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Regulatory Reform and Digital Transformation of Pharmacovigilance in Uzbekistan: A National Mixed-Methods Analysis of Reporting Patterns, 2023–Mid-2026

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ABSTRACT:

Background: Pharmacovigilance systems in emerging regulatory settings are increasingly shaped by concurrent legal, institutional, and digital reforms. Evidence on how these reforms affect national reporting patterns remains limited in Central Asia.

Objective: To assess the development of Uzbekistan's national pharmacovigilance system and changes in safety-reporting patterns between January 2023 and June 2026.

Methods: A retrospective mixed-methods study combined structured analysis of national legislation, regulatory standards, implementation records, and training reports with analysis of aggregated pharmacovigilance data. All 1,500 safety reports recorded during the study period were included. Reporting volume, source, and seriousness were summarised using counts and percentages. Between-period differences were assessed using Pearson's chi-square test and Cramér's V. Relative risk was calculated for serious-report proportions in 2025 and the first half of 2026.

Results: The national system received 380 reports in 2023, 295 in 2024, 285 in 2025, and 540 during January–June 2026. Healthcare professionals' contribution increased from 21.1% in 2023 to 53.7% in the first half of 2026, while that of marketing authorisation holders decreased from 53.7% to 32.6%. Reporter-source composition differed significantly across periods (χ^2=120.02; df=6; p<0.001; Cramér's V=0.20). Serious-report proportions also differed (χ^2=87.58; df=3; p<0.001; Cramér's V=0.24), decreasing from 47.0% in 2025 to 16.7% in the first half of 2026 (RR=0.35; 95% CI: 0.28–0.44). By June 2026, approximately 700 public healthcare institutions had joined the electronic platform, and 1,880 healthcare professionals had received pharmacovigilance training.

Conclusions: Electronic reporting was introduced alongside regulatory reform, institutional registration, and professional training and coincided with expanded direct reporting by healthcare professionals. Because the interventions were concurrent and the 2026 observation covered only six months, the findings indicate temporal association rather than causality. Further evaluation should use equivalent observation periods and case-level indicators of report quality, signal management, and regulatory outcomes.

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INTRODUCTION

Pharmacovigilance encompasses the science and activities concerned with the detection, assessment, understanding, and prevention of adverse effects or any other medicine- or vaccine-related problem [1]. It is an essential component of public health and medicines regulation because the safety profile of a medicinal product cannot be fully characterised before marketing authorisation. Pre-authorisation clinical trials are generally conducted in selected populations, under controlled conditions, and over limited periods. Consequently, rare, delayed, population-specific, or interaction-related adverse reactions may become apparent only after a medicinal product has entered routine clinical practice [2,3].

Contemporary pharmacovigilance extends well beyond the passive collection of spontaneous reports. A functional national system must support the validation and medical assessment of individual case safety reports, follow-up of incomplete cases, detection and prioritisation of safety signals, periodic benefit–risk evaluation, risk-management planning, implementation of risk-minimisation measures, safety communication, quality management, audits, and regulatory inspections [4–7]. These activities require coordinated information exchange among the competent regulatory authority, marketing authorisation holders, healthcare institutions, healthcare professionals, patients, and other stakeholders. The performance of such a system therefore depends not only on the number of reports received but also on their completeness, clinical relevance, timeliness, traceability, and subsequent use in regulatory decision-making [8].

National pharmacovigilance capacity remains uneven across countries. Studies conducted in low- and middle-income settings have identified under-reporting, limited institutional capacity, insufficiently trained personnel, fragmented reporting channels, weak quality-management arrangements, and inadequate integration of safety information into regulatory and clinical practice as persistent constraints [9–11]. These limitations may reduce the ability of a national authority to recognise new safety concerns, assess changes in known risks, and implement timely measures to protect patients.

Digital reporting platforms have the potential to reduce administrative barriers, improve report traceability, facilitate follow-up, and enable centralised management of safety information. However, digitalisation alone does not ensure effective pharmacovigilance. An electronic platform must operate within a clear regulatory framework, with defined institutional responsibilities, trained users, standardised reporting procedures, data-quality controls, appropriate medical terminology, and established mechanisms for signal assessment and regulatory action. Early evaluation of digital transformation should therefore examine not only changes in reporting volume but also reporter participation, report-source composition, seriousness patterns, implementation coverage, and the organisational conditions under which electronic reporting is introduced.

Uzbekistan has recently undertaken a substantial reform of its national pharmacovigilance system. The general legal mandate for monitoring the safety of medicinal products was established by Law of the Republic of Uzbekistan No. O‘RQ–399 “On Medicines and Pharmaceutical Activity” [12]. The subsequent adoption of the national Good Pharmacovigilance Practice standard, O‘zMSt 339:2024, introduced internationally recognised requirements for pharmacovigilance system master files, risk-management plans, periodic safety reporting, signal management, quality systems, audits, and corrective and preventive actions [13].

This regulatory framework was further operationalised through Order No. 18 of the Minister of Health, dated 30 December 2025. The order established updated reporting timelines, clarified the responsibilities of healthcare professionals and marketing authorisation holders, regulated the assessment of safety information, and introduced requirements for evaluating pharmacovigilance systems [14]. Order No. 15, dated 21 January 2026, provided the organisational basis for electronic submission of pharmacovigilance information and the development of a centralised national reporting environment [15]. Implementation was accompanied by the registration of responsible representatives from public healthcare institutions through OneID and by national training activities intended to strengthen the recognition and reporting of suspected adverse reactions.

These measures represented a combined regulatory, organisational, and technological intervention. Nevertheless, their early association with national reporting patterns has not been systematically evaluated. In particular, it remained unclear whether implementation was accompanied by changes in the proportional contribution of healthcare professionals, marketing authorisation holders, patients, and other reporting sources, or by changes in the proportion of reports classified as serious. Furthermore, the legal, institutional, and digital components of the reform had not previously been analysed as interconnected elements of a single national pharmacovigilance framework.

Accordingly, this study aimed to assess the regulatory and organisational development of Uzbekistan’s national

pharmacovigilance system between January 2023 and June 2026 and to examine changes in the distribution of national safety reports by reporting source and seriousness. The study also sought to integrate regulatory, implementation, and quantitative findings into a conceptual framework for further system development. As an early implementation evaluation based on aggregated observational data, the study was designed to identify temporal changes and system-level patterns rather than to establish a causal effect of any individual regulatory, educational, or digital intervention.

2. MATERIALS AND METHODS

2.1. Study Design

A retrospective mixed-methods organisational study was conducted to evaluate the regulatory, institutional, and digital development of Uzbekistan's national pharmacovigilance system. The study combined structured qualitative analysis of national regulatory and implementation documents with quantitative analysis of aggregated national safety-reporting data.

The qualitative component examined changes in the legal framework, stakeholder responsibilities, reporting procedures, quality-management requirements, and electronic pharmacovigilance infrastructure. The quantitative component assessed changes in reporting volume, reporter-source composition, and the proportion of reports classified as serious. The two components were integrated at the interpretation stage to identify relationships between regulatory developments, implementation activities, and observed reporting patterns.

The study covered the period from 1 January 2023 to 30 June 2026. This interval included three complete calendar years preceding nationwide electronic implementation and the first six months following the introduction of the national electronic pharmacovigilance platform.

2.2. Study Setting

The study was conducted within the national pharmacovigilance system of the Republic of Uzbekistan. The State Institution "Center for Safety of Pharmaceutical Products" under the Ministry of Health of the Republic of Uzbekistan served as the competent authority responsible for receiving, processing, and evaluating medicine-safety information.

During the study period, the national system included the competent authority, marketing authorisation holders, public and private healthcare institutions, healthcare professionals, patients, and other sources of safety information. Reports were submitted using paper forms, official electronic communication channels, and, from 2026, the national electronic pharmacovigilance platform.

For the purposes of this study, a safety report was defined as a notification of a suspected adverse reaction recorded in the official national pharmacovigilance dataset during the relevant reporting period.

2.3. Qualitative Data Sources and Document Selection

The regulatory corpus comprised four core national instruments governing the development of pharmacovigilance in Uzbekistan:

1. Law of the Republic of Uzbekistan No. O'RQ–399 "On Medicines and Pharmaceutical Activity";
2. the national Good Pharmacovigilance Practice standard, O'zMSt 339:2024;
3. Order No. 18 of the Minister of Health, dated 30 December 2025;
4. Order No. 15 of the Minister of Health, dated 21 January 2026.

Supporting materials included official implementation records relating to the national electronic pharmacovigilance platform, OneID registration records, healthcare professional training reports, aggregated national pharmacovigilance summaries, and internal analytical and organisational reports prepared by the competent authority.

Documents were eligible for inclusion if they directly addressed at least one of the following areas: the legal mandate for pharmacovigilance, responsibilities of stakeholders, reporting requirements, safety-data assessment, quality management, signal management, risk minimisation, pharmacovigilance system evaluation, or electronic reporting. Draft documents, duplicate copies, and materials without a direct relationship to national pharmacovigilance operations were excluded.

International guidance issued by the World Health Organization, the European Medicines Agency, the International Council for

Harmonisation, and the Uppsala Monitoring Centre was used to contextualise the national requirements and inform the analytical domains.

2.4. Regulatory and Institutional Content Analysis

A structured content-analysis matrix was developed before document review. Each national regulatory instrument was assessed across the following predefined domains:

1. legal mandate for pharmacovigilance;
2. responsibilities of the competent authority;
3. obligations of marketing authorisation holders;
4. responsibilities of healthcare institutions and healthcare professionals;
5. adverse reaction reporting procedures and timelines;
6. pharmacovigilance quality-system requirements;
7. signal detection and assessment;
8. risk-management and risk-minimisation requirements;
9. audits and regulatory evaluation of pharmacovigilance systems;
10. electronic reporting and safety-data management.

The documents were reviewed chronologically to identify major stages in regulatory development. Relevant provisions were extracted into the analytical matrix and grouped according to their regulatory purpose and operational function. Ambiguous provisions were rechecked against the complete official text and relevant implementation records.

The institutional analysis examined how responsibilities and safety information were distributed among the competent authority, marketing authorisation holders, healthcare institutions, healthcare professionals, and patients. The analysis was performed by the principal investigator. Independent duplicate coding and inter-rater agreement assessment were not performed.

2.5. Quantitative Study Population

The quantitative study population comprised all safety reports recorded in the national pharmacovigilance dataset between 1 January 2023 and 30 June 2026. No sampling was applied, and no formal sample-size calculation was required because the analysis included the complete aggregated dataset available for the study period.

Reports were grouped into four predefined periods:

1. 1 January–31 December 2023;
2. 1 January–31 December 2024;
3. 1 January–31 December 2025;
4. 1 January–30 June 2026.

A total of 1,500 reports were included. Because the analysis used aggregated administrative data, individual reports were not independently reassessed for minimum validity criteria, clinical completeness, duplicate status, causality, expectedness, medical coding, or reporting timeliness.

2.6. Study Variables and Operational Definitions

The primary variables were:

1. total number of safety reports recorded during each reporting period;
2. number and proportion of reports submitted by healthcare professionals;
3. number and proportion of reports submitted by marketing authorisation holders;

4. number and proportion of reports submitted by patients and other sources;
5. number and proportion of reports classified as serious;
6. number of healthcare institutions connected to the electronic platform;
7. number of responsible institutional representatives registered through OneID;
8. number of healthcare professionals who completed pharmacovigilance training.

Reporting source was classified into three mutually exclusive categories: healthcare professionals, marketing authorisation holders, and patients and other sources. The final category included patient reports and reports received from sources that did not meet the definition of either a healthcare professional or a marketing authorisation holder.

Seriousness was analysed as a binary variable: serious or non-serious. Classification in the administrative dataset followed the applicable national regulatory criteria. A report was considered serious when the reported event involved death, was life-threatening, required or prolonged hospitalisation, resulted in persistent or clinically significant disability, involved a congenital anomaly, or was considered medically important. The study relied on the seriousness classification recorded by the competent authority and did not reclassify individual cases.

2.7. Implementation and Training Indicators

Implementation indicators were obtained from official platform-registration records and training reports. The number of connected institutions was defined as the number of public healthcare institutions for which a responsible representative had been registered through OneID and access to the electronic pharmacovigilance platform had been established.

Training indicators covered activities conducted between January and May 2026. Online and in-person training registers were reviewed separately. The 1,262 professionals trained online and the 618 professionals trained in person represented distinct participants; therefore, the combined number of trained healthcare professionals was 1,880 without double counting.

Training activities addressed recognition of suspected adverse reactions, applicable reporting timelines, minimum information required for a valid report, differentiation between serious and non-serious reactions, completion of electronic reporting forms, and institutional responsibilities within the national pharmacovigilance system.

2.8. Outcome Measures

The primary quantitative outcome was the difference in reporter-source composition across the four reporting periods.

Secondary outcomes were:

1. changes in the total number of reports recorded;
2. differences in the proportion of reports classified as serious;
3. initial institutional coverage of the electronic platform;
4. the number of registered responsible representatives;
5. healthcare professional training coverage;
6. development of the regulatory and institutional components of the national pharmacovigilance system.

Because the observation periods were unequal, the number of reports recorded during January–June 2026 was not treated as directly equivalent to the annual totals for 2023–2025. The 2026 data were considered an early implementation-period observation. Inferential comparisons focused on the composition of reports within each period rather than on causal changes in annual reporting rates.

2.9. Data Consistency and Quality Control

Aggregated totals were checked for internal consistency before analysis. For each reporting period, the sum of reports across the three reporter-source categories was reconciled with the corresponding period total. Serious and non-serious report counts were similarly checked against the total number of reports recorded in each period.

No missing aggregate cells were identified, and no imputation was performed. The study did not have access to individual case-level data and therefore could not independently assess missing clinical fields, duplicate reports, follow-up status, or coding accuracy.

2.10. Statistical Analysis

Categorical variables were summarised as absolute numbers and percentages. Percentages for reporter source and seriousness were calculated using the total number of reports recorded during the corresponding period as the denominator.

Differences in reporter-source composition were evaluated using Pearson's chi-square test in a 4×3 contingency table. Differences in the distribution of serious and non-serious reports were assessed using Pearson's chi-square test in a 4×2 contingency table. Expected cell counts were examined to confirm the applicability of the chi-square procedure.

Cramér's V was calculated to quantify the magnitude of between-period differences. Values of approximately 0.10, 0.30, and 0.50 were interpreted as small, moderate, and large effects, respectively, while recognising that interpretation depends on contingency-table dimensions.

The relative risk and corresponding 95% confidence interval were calculated to compare the proportion of reports classified as serious during the first half of 2026 with the proportion recorded in 2025. The confidence interval was estimated using the logarithmic method.

All statistical tests were two-sided, and $p<0.05$ was considered statistically significant. No correction for multiple testing was applied because the analyses addressed a limited number of distinct, predefined outcomes. Statistical analyses were performed using Python version 3.12.13 and SciPy version 1.17.0.

Because the dataset contained all reports recorded during the study period, inferential statistics were used to assess the magnitude and consistency of differences in reporting composition rather than to extrapolate prevalence or incidence to the treated population. No medicine-exposure, prescription-volume, or patient-population denominators were available.

2.11. Integration of Qualitative and Quantitative Findings

Qualitative and quantitative findings were integrated using a chronological analytical matrix. Regulatory milestones were mapped against platform implementation, institutional registration, training activities, reporting volume, reporter-source composition, and seriousness patterns.

The integrated findings were grouped according to their functional relationships. This process resulted in five overarching components: legal and regulatory foundation, institutional governance, digital infrastructure, safety-data and signal management, and regulatory action with continuous quality improvement.

The resulting framework was intended as an evidence-informed organisational model for national pharmacovigilance development. It was not treated as a formally validated measurement instrument.

2.12. Ethical Considerations

The study protocol was reviewed and approved by the competent institutional ethics committee. The analysis was based exclusively on aggregated, non-identifiable administrative and regulatory data. No individual patient records, personal identifiers, or identifiable safety narratives were accessed.

Because the study involved secondary analysis of anonymised aggregated data and no direct participation by patients or healthcare professionals, individual informed consent was not required. Confidentiality of non-public regulatory and organisational information was maintained throughout the study.

3. RESULTS

3.1. Regulatory Development of the National Pharmacovigilance System

The structured document analysis identified four successive stages in the regulatory development of Uzbekistan's national pharmacovigilance system. The first stage established the general legal mandate for monitoring the safety of medicinal products. The second introduced national Good Pharmacovigilance Practice requirements and formal quality-management processes. The third defined operational reporting requirements and stakeholder responsibilities. The fourth established the organisational basis

for electronic reporting and centralised safety-data management.

Table 1. Principal stages in the regulatory development of Uzbekistan's national pharmacovigilance system

Stage	Regulatory instrument	Principal contribution to the national system
I	Law No. O'RQ–399	Established the general legal mandate for monitoring the safety of medicinal products
II	O'zMSt 339:2024	Introduced national Good Pharmacovigilance Practice requirements, quality systems, risk management, signal management, audits, and corrective and preventive actions
III	Order No. 18	Defined reporting timelines, stakeholder responsibilities, safety-data assessment procedures, and requirements for evaluating pharmacovigilance systems
IV	Order No. 15	Established the organisational basis for electronic reporting, user identification, and centralised exchange of pharmacovigilance information

The chronological analysis showed that the four instruments addressed complementary functions. Law No. O'RQ–399 provided the overarching legal basis, whereas O'zMSt 339:2024 specified the principal components of a pharmacovigilance system. Order No. 18 translated these principles into operational obligations, and Order No. 15 supported the transition to electronic reporting and centralised information management.

3.2. Initial Implementation of the Electronic Pharmacovigilance System

By 30 June 2026, approximately 700 public healthcare institutions had been connected to the national electronic pharmacovigilance platform. A responsible pharmacovigilance representative was registered for each participating institution through OneID.

Between January and May 2026, 1,880 healthcare professionals completed pharmacovigilance training. Of these, 1,262 participated in online training and 618 attended in-person sessions. The online and in-person groups consisted of distinct individuals, and no participant was counted in both categories.

Table 2. Initial implementation indicators for the national electronic pharmacovigilance system

Indicator	Number	Reporting period
Public healthcare institutions connected to the platform	Approximately 700	January–June 2026
Responsible institutional representatives registered through OneID	Approximately 700	January–June 2026
Healthcare professionals trained online	1,262	January–May 2026
Healthcare professionals trained in person	618	January–May 2026
Total unique healthcare professionals trained	1,880	January–May 2026

The implementation process therefore included three concurrent organisational components: connection of healthcare institutions to the platform, registration of responsible representatives, and pharmacovigilance training for healthcare professionals.

3.3. Reporting Volume

A total of 1,500 safety reports were recorded between 1 January 2023 and 30 June 2026. The national system recorded 380 reports in 2023, 295 in 2024, and 285 in 2025. A further 540 reports were recorded during the first six months of 2026.

Because the observation periods differed in duration, an average monthly reporting volume was calculated for descriptive comparison. The average number of reports per month was 31.7 in 2023, 24.6 in 2024, 23.8 in 2025, and 90.0 during January–June 2026. The average monthly reporting volume during the first half of 2026 was therefore 3.79 times the corresponding descriptive monthly average for 2025.

Table 3. Safety-reporting volume during the study period

Reporting period	Duration, months	Number of reports	Average number of reports per month
2023	12	380	31.7
2024	12	295	24.6
2025	12	285	23.8
January–June 2026	6	540	90.0
Total	42	1,500	35.7

The monthly values represent descriptive averages and do not account for potential seasonal variation. Monthly or quarterly source data for equivalent pre-implementation periods were not available.

3.4. Changes in Reporter-Source Composition

The composition of reporting sources changed across the four study periods. In 2023, marketing authorisation holders were the largest reporting group, submitting 204 of 380 reports (53.7%). Healthcare professionals submitted 80 reports (21.1%), while patients and other sources accounted for 96 reports (25.3%).

The contribution of healthcare professionals increased to 101 reports (34.2%) in 2024 and remained similar in 2025, when 96 reports (33.7%) were attributed to this group. During January–June 2026, healthcare professionals submitted 290 reports and became the largest reporting source, accounting for 53.7% of the period total.

Marketing authorisation holders submitted 123 reports (41.7%) in 2024, 104 reports (36.5%) in 2025, and 176 reports (32.6%) during the first half of 2026. Although their proportional contribution decreased, the absolute number recorded during January–June 2026 exceeded the number recorded during the complete 2025 calendar year.

Reports from patients and other sources accounted for 25.3% of reports in 2023, 24.1% in 2024, 29.8% in 2025, and 13.7% during January–June 2026.

Table 4. Distribution of safety reports by reporting source

Reporting source	2023, n (%)	2024, n (%)	2025, n (%)	January–June 2026, n (%)
Healthcare professionals	80 (21.1)	101 (34.2)	96 (33.7)	290 (53.7)
Marketing authorisation holders	204 (53.7)	123 (41.7)	104 (36.5)	176 (32.6)
Patients and other sources	96 (25.3)	71 (24.1)	85 (29.8)	74 (13.7)
Total	380 (100.0)	295 (100.0)	285 (100.0)	540 (100.0)

Reporter-source composition differed significantly across the study periods ($\chi^2=120.02$; df=6; $p<0.001$). Cramér's V was 0.20, indicating a small-to-moderate difference in reporter-source distribution.

Between 2023 and the first half of 2026, the proportional contribution of healthcare professionals increased by 32.6 percentage points. Over the same comparison, the contribution of marketing authorisation holders decreased by 21.1 percentage points, and that of patients and other sources decreased by 11.6 percentage points.

3.5. Distribution of Reports by Seriousness

The national system recorded 105 serious reports in 2023, corresponding to 27.6% of all reports received during that year. In 2024, 95 reports (32.2%) were classified as serious. The highest proportion was recorded in 2025, when 134 of 285 reports (47.0%) were classified as serious.

During January–June 2026, 90 of 540 reports (16.7%) were classified as serious, while 450 reports (83.3%) were classified as non-serious.

Table 5. Distribution of safety reports according to seriousness

Reporting period	Serious reports, n (%)	Non-serious reports, n (%)	Total

2023	105 (27.6)	275 (72.4)	380
2024	95 (32.2)	200 (67.8)	295
2025	134 (47.0)	151 (53.0)	285
January–June 2026	90 (16.7)	450 (83.3)	540
Total	424 (28.3)	1,076 (71.7)	1,500

The distribution of serious and non-serious reports differed significantly across the four study periods (χ^2=87.58; df=3; p<0.001). Cramér's V was 0.24, indicating a small-to-moderate between-period difference.

The proportion of reports classified as serious decreased by 30.3 percentage points between 2025 and the first half of 2026. The relative probability that a report was classified as serious during January–June 2026 compared with 2025 was 0.35 (95% CI: 0.28–0.44).

This estimate describes the seriousness composition of submitted reports and does not represent the relative risk of a patient experiencing a serious adverse reaction.

3.6. Integration of Regulatory, Organisational, and Quantitative Findings

Integration of the qualitative and quantitative findings identified three concurrent developments during the first half of 2026:

1. implementation of revised national pharmacovigilance requirements;
2. connection of approximately 700 public healthcare institutions to the electronic platform and registration of responsible representatives through OneID;
3. an increase in both the absolute number and proportional contribution of reports submitted by healthcare professionals.

Healthcare professionals accounted for 21.1% of reports in 2023 and 53.7% during January–June 2026. This change occurred during the same implementation period as institutional connection, OneID registration, and professional training. The aggregated study design did not permit the independent contribution of each component to be estimated.

The integrated results also showed that increased reporting volume was accompanied by a change in the seriousness composition of the national dataset. Non-serious reports accounted for 53.0% of reports in 2025 and 83.3% during January–June 2026.

3.7. Conceptual Framework for Further System Development

The integrated analysis resulted in a five-component conceptual framework for the further development and evaluation of Uzbekistan's national pharmacovigilance system. The framework linked the legal and regulatory foundation with institutional governance, digital infrastructure, safety-data and signal management, and regulatory action with continuous quality improvement.

Table 6. Components of the proposed national pharmacovigilance framework

Component	Principal functions	Proposed performance indicators
Legal and regulatory foundation	Legal mandate, stakeholder obligations, reporting timelines, regulatory oversight	Regulatory coverage, implementation status, compliance findings
Institutional governance	Coordination among the competent authority, marketing authorisation holders, healthcare institutions, healthcare professionals, and patients	Institutional participation, appointment of responsible representatives, training coverage, audit findings
Digital infrastructure	Electronic submission, user identification, traceability, database management, and interoperability	Proportion of electronic reports, platform availability, technical rejection rate, processing time
Safety-data and signal management	Report validation, duplicate detection, medical coding, follow-up, signal detection, prioritisation, and	Report completeness, follow-up completion, duplicate rate, time to validation, signal-

	assessment	cycle duration
Regulatory action and continuous improvement	Risk minimisation, safety communication, corrective and preventive actions, audit, and effectiveness evaluation	Regulatory actions implemented, CAPA completion, communication coverage, risk-minimisation effectiveness

The framework represents the national system as a continuous cycle. Regulatory requirements define stakeholder responsibilities; healthcare institutions, professionals, patients, and marketing authorisation holders generate safety information; the competent authority validates and evaluates the submitted data; identified risks inform regulatory decisions and risk-minimisation measures; and the outcomes of these measures are reassessed through monitoring and quality-management processes.

4. DISCUSSION

4.1. Principal Findings

This study provides an integrated national-level assessment of the regulatory, organisational, and digital transformation of pharmacovigilance in Uzbekistan between January 2023 and June 2026. The principal finding was a substantial change in reporter-source composition during the reform period. Healthcare professionals accounted for 21.1% of national safety reports in 2023 but 53.7% during the first half of 2026, becoming the largest reporting group. This redistribution was statistically significant and had a small-to-moderate effect size.

Reporting activity also increased markedly during the initial electronic implementation period. The national system recorded 540 reports during January–June 2026, compared with 285 during the complete 2025 calendar year. The descriptive average increased from 23.8 reports per month in 2025 to 90.0 reports per month during the first half of 2026. However, the unequal observation periods, potential seasonal variation, and concurrent implementation of regulatory, organisational, educational, and technological measures preclude attribution of this increase to the electronic platform alone.

The proportion of reports classified as serious decreased from 47.0% in 2025 to 16.7% during January–June 2026. This change describes the composition of submitted reports and should not be interpreted as evidence that serious adverse reactions became less frequent in the treated population. Collectively, the findings represent early changes in system participation and reporting output rather than demonstrated improvements in medicine-safety or public-health outcomes.

4.2. Comparison with International Evidence

The reporting changes observed in Uzbekistan are consistent with international evidence indicating that digital reporting tools can increase the accessibility and volume of pharmacovigilance reporting. Following the introduction of the Med Safety App in Nigeria, the number of adverse-event reports recorded in VigiFlow increased from 2,051 during the baseline period to 18,995 during the post-implementation period, with 81.7% of post-implementation reports submitted through the application [16]. The Nigerian study also reported high completeness scores among app-based reports. Nevertheless, its post-implementation period overlapped with large-scale COVID-19 vaccine safety monitoring, illustrating the difficulty of separating the effect of a digital platform from concurrent public-health interventions.

Experience from Ghana similarly showed that mobile reporting was considered acceptable and convenient by many users, while initial registration requirements, multiple reporting fields, limited feedback, and technical barriers could restrict sustained use [17]. A qualitative study from Uganda identified practical training, offline functionality, two-way risk communication, and healthcare workers' willingness to report as important facilitators. Report complexity, internet costs, connectivity problems, language barriers, and insufficient feedback were identified as potential obstacles [18].

The strongest comparative evidence is provided by a 2025 cluster-randomised controlled trial conducted in Uganda. Healthcare facilities using the Med Safety App achieved a higher overall adverse-reaction reporting rate than control facilities using conventional reporting methods (incidence rate ratio 1.73; 95% CI: 1.26–2.37) [21]. The increase was particularly evident for non-serious reports, whereas the difference in serious-reporting rates was not statistically significant. This finding is relevant to the Uzbekistan results because it provides a plausible explanation for an increase in overall reporting accompanied by a lower proportional contribution of serious reports.

The international evidence nevertheless demonstrates that a digital channel does not act independently of its implementation environment. Smartphone-based pharmacovigilance applications vary in their technical functions, integration with national

databases, feedback mechanisms, user authentication, offline capability, and support for standardised data entry [19]. Their effect therefore depends on regulatory recognition, institutional adoption, user training, technical accessibility, and the ability of the competent authority to process and use the additional information generated.

4.3. Interpretation of Reporter-Source Redistribution

The change in reporter-source composition is more informative than the comparison of absolute annual totals because proportions are less directly affected by the unequal duration of the study periods. The increase in healthcare professionals' contribution from 21.1% to 53.7% indicates that the national reporting base became more directly connected to clinical practice.

Healthcare professionals are positioned to recognise suspected adverse reactions, document clinical manifestations, evaluate treatment changes, and provide relevant information on medical history, concomitant medicines, laboratory findings, dechallenge, and rechallenge. Broader participation by this group may therefore increase the clinical diversity and potential usefulness of the national safety database. This benefit cannot be assumed from report numbers alone, however, because clinical value also depends on completeness, diagnostic detail, follow-up, coding accuracy, and duplicate control.

The proportional contribution of marketing authorisation holders decreased from 53.7% in 2023 to 32.6% during January–June 2026. This finding does not indicate a reduction in their absolute reporting activity. Marketing authorisation holders submitted 176 reports during the first half of 2026, compared with 104 during the complete 2025 calendar year. The lower percentage was primarily attributable to the expansion of reporting from healthcare professionals and the resulting increase in the overall denominator.

Reports from patients and other sources decreased proportionally during the first half of 2026. This may reflect the institutional focus of the initial implementation phase, which prioritised connection of healthcare institutions, appointment of responsible representatives, and professional training. The available data do not establish whether patient reporting decreased in absolute terms, shifted to other channels, or was diluted by the growth of healthcare professional reporting. Future evaluations should therefore analyse patient reports as a separate category rather than combining them with other sources.

4.4. Interpretation of Seriousness Patterns

The increase in the proportion of serious reports between 2023 and 2025 may indicate that the earlier reporting system disproportionately captured clinically severe or administratively prioritised cases. When reporting requires paper forms, e-mail correspondence, or additional administrative effort, reporters may be more likely to submit cases perceived as urgent or serious.

The lower proportion of serious reports during the first half of 2026 may indicate that electronic reporting and training broadened the reporting base to include non-serious suspected reactions that would previously have remained unreported. The Uganda cluster-randomised trial supports this interpretation: access to the Med Safety App increased non-serious reporting without producing a statistically significant change in serious-reporting rates [21].

Other explanations remain possible. Changes in reporter-source composition, application of seriousness criteria, validation procedures, reporting obligations, therapeutic-product mix, medicine utilisation, or duplicate management may have contributed to the observed pattern. Aggregated data did not permit assessment of deaths, life-threatening reactions, hospitalisations, disability, congenital anomalies, or other medically important events as separate outcomes.

The relative risk of 0.35 therefore represents the probability that a submitted report was classified as serious in January–June 2026 relative to 2025. It is not an estimate of the risk of a patient experiencing a serious adverse reaction. Calculation of patient-level risk would require reliable denominators such as the number of treated patients, prescriptions, administered doses, or medicine-exposure time.

4.5. Role of Institutional Registration and Professional Training

The electronic platform was introduced as part of a broader organisational intervention. Approximately 700 public healthcare institutions were connected, responsible representatives were registered through OneID, and 1,880 healthcare professionals completed training. These components may have reduced uncertainty regarding institutional responsibility and created a direct reporting pathway between clinical facilities and the competent authority.

Training may improve the recognition of suspected adverse reactions, understanding of reporting timelines, differentiation

between serious and non-serious cases, completion of minimum reporting fields, and use of electronic reporting tools. A mixed-methods study in Malawi found that in-service pharmacovigilance training was associated with better knowledge and reporting practices among healthcare professionals [20]. Studies from Ghana and Uganda similarly emphasised that practical instruction and continuing support were important for adoption of mobile reporting systems [17,18].

The present study measured training reach but did not assess learning outcomes. The number of trained professionals should therefore be interpreted as a process indicator rather than evidence of improved competence. Future training evaluation should include pre-training and post-training knowledge assessments, practical case exercises, electronic-platform competency, report-completeness scores, and follow-up evaluation of reporting behaviour.

OneID registration provides institutional traceability, but registration alone does not demonstrate active or sustained participation. Future monitoring should distinguish between registered institutions, institutions submitting at least one valid report, institutions meeting reporting-timeliness requirements, and institutions providing complete follow-up information.

4.6. Implications for National Pharmacovigilance Development

The results support evaluation of the national system across five interconnected components: legal and regulatory foundation, institutional governance, digital infrastructure, safety-data and signal management, and regulatory action with continuous quality improvement. Progress in one component cannot compensate fully for weakness in another. An electronic platform may increase reporting, but its public-health value depends on whether the submitted information can be validated, medically assessed, coded, followed up, analysed, and translated into regulatory action.

The next stage of platform development should incorporate structured validation of minimum report criteria, standardised medical terminology using the Medical Dictionary for Regulatory Activities, classification of medicinal products using the Anatomical Therapeutic Chemical system, automated identification of potential duplicates, structured follow-up workflows, and measurement of case-processing timelines. Analytical dashboards should support monitoring by reporting source, region, institution, therapeutic group, seriousness, outcome, and data completeness.

Evaluation should extend beyond the total number of reports. Recommended indicators include the proportion of valid reports, completeness of clinically important fields, median time from receipt to validation and medical assessment, proportion of cases requiring follow-up, follow-up completion rate, duplicate-report rate, coding quality, number of signals detected and validated, time from signal identification to regulatory decision, and effectiveness of risk-minimisation measures. These indicators are consistent with the systems-based approach promoted by the World Health Organization [8].

4.7. Strengths and Limitations

A major strength of this study was the integration of national regulatory documents, implementation records, training data, and the complete aggregated reporting dataset available for the study period. The analysis included both absolute reporting volume and proportional reporter-source composition. Statistical significance was complemented by effect-size estimates, and causal claims were deliberately separated from temporal associations.

Several limitations should be considered. First, the retrospective observational design does not permit causal attribution of reporting changes to the electronic platform, regulatory reforms, institutional registration, or training. These measures were implemented concurrently and could not be evaluated independently.

Second, the observation periods were unequal. Data for 2023–2025 represented complete calendar years, whereas the 2026 data covered six months. Monthly averages partially addressed differences in duration but could not account for seasonal reporting patterns. Equivalent monthly or quarterly pre-implementation data were unavailable.

Third, the analysis used aggregated administrative data. Individual reports could not be reassessed for validity, clinical completeness, duplicate status, causality, expectedness, coding quality, seriousness classification, follow-up, or compliance with reporting timelines.

Fourth, medicine-exposure and population denominators were unavailable. The findings therefore describe reporting activity rather than the incidence or prevalence of adverse reactions.

Fifth, the analysis could not account for clustering of reports within healthcare institutions or marketing authorisation holders. It also did not examine variation by region, institution type, reporter profession, medicinal product, therapeutic group, patient

characteristics, or clinical manifestation.

Sixth, the study did not assess signal detection, signal-validation outcomes, product-information changes, regulatory restrictions, safety communications, or the effectiveness of risk-minimisation measures. Consequently, the outcomes primarily represent system structures, implementation processes, and reporting outputs.

Finally, regulatory content analysis was performed by a single investigator. Independent duplicate coding and inter-rater agreement assessment were not conducted. The conceptual framework should therefore be regarded as an evidence-informed organisational model requiring external validation.

4.8. Future Research

Future studies should compare equivalent monthly or quarterly periods before and after implementation. Once sufficient time points are available, interrupted time-series analysis could assess whether changes in reporting level and trend were sustained beyond the initial implementation phase.

Case-level studies should evaluate report validity, completeness, timeliness, duplicate frequency, medical coding, follow-up success, seriousness classification, causality assessment, and clinical outcome. Analyses should be stratified by region, institution type, healthcare profession, reporting channel, patient characteristics, therapeutic group, and active substance.

Comparisons between trained and untrained institutions should account for institution size, patient volume, medicine use, and baseline reporting activity. Platform-use data should also be examined to distinguish registration from active engagement and sustained reporting.

Further evaluation should determine whether increased reporting contributes to earlier signal detection and more timely regulatory action. Relevant outcomes include validated signals, changes to product information, safety communications, restrictions of use, additional risk-minimisation measures, and measured effectiveness of those interventions.

The proposed five-component framework should be assessed using predefined indicators, independent expert review, and formal consensus methods. Comparative evaluation with other countries undergoing similar regulatory and digital reforms would help establish its transferability and identify context-specific determinants of pharmacovigilance performance.

5. CONCLUSION

Uzbekistan's national pharmacovigilance system underwent substantial regulatory, organisational, and digital transformation between January 2023 and June 2026. The reform combined a strengthened legal framework, national Good Pharmacovigilance Practice requirements, clarification of stakeholder responsibilities, electronic reporting, institutional registration through OneID, and large-scale professional training. During the same period, the contribution of healthcare professionals to national safety reporting increased from 21.1% to 53.7%, indicating a marked expansion of direct reporting from clinical practice.

The increase in reporting activity and the lower proportion of reports classified as serious during the first half of 2026 should be interpreted as changes in the volume and composition of submitted reports, rather than as evidence of a causal effect of the electronic platform or a reduction in the occurrence of serious adverse reactions. Regulatory reform, institutional accountability, professional training, and digital reporting were introduced concurrently, and the available aggregated data did not permit their independent effects to be estimated.

Sustained development of the national system will require evaluation beyond reporting volume. Priority indicators should include report validity, clinical completeness, processing timeliness, duplicate control, follow-up outcomes, standardised medical coding, signal-detection performance, regulatory actions, risk communication, and the effectiveness of risk-minimisation measures. Uzbekistan's early experience suggests that digitalisation is most likely to strengthen pharmacovigilance when it is embedded within an integrated system of legal authority, institutional governance, trained personnel, safety-data management, and continuous quality improvement.

DECLARATIONS

Ethical Considerations

Formal ethics committee approval was not sought because the study was limited to the secondary analysis of aggregated, non-identifiable administrative and regulatory data. No individual-level patient records, personal identifiers, or identifiable case

narratives were accessed, and the study involved no direct interaction with human participants.

Ethics Approval

Formal ethics committee approval was not obtained. The study was based exclusively on aggregated, non-identifiable administrative and regulatory data. No individual patient records, personal identifiers, or identifiable safety narratives were accessed or analysed.

Consent to Participate

Not applicable. The study did not involve the recruitment of or direct interaction with human participants, and no individual-level personal data were analysed.

Consent for Publication

Not applicable. The manuscript contains no identifiable personal or patient-level information.

Data Availability

The aggregated data supporting the findings of this study were obtained from the official records of the State Institution "Center for Safety of Pharmaceutical Products" under the Ministry of Health of the Republic of Uzbekistan. Additional aggregated data may be made available by the author upon reasonable request, subject to applicable institutional, regulatory, and confidentiality requirements.

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Conflict of Interest

The author declares that there are no conflicts of interest relevant to this study.

Author Contributions

Sabohat Mamadiyorovna Khayitova: Conceptualisation, Methodology, Formal Analysis, Investigation, Data Curation, Interpretation of Results, Writing—Original Draft, Writing—Review and Editing, and Project Administration. The author read and approved the final version of the manuscript.

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ABBREVIATIONS

ADR — Adverse Drug Reaction
ATC — Anatomical Therapeutic Chemical classification
CAPA — Corrective and Preventive Action
CI — Confidence Interval
EMA — European Medicines Agency
GVP — Good Pharmacovigilance Practice
HCP — Healthcare Professional
ICH — International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICSR — Individual Case Safety Report
MAH — Marketing Authorisation Holder
MedDRA — Medical Dictionary for Regulatory Activities
PSMF — Pharmacovigilance System Master File
PSUR — Periodic Safety Update Report
RMP — Risk Management Plan
RR — Relative Risk

UMC — Uppsala Monitoring Centre
WHO — World Health Organization

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