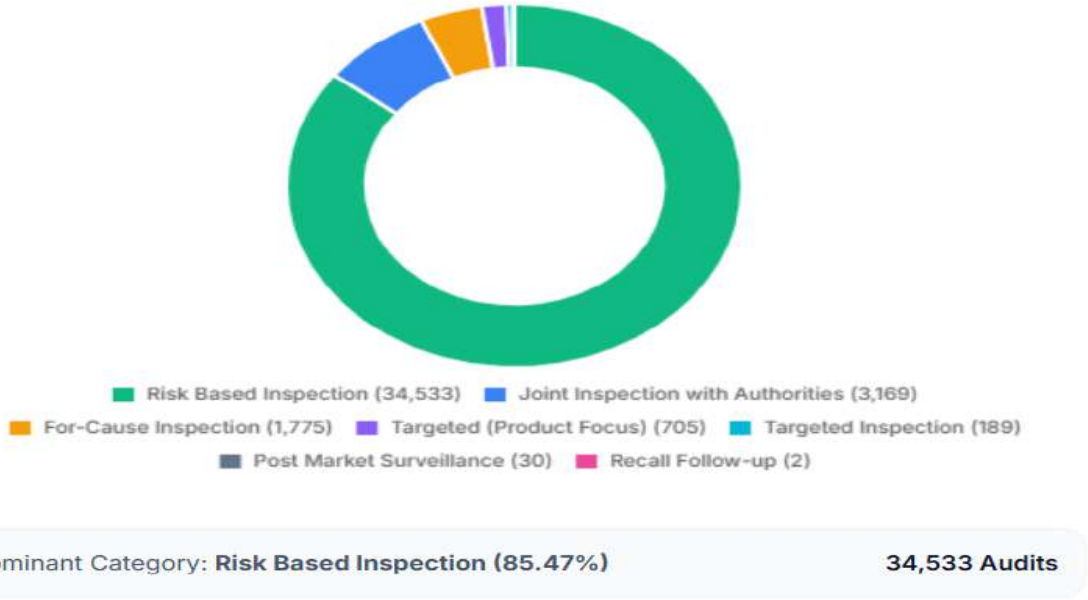
Note: Pharmacies may be inspected more than once during a quarter. For this analysis, only the most recent inspection result for each pharmacy is included, ensuring that each pharmacy is counted once and reducing the risk of duplicate or misleading results.

Type of Inspection

For Community pharmacies

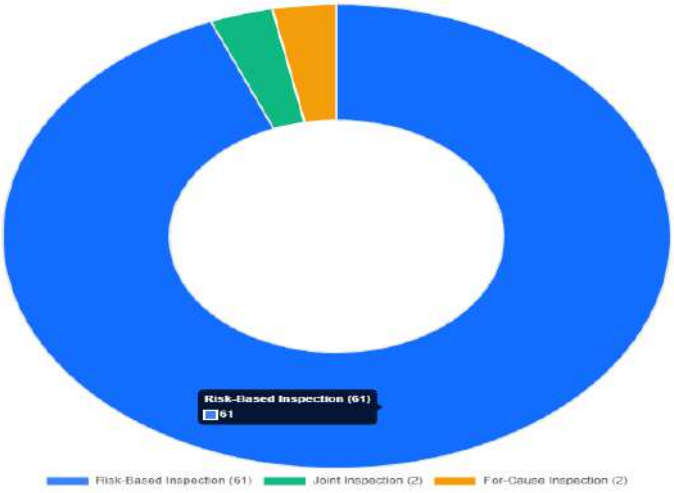
- Targeted Inspection (Focused on a Specific Product): **705 inspections**
- Risk-Based Inspection: **34,533 inspections**

- Joint Inspection with Relevant Authorities: **3,169 inspections**
- Post-Market Surveillance Inspection: **30 inspections**
- For-Cause Inspection: **1,775 inspections**
- Targeted Inspection: **189 inspections**
- Recall Follow-Up Inspection: **2 inspections**



For Hospital pharmacies

- **Risk-Based Inspection:** 61
- **Joint Inspection with Relevant Authorities:** 2
- **For-Cause Inspection:** 2


Risk-Based Inspection (61)
61
Risk-Based Inspection (61)
Joint Inspection (2)
For-Cause Inspection (2)

2. Overview Section

A) Total Number of Violations

For Community Pharmacies

Total No. of Violations: **4,897 violations** (Note: The same violation may be recorded more than once for the same pharmacy.)

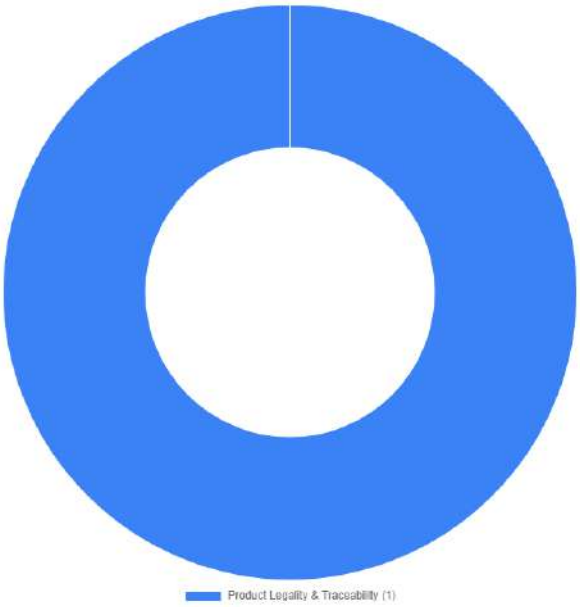
Violation Category	No.	%
Licensing & Professional Practice	4,352	88.9%
Product Legality, Authenticity & Traceability	232	4.7%
Storage & Operational Requirements	167	3.4%
Controlled Products & Regulatory Compliance	146	3.0%



For Hospital Pharmacies

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

Violation Category	No.	%
Product Legality, Authenticity & Traceability	1	100%

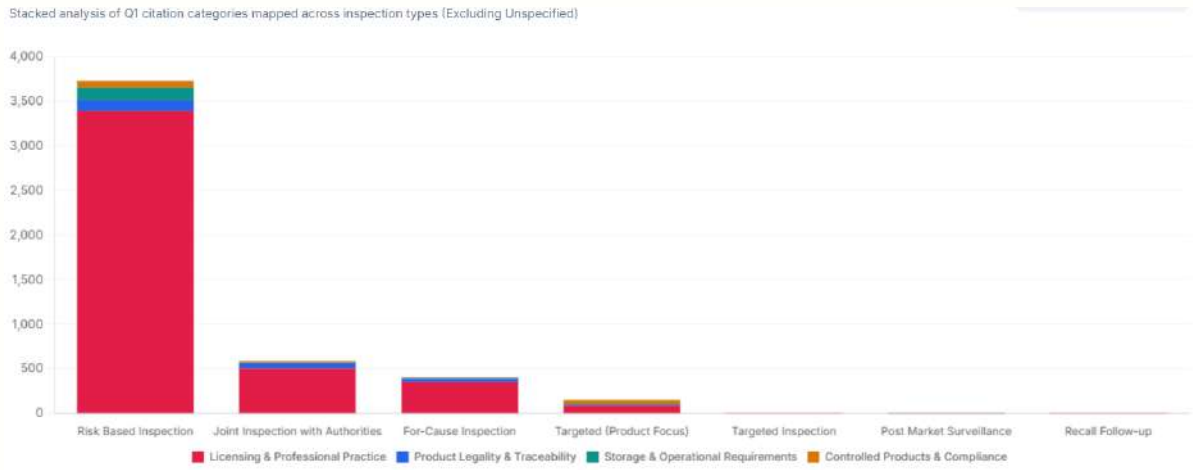


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B) Distribution of Violations by Type of Pharmacy Establishment
Total Community Pharmacy violations: **4,897 violations**
Total Hospital Pharmacy violations: **1violations**

C) Distribution of Violations by Inspection Type
For Community Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Risk-Based Inspection	**34,533**	**3,726**	**10.8%**
For-Cause Inspection	**1,775**	**407**	**22.9%**
Joint Inspection with Authorities	**3,169**	**588**	**18.6%**
Targeted (Specific Product)	**705**	**152**	**21.6%**
Recall Follow-Up Inspection	**2**	**1**	**50.0%**
Follow-Up Inspection	**189**	**3**	**1.6%**
Post-Market Surveillance	**30**	**5**	**16.7%**



For Hospital Pharmacies

Inspection Type	No. of Inspections	No. with Violations	% with Violations
Risk-Based Inspection	**61**	**1**	**1.6%**
Joint Inspection with Authorities	**2**	**0**	**0%**
For-Cause Inspection	**5**	**0**	**0%**



D) Trend Analysis

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

For Community Pharmacies

1. Licensing & Professional Practice (4,352)
2. Product Legality, Authenticity & Traceability (232)
3. Storage & Operational Requirements (167)

For Hospital Pharmacies

1. Product Legality, Authenticity & Traceability

Increasing Trends

For Community Pharmacies

1.**Noticeable Drop in Total Inspections and "Not Comply" Findings**

Inspection volume decreased from 43,755 in Q4 2025 to 40,593 in Q1 2026. More significantly, absolute "Not Comply" findings nearly halved, dropping from 5,163 in Q4 2025 to 2,562 in Q1 2026. This indicates a substantial improvement in overall compliance rates (rising from roughly 80.5% to 84.5%).

2. **Surge in Licensing & Professional Practice Violations**

While total violations decreased, the *share* of Licensing & Professional Practice issues grew. Q4 2025 recorded 5,197 of these violations (approx. 89% of total violations), whereas Q1 2026 recorded 4,352 (approx. 88.8%). This category remains the overwhelming driver of non-compliance across both quarters.

3. **Shifting Hotspots in Specific Governorates**

The regional concentration of "Not Comply" findings changed. In Q4 2025, the highest failures were in Qalyubia (707) and Gharbia (619). By Q1 2026, while these remained high, Kafr El Sheikh became the most acute hotspot (372 "Not Comply"), followed by Qalyubia (322). This indicates a need for dynamic resource allocation based on emerging regional risks.

For Hospital Pharmacies

1. **Significant Drop in Inspection Volume**
   Total hospital inspections decreased by more than half, dropping from 135 in Q4 2025 to 65 in Q1 2026. This was driven by a reduction in Risk-Based Inspections (from 128 down to 61), while Joint and For-Cause inspections remained low but stable.
2. **Shifts in Violation Categories**
   Violation profiles changed significantly between quarters. In Q4 2025, violations were primarily split between Licensing (2) and Controlled Products (2), with Storage issues (1) also recorded. By Q1 2026, the only violation recorded was in Product Legality, Authenticity & Traceability (1).
3. **Improved Compliance Rate**
   Despite the drop in inspection volume, the overall compliance rate slightly improved from 95.5% in Q4 2025 to 98.46% in Q1 2026. The absolute number of "Not Comply" findings fell from 5 to 1.

- **Recurring Violations**

For Community Pharmacies

1. Licensing & Professional Practice (Accounts for 88.9% of all violations).
2. Product Legality, Authenticity & Traceability.

3. Storage & Operational Requirements.

For Hospital Pharmacies

Product Legality, Authenticity & Traceability

- **<u>Emerging Areas of Concern</u>**

For Community Pharmacies

1. **High absolute numbers of "Not Comply" findings in Kafr El Sheikh (372) and Qalyubia (322).**
   While overall compliance remains stable, specific governorates show acute localized gaps. Kafr El Sheikh recorded a disproportionately high failure rate, and Qalyubia recorded the second highest absolute number of non-compliant findings. This indicates a need to reallocate inspection resources or investigate systemic root causes in these specific regions.
2. **High volume of violations found during Risk-Based inspections (3,726), indicating widespread systemic issues.**
   As the primary driver of inspection volume (34,533 audits), Risk-Based inspections uncovered 3,726 violations (a 10.8% hit rate). This high yield from routine, broad-coverage audits suggest that non-compliance is not isolated to a few bad actors, but is embedded across the baseline community pharmacy sector.
3. **For-Cause inspections yielded a high hit rate (22.9%), validating the intelligence triggers.**
   Out of 1,775 For-Cause inspections, 407 yielded violations. This hit rate is more than double that of routine Risk-Based inspections. It confirms that intelligence-led triggers (e.g., complaints, suspicious data) are highly accurate at identifying non-compliance and should remain a priority for resource allocation.

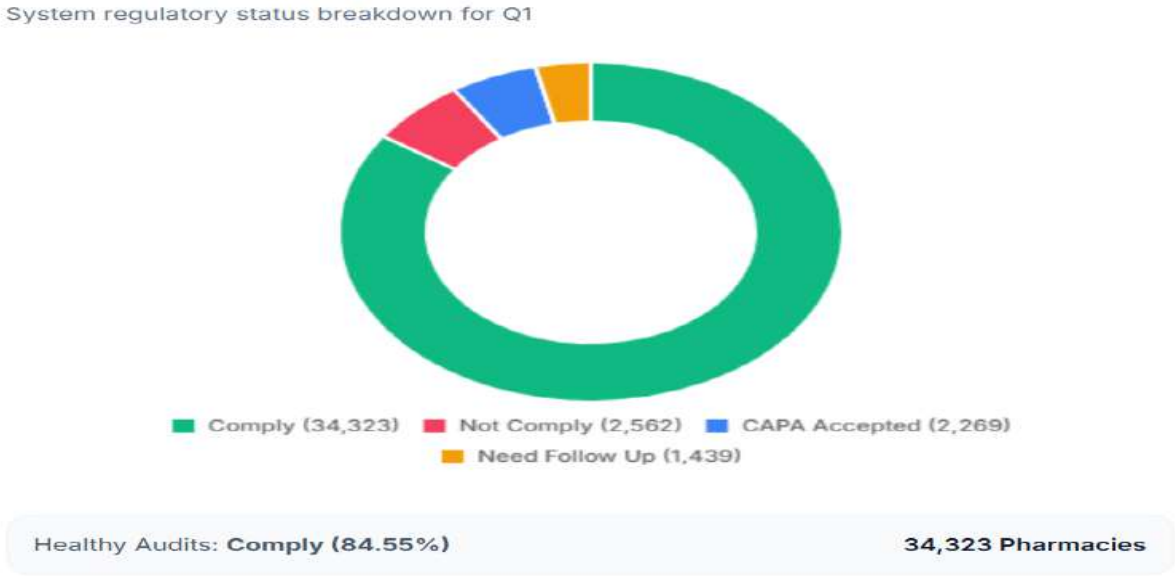
For Hospital Pharmacies

1. Significant While overall compliance is exceptionally high (98.46%), a traceability violation was identified.
2. Very low utilization of For-Cause or Targeted inspections in hospitals (only 2 total).
3. 1 "Not Comply" finding in "Other Governorates".

E) Regulatory/Enforcement Actions

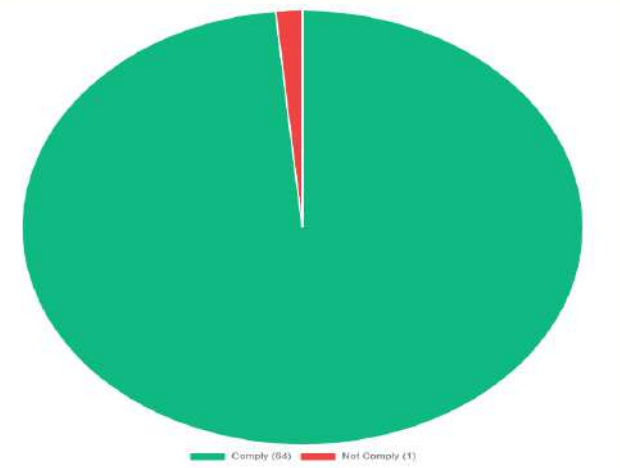
For Community Pharmacies

- No. of regulatory/enforcement actions: **2,562** (Based on "Not Comply" status)
- No. of follow-up inspections: **1,439** (Based on "Need Follow Up" status)
- No. of recall follow-up inspections: **2**
- No. of other applicable regulatory actions: **2,269** (Based on "CAPA Accepted" status)



For Hospital Pharmacies

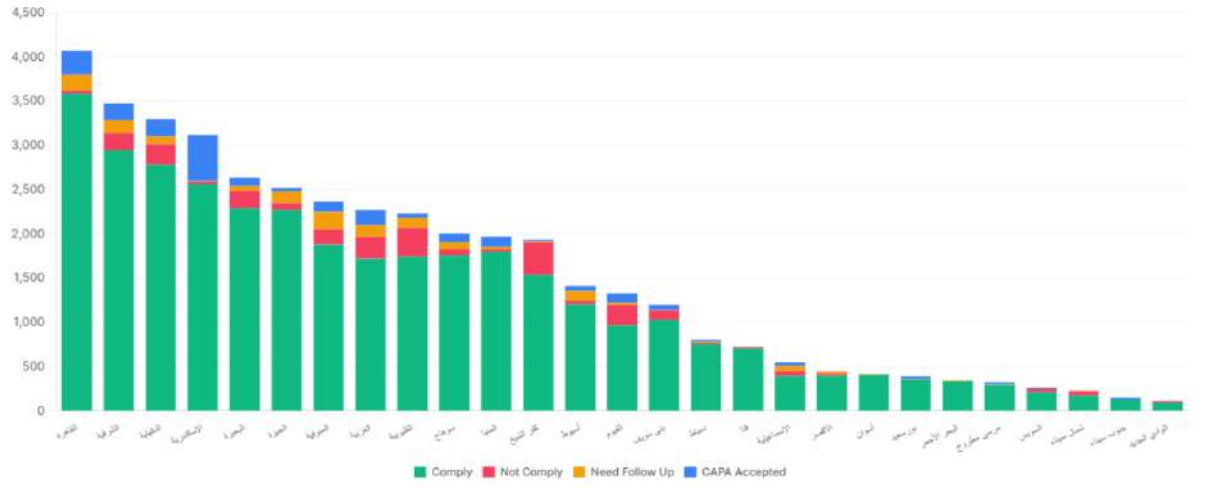
- No. of regulatory/enforcement actions: **1** (Based on "Not Comply" status)
- No. of follow-up inspections: **0**
- No. of recall follow-up inspections: **0**
- No. of other applicable regulatory actions: **0**



3. Conclusion

For Community Pharmacies

- % of pharmacy inspections with no violations: **84.55%** (34,323 Comply / 40,593 Total)
- % of pharmacy inspections with violations: **15.45%** (2,562 Not Comply + 1,439 Need Follow Up + 2,269 CAPA Accepted = 6,270 / 40,593 Total)
- % of pharmacy inspections requiring follow-up: **3.54%** (1,439 Need Follow Up / 40,593 Total)
- % of pharmacy inspections resulting in regulatory/enforcement actions: **6.31%** (2,562 Not Comply / 40,593 Total)
- Most frequent violation category: **Licensing & Professional Practice** (88.9%)
- Most frequent recurring violation: **Licensing & Professional Practice**
- Governorate/EDA Branch requiring increased attention: **Kafr El Sheikh** (372 "Not Comply") and **Qalyubia** (322 "Not Comply").

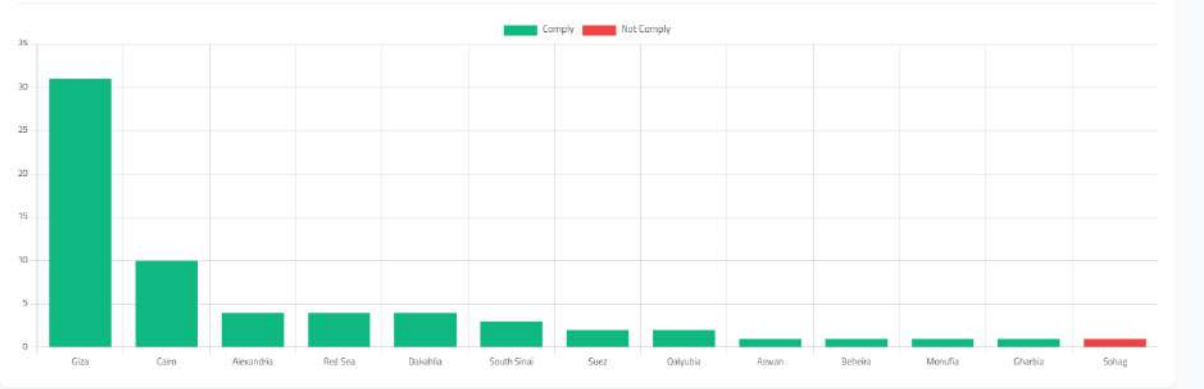


- Inspection type requiring adjustment/increase: **For-Cause Inspection** (High hit rate of 22.9%, proving highly effective).

For Hospital Pharmacies

- **% of pharmacy inspections with no violations: 98.46%** (64 Comply / 65 Total)
- **% of pharmacy inspections with violations: 1.54%** (1 Total Violation / 65 Total)
- **% of pharmacy inspections requiring follow-up: 0.00%** (0 Need Follow Up / 65 Total)
- **% of pharmacy inspections resulting in regulatory/enforcement actions: 1.54%** (1 Not Comply / 65 Total)
- **Most frequent violation category:** Product Legality, Authenticity & Traceability (100%)
- **Most frequent recurring violation:** Product Legality, Authenticity & Traceability

- **Governorate/EDA Branch requiring increased attention: Sohag** (Recorded the single "Not Comply" finding in Q1).



- **Inspection type requiring adjustment/increase: Joint Inspection with Authorities** (0% hit rate in Q1, suggesting a need to refine hospital targeting).