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**Research Article**

# Implementation Status, Operational Workflow, and Challenges of Iraq's National Pharmaceutical Track-and-Trace System (Gudea): From Health Officials' Perspectives

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**Abstract**

***Background***: The Iraqi private pharmaceutical sector faces challenges related to medicine authenticity, price variation, smuggling, and limited post-market control. The Iraqi Ministry of Health introduced the National Pharmaceutical Track-and-Trace System, known as Gudea, to strengthen medicine authentication, price regulation, and supply-chain oversight. ***Objectives***: To describe the implementation status, operational workflow, key administrative indicators, and challenges of the Gudea system in Iraq's private pharmaceutical sector from the Ministry of Health's perspective. ***Methods***: A qualitative-dominant descriptive mixed-methods design was used between 22 October 2025 and 15 February 2026. Qualitative data were collected through two semi-structured key-informant interviews with Ministry of Health pharmacists involved in Gudea implementation and regulatory use and analyzed thematically. Administrative quantitative data were extracted from official system records and summarized descriptively. ***Results***: The Gudea system functions as an integrated digital regulatory platform linking serialization, official price control, laboratory testing, customs-related information, field inspection, and public verification. Administrative indicators showed substantial activity, including more than 1.8 billion official medicine labels, 22,120 medicine items, 78,817 tested batches, and 3,263 inspection visits. Qualitative findings indicated a transition from paper-based procedures to electronic regulatory verification, particularly in field inspection. Key challenges were partial coverage, low stakeholder cooperation, customs-release gaps, laboratory delays, and the need for wider system integration. ***Conclusions***: The Gudea represents an important national step toward strengthening pharmaceutical governance, medicine authentication, price transparency, and regulatory oversight in Iraq. Future efforts should focus on expanding system coverage, improving institutional coordination, completing technical integration, and evaluating its impact on medicine safety and market regulation.

***Keywords***: Gudea; Iraq; Medicine authentication; Pharmaceutical regulation; Serialization; Track-and-trace system.

**حالة التنفيذ، سير العمل التشغيلي، وتحديات النظام الوطني للأدوية في العراق (غوديا): من وجهات نظر المسؤولين الصحيين**

**الخلاصة**

**الخلفية**: يواجه قطاع الأدوية الخاص العراقي تحديات تتعلق بأصالة الأدوية، وتقلبات الأسعار، والتهريب، والسيطرة المحدودة بعد السوق. قدمت وزارة الصحة العراقية نظام تتبع الأدوية الوطني المعروف باسم جوديا، لتعزيز رصانة الأدوية، وتنظيم الأسعار، والرقابة على سلسلة التوريد. **الأهداف**: وصف حالة التنفيذ، وسير العمل التشغيلي، والمؤشرات الإدارية الرئيسية، والتحديات التي يواجهها نظام جوديا في قطاع الأدوية الخاص العراقي من منظور وزارة الصحة. **الطرائق**: تم استخدام تصميم طرق مختلطة وصفي يهيمن على النوعية بين 22 أكتوبر 2025 و15 فبراير 2026. تم جمع البيانات النوعية من خلال مقابلتين شبه منظمتين مع صيادلة وزارة الصحة المشاركين في تنفيذ جوديا واستخدامها التنظيمي، وتم تحليلها موضوعيا. تم استخراج البيانات الكمية الإدارية من سجلات النظام الرسمية وتلخيصها بشكل وصفي. **النتائج**: يعمل نظام جوديا كمنصة تنظيمية رقمية متكاملة تربط بين التسلسل التنظيمي، والتحكم الرسمي في الأسعار، والفحوص المخبرية، والمعلومات المتعلقة بالجمارك، والفحص الميداني، والتحقق العام. أظهرت المؤشرات الإدارية نشاطا كبيرا، شمل أكثر من 1.8 مليار ملصق طبي رسمي، و22,120 دوية، و78,817 دفعة مختبرية، و3,263 زيارة تفتيش. أشارت النتائج إلى انتقال من الإجراءات الورقية إلى التحقق التنظيمي الإلكتروني، لا سيما في التفتيش الميداني. كانت التحديات الرئيسية هي التغطية الجزئية، وانخفاض التعاون بين أصحاب المصلحة، وفجوات في الإفراج الجمركي، وتأخير المختبرات، والحاجة إلى تكامل أوسع للأنظمة. **الاستنتاجات**: يمثل جوديا خطوة وطنية مهمة نحو تعزيز حوكمة الأدوية، ومصادقة الأدوية، وشفافية الأسعار، والرقابة التنظيمية في العراق. يجب أن تركز الجهود المستقبلية على توسيع تغطية النظام، وتحسين التنسيق المؤسسي، وإكمال التكامل الفني، وتقييم تأثيره على سلامة الأدوية وتنظيم الأسواق.

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## INTRODUCTION

Ensuring the integrity of pharmaceutical supply chains is a major public health priority, particularly in countries facing regulatory and healthcare system challenges [1]. In 2024, Iraq had a population of approximately 46.0 million and a gross domestic product (GDP) of US$ 279.64 billion [2]. Despite the availability of governmental healthcare services, the majority of the Iraqi population relies on the private sector for medicine procurement [3], with national spending on imported medications estimated at nearly US$3.0 billion annually [4]. Medicine quality and authenticity remain critical concerns. In 2025, Iraq had 16,993 community pharmacies, 455 wholesale distributors, and 611 scientific drug bureaus [5]. Globally, pharmaceutical track-and-trace systems have been adopted to enhance supply chain transparency, prevent counterfeit medicines, and improve patient safety [6]. These systems assign

unique identifiers to medicines and monitor their movement across the supply chain from manufacturing to dispensing [7]. In Iraq, decades of political instability have weakened regulatory oversight and healthcare infrastructure, highlighting the need for digital regulatory solutions to strengthen pharmaceutical governance [8,9]. Persistent healthcare system challenges over the past three decades have further affected service quality and medicine regulation [8]. According to the former Iraqi Ministry of Health (MOH) in 2019, registered medicines represented approximately 30–40% of products available in the private sector, while 60–70% remain unregistered and lack official price labels [3]. Factors contributing to this situation include parallel importation driven by price differences with neighboring countries, insufficient border control, and shortages of essential medicines [10]. A 2021 study reported that Iraq had no medicine track-and-trace system at that time, representing a key limitation in controlling medicine distribution [11]. In 2023, the Iraqi Ministry of Health launched Gudea to support medicine authentication, price regulation, and monitoring of medicines in the private sector. Gudea includes an official medicine label affixed to registered medicines and a mobile application that allows users to scan the label and verify medicine-related information [12]. Despite the national importance of Gudea, limited published evidence is available on its implementation status, operational workflow, administrative indicators, and practical challenges. Therefore, this study aimed to describe the implementation status, operational workflow, key administrative indicators, and challenges of the Gudea system in Iraq's private pharmaceutical sector.

## METHODS

### *Study design and setting*

This study employed a qualitative-dominant descriptive concurrent mixed-methods design, in which qualitative insights from key-informant interviews were integrated with administrative, system-generated quantitative data. The study was conducted at the Ministry of Health and its directorate offices in Baghdad, Iraq. The first interview was with a pharmacist who was the director of the National Pharmaceutical Track-and-Trace System Division. This division is part of the Popular Medical Clinics Directorate and is based in Al-Mansour district, Baghdad. The second interview involved a pharmacist from the Inspection Directorate, Private Health Institutions Inspection Department, at the Ministry of Health headquarters in Baghdad.

### *Participant recruitment and sampling*

Purposive sampling was used to select pharmacist key-informants with direct knowledge and practical involvement in the implementation and regulatory use of the Gudea system. Two Ministry of Health personnel were recruited because their official roles were directly relevant to the study objectives.

### *Interview guide and data collection*

Face-to-face, semi-structured interviews were conducted in Arabic by the principal researcher, a registered community pharmacist and MSc student with 14 years of community pharmacy experience. The first interview was conducted with the pharmacist director of the National Pharmaceutical Track-and-Trace System Division on 22 October 2025 and lasted more than two hours. The second interview was conducted with a pharmacist from the Inspection Directorate, Private Health Institutions Inspection Department, on 15 February 2026 and lasted approximately 34 minutes. Both interviews were audio-recorded with participants' permission and transcribed for analysis. The interview guide was developed to explore the implementation and regulatory use of the Gudea system. It covered system establishment and governance, operational workflow, serialization and official medicine labeling, laboratory testing and label release, customs-related verification, field inspection and regulatory enforcement, implementation challenges, and future development plans. The questions were open-ended to allow participants to describe their experiences and provide detailed information based on their official roles and practical involvement in the system. Administrative data were obtained through an official institutional request submitted to the Ministry of Health, National Pharmaceutical Track-and-Trace System Division. The request was No. 5417 dated 20 October 2025, and the official response was received on 2 January 2026.

### *Ethical considerations*

Ethical approval was obtained from the relevant institutional research ethics committee before data collection (Approval No. RECAUBCP0625154R; approval date: 19 October 2025). Official permission was obtained to collect Gudea-related data. Interview participation was voluntary, and permission was obtained before audio recording. All qualitative data were de-identified, and administrative quantitative data were reported in aggregate form without disclosing identifiable or confidential information about products or pharmaceutical companies.

### Data analysis

Interview recordings were transcribed verbatim to preserve participants' original expressions. Qualitative data were analyzed manually using thematic analysis, following Braun and Clarke's six-phase approach: familiarization with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and producing the final report [13]. The analysis focused on implementation-related themes concerning Gudea governance, operational workflow, regulatory use, and implementation challenges. Codes and candidate themes were

reviewed through repeated reading of the transcripts and discussion among the research team until consensus was reached. Representative quotations were selected to illustrate the final themes. Administrative quantitative data were analyzed descriptively using totals and frequencies to summarize system coverage and operational outputs. No inferential statistical testing was performed because the quantitative component was descriptive.

## RESULTS

The results are presented in three sections. First, qualitative findings from the two key-informant interviews are presented. Second, the system description and operational workflow of Gudea are described using interview data and an Arabic system-description document from the National Pharmaceutical Track-and-Trace System Division, the MOH. Third, administrative quantitative indicators are summarized to describe system coverage and operational outputs. The qualitative findings were based on two key-informant interviews with the MOH pharmacists involved in Gudea implementation and regulatory use: the Director of the National Pharmaceutical Track-and-Trace System Division and a pharmacist from the Inspection Directorate, Private Health Institutions Inspection Department, the MOH. The interview with the Director of the National Pharmaceutical Track-and-Trace System Division generated five implementation-related themes: governance and implementation structure, digital transformation of medicine regulation, serialization and price control, supply-chain integration, and implementation challenges with future expansion (Table 1).

**Table 1**: Themes and subthemes identified from key-informant interviews

| No. | Theme | Subthemes | Illustrative quotation |
|---|---|---|---|
| 1 | Governance and implementation structure of Gudea | System launches and development partnership; ministerial supervision; policy drivers | "Gudea was introduced to establish a transparent pricing system for medicines in the private sector, following public complaints and official directives." |
| 2 | Digital transformation of medicine regulation and inspection | Electronic import approvals; electronic inspection; tablet-supported field verification | "Through the system, inspectors can easily identify official and unofficial medicines during field inspection." |
| 3 | Serialization, pricing control, and product authentication | Unique QR code; serial number; non-removable laser label; price matrix; cloned-label detection | "The official label contains a unique QR code and serial number for each item, making it possible to detect duplicated or falsified labels." |
| 4 | Integration across the pharmaceutical supply chain | Registration linkage; laboratory testing; customs release; border verification; field inspection | "Each inspector has a tablet containing medicine information, including customs release, laboratory test results, importing scientific bureau, label receipt status, and official selling prices." |
| 5 | Implementation challenges and future expansion | Partial coverage; syndicate cooperation; customs-release gaps; laboratory delays; offline/GPS improvements; ASYCUDA linkage; e-prescription | "Some challenges remain, including incomplete coverage, weak cooperation from professional syndicates, customs-release gaps, and the need for future linkage with other national systems." |

**Theme 1. Governance and implementation structure**. The Gudea system was launched on 16 April 2023 and developed through a partnership with a local Iraqi information technology company according to the MOH requirements. Its implementation is supervised by a multidisciplinary ministerial committee affiliated with the Popular Medical Clinics Directorate, the MOH. The main policy driver was the need to regulate medicine prices in the private sector in response to public complaints and official oversight demands. As the informant explained, the system was introduced because of "*public complaints due to variation in medicine prices, along with parliamentary demands and directives from higher oversight bodies*" (GSD). **Theme 2. Digital transformation of private-sector medicine regulation**. The Gudea system shifted several regulatory and inspection procedures from paper-based document checking to electronic verification. Inspectors can scan the official medicine label or search for a product in the system to verify import approval, customs clearance information, label receipt, and official pricing. The informant explained that inspection became "electronic through the application," replacing the previous paper-based checking of documents. The system also introduced electronic import approvals, allowing scientific bureaus to submit import requests, follow their status, and address deficiencies digitally (Figure 1). **Theme 3. Serialization, pricing control, and product authentication**. The Gudea system uses a non-removable laser-etched official medicine label containing a unique QR code and serial number for each medicine unit. This supports differentiation between registered products and smuggled, falsified, or unauthorized medicines. Pricing is supported by a price matrix linked to registration prices and official pricing committees. The informant described the label as "laser and non-removable" and explained that it contains a "unique QR" and "serial number for each item," (GSD) allowing the system to distinguish official products from falsified or smuggled products. **Theme 4. Integration across the pharmaceutical supply chain**. The Gudea system links several regulatory stages within the pharmaceutical supply chain, including registration, import approval, customs clearance information, laboratory testing, official medicine label release, and field inspection (Figure 1). Although labels may be printed before completion of laboratory testing, they are not released to scientific bureaus or national manufacturers until successful verification by the National Center for Drug Control and Research. Border verification was also supported by providing tablets to the State Company for Marketing Drugs and Medical

Appliances (KIMADIA) at seven border outlets to document and verify incoming shipments.

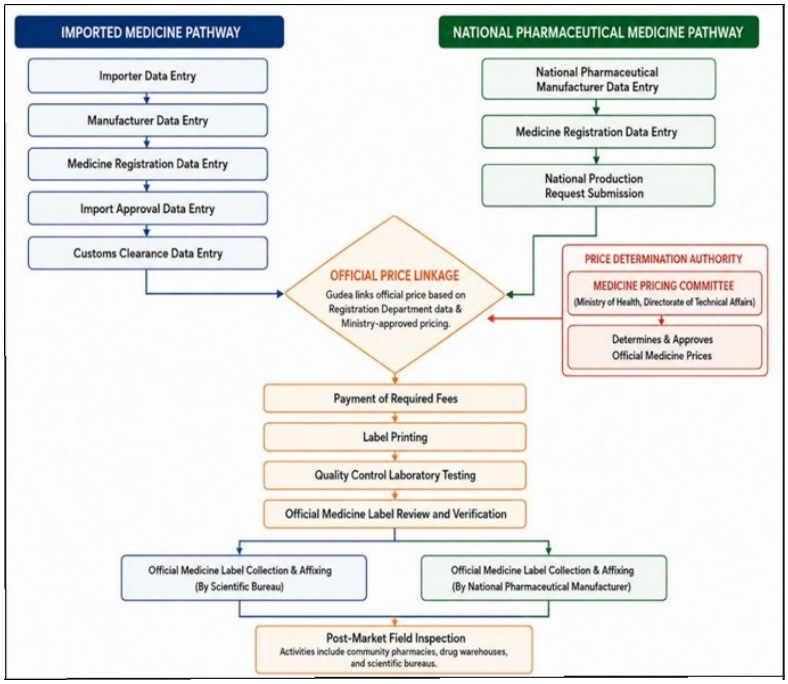


**Figure 1**: Operational workflow of Gudea for imported and nationally manufactured medicines.

As the informant stated, scientific bureaus "*do not receive the labels except after confirming the validity of the National Center for Drug Control and Research results*" (GSD). **Theme 5. Implementation challenges and future expansion**. The Gudea system remains partially implemented, with estimated coverage of approximately 50–60% of imported and nationally manufactured medicines in the private sector. Key challenges included limited cooperation from the Pharmacists Syndicate, technical gaps in customs clearance, absence of pharmacists at some border points, and delays in laboratory testing that may lead to accumulation of printed labels. The informant stated that "the Pharmacists Syndicate is not very cooperative" and that laboratory delays may cause label accumulation for "about six months." Planned future expansion includes linkage with customs and the Automated System for Customs Data (ASYCUDA), broader inter-ministerial integration, inclusion of selected pharmaceutical-like products, and the implementation of electronic prescriptions in 2026. The interview with the pharmacist from the Inspection Directorate generated one main theme: digital transformation of pharmaceutical field inspection through the Gudea system. This theme covered mandatory system use during field inspection, electronic verification of medicine legality and pricing, perceived usefulness and ease of use, and early operational challenges. The participant reported that the Gudea system had been used during inspection activities since April 2024 and that its use was mandatory through iPads provided to inspection teams. The system was described as highly effective in distinguishing official from unofficial medicines: "*We use the system during inspection activities, and the experience is excellent… we currently consider it about 95% effective, as the system makes it easy for us to identify official medicines from unofficial ones*" (IDP). The participant explained that the Gudea provided inspectors with immediate access to key regulatory information, including customs clearance documents, laboratory test results, the importing scientific bureau, official medicine label receipt status and date, and official selling prices for drug warehouses and pharmacies. This was perceived to improve inspection efficiency, as the participant stated that the system "*saved time and effort and made the work very smooth and simple*" (IDP). The system was also described as easy to use in field settings. Verification was performed by scanning the QR code on the official medicine label using the Gudea system camera. The participant (IDP) stated that "*once the QR code on the label is scanned through the Gudea system camera, all information becomes available*," allowing inspectors to assess the compliance of scientific bureaus, drug warehouses, and pharmacies. Early implementation challenges were mainly technical. These included dependence on internet connectivity and difficulty identifying the locations of some scientific bureaus. However, the participant indicated that these issues had partly improved: "*At the beginning, there were technical problems and difficulties because the system worked only with internet access… now the system works normally without internet, and part of the location problem has been solved by adding GPS*" (IDP). Overall, the participant expressed a positive attitude toward the Gudea as a field inspection tool because it facilitated regulatory action against violators. As stated in the interview, "*my general impression is excellent; it saved us a lot of time and effort and helped us take appropriate legal actions against violators more quickly*" (IDP). The participant also emphasized the importance of compliance with official medicine labels and cooperation with inspection teams to reduce falsified and smuggled medicines and unify

prices in the private sector. The themes and subthemes identified from the two key-informant interviews are summarized in Table 1. The system description and operational workflow were developed from key-informant interview data and an official Arabic version of the Gudea system-description document provided as part of the official institutional response to request No. 5417, dated 20 October 2025, received on 2 January 2026.

## Overview of the Gudea System

The Gudea system is a national digital regulatory platform introduced by the Iraqi MOH to support pharmaceutical supply-chain governance, medicine authentication, price control, and post-market regulatory oversight. It was developed as part of Iraq's wider governmental digital transformation efforts and as a response to persistent challenges in the private pharmaceutical sector, including medicine smuggling, falsification, unauthorized products, and price irregularities. This purpose was consistent with the key informant's explanation that the system was introduced in response to "public complaints due to variation in medicine prices," along with parliamentary and official oversight demands. The Gudea system assigns an official medicine label to each medicine package covered by it. Each label contains a unique QR code and serial number linked to product-specific regulatory information, including medicine name, dosage form, country of origin, batch-related information, laboratory testing status, importing scientific bureau or national manufacturer, and the Ministry of Health–approved price. The Director of the National Pharmaceutical Track-and-Trace System Division explained that the label is "laser and non-removable" and has a "unique QR" and "serial number for each item," which helps to confirm the product's authenticity and distinguish it from fake, smuggled, or unauthorized medicines. The Gudea mobile application allows users to scan the QR code on the official medicine label and access verified medicine-related information, including product name, dosage form, country of origin, official price in Iraqi dinars, and available product information. The application also allows users to submit reports about price discrepancies, suspected product irregularities, absence of an official medicine label, data mismatch, or medicines of unknown origin. This way, the Gudea app allows regular people to help check medicines, not just inspection teams. The operational workflow differs according to product origin. For imported medicines, the process involves entering data into the scientific bureau, manufacturer, medicine, import approval, customs clearance, payment of fees, printing the official label, entering lab test results, reviewing and verifying the label, releasing the label, and post-market inspection. For nationally manufactured medicines, the workflow includes national manufacturer data entry, medicine data entry, manufacturer request submission, payment of required fees, official medicine label printing, entry of laboratory test results, official label review and verification, official medicine label release and collection by the national manufacturer, and post-market field inspections. This workflow reflects the broader regulatory integration described by the key informant, who explained that the Gudea system links registration, import approval, customs clearance, laboratory testing, label release, and inspection. The operational workflow for imported and nationally manufactured medicines is illustrated in Figure 1. A key regulatory feature of the Gudea system is the linkage between official medicine labels and laboratory testing by the National Center for Drug Control and Research. Although labels may be printed after fee payment and before completion of laboratory testing, they are not released to the scientific bureau or national manufacturer unless the laboratory result is valid and the required regulatory procedures are fulfilled (Figure 1). This was emphasized by the Director of the National Pharmaceutical Track-and-Trace System Division, who stated that scientific bureaus "do not receive the labels except after confirming the validity of the National Center for Drug Control and Research results." This linkage is intended to prevent unauthorized label release and ensure that labeled products have completed the required regulatory steps. The Gudea system supports digital field inspection by giving inspection teams tablet-based access to system data (Figure 2). During inspection visits to private pharmacies, drug warehouses, and scientific bureaus, inspectors can verify product legality, label status, customs clearance documents, laboratory test results, importing scientific bureau or national manufacturer, and official selling prices. This function was confirmed by the Inspection Directorate participant, who reported that Gudea had been used during inspection activities since April 2024 and that its use was mandatory through iPads provided to inspection teams. The participant described the system as highly effective, stating that "*We use the system during inspection activities, and the experience is excellent… we currently consider it to be about 95% effective"* (IDP). The system also allows inspectors to search by batch number or pharmaceutical institution and to document inspection findings electronically. According to the Inspection Directorate participant, once the QR code is scanned through the Gudea system camera, "all information becomes available," allowing inspectors to assess the compliance of scientific bureaus, drug warehouses, and pharmacies. This represents a shift from paper-based inspection toward electronic verification and data-supported regulatory enforcement. The Gudea system includes mechanisms for detecting potential irregularities in the use of official medicine labels. For example, repeated scanning of the same QR code in geographically distant locations within short time intervals may indicate possible duplication or cloning of labels. Such patterns can support further regulatory investigation and help identify potentially falsified or unauthorized products. In field inspection, this function contributes to distinguishing official from unofficial medicines, which the Inspection Directorate participant described as one of the main practical

benefits of the system. Therefore, a missing Gudea label on products expected to be covered by the system may indicate unregistered, unauthorized, or potentially falsified medicines, although final classification requires regulatory verification.

## Overall Regulatory Role of the Gudea

Overall, the Gudea system functions as an integrated national platform for medicine serialization, authentication, price regulation, inspection support, and pharmaceutical data generation (Figure 2).

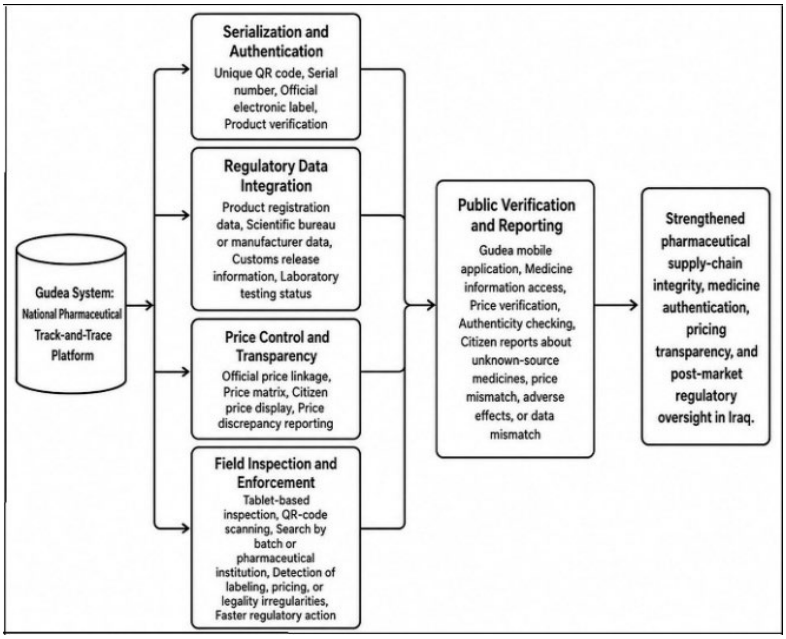


**Figure 2**: Regulatory functions and expected outcomes of the Gudea system.

By linking regulatory approval, laboratory testing, customs clearance information, official pricing, and field inspection within a single digital system, Gudea provides the Ministry of Health with a centralized mechanism to monitor private-sector medicine circulation and strengthen pharmaceutical governance in Iraq. This role was reflected in both interviews: the Director emphasized linkage across registration, laboratory testing, customs-related processes, and inspection, while the Inspection Directorate participant reported that the system "saved time and effort and made the work very smooth and easy" and helped accelerate appropriate legal action against violators.

## Quantitative Administrative Indicators

Administrative quantitative indicators were obtained through an official institutional request submitted to the Ministry of Health, National Pharmaceutical Track-and-Trace System Division. The request was No. 5417, dated 20 October 2025, and the official response was received on 2 January 2026. These indicators are summarized in Tables 2–4.

**Table 2**: Administrative quantitative indicators of Gudea implementation from system launch to 2026

| Indicator | Imported medicines/Scientific bureaus | Nationally manufactured medicines | Total |
|---|---|---|---|
| official medicine labels supplied | 1,448,951,881 | 362,520,998 | 1,811,472,879 |
| Priced pharmaceutical products | 9,058 | 3,018 | 12,076 |
| Active products with labels | 8,801 | 1,243 | 10,044 |
| Active pharmaceutical entities | 353 | 26 | 379 |
| Successful tested batches | 61,315 | 14,414 | 75,729 |
| Failed tested batches | 3,016 | 72 | 3,088 |
| Total tested batches | 64,331 | 14,486 | 78,817 |
| Import approvals entered into the system | — | — | 6,707 |
| Irregular or suspected counterfeit labels flagged | — | — | 18,581,385 |

Note: Imported medicines refer to products supplied through scientific bureaus, whereas nationally manufactured medicines refer to products supplied by national pharmaceutical manufacturers. Irregular or suspected counterfeit labels refer to labels flagged within the system because of suspected falsification, duplication, damage, price alteration, mismatch, or other forms of non-compliance, according to the available administrative classification.

**Table 3**: Annual distribution of official medicine labels supplied through Gudea

| Year | Imported medicine/ Scientific bureaus | Nationally manufactured medicines | Total labels |
|---|---|---|---|
| 2023 | 241,239,868 | 907,966 | 242,147,834 |
| 2024 | 691,880,864 | 142,157,369 | 834,038,233 |
| 2025 | 501,228,460 | 215,611,369 | 716,839,829 |
| Jan-Feb 2026 | 14,602,689 | 3,844,294 | 18,446,983 |
| Total | 1,448,951,881 | 362,520,998 | 1,811,472,879 |

Note: Data for 2026 represent the available administrative data up to the time of data extraction and should not be interpreted as a complete full-year total unless the dataset covered the entire year.

**Table 4**: Distribution of inspection visits by the Inspectors of the Ministry of Health since April 2023

| Institution type | Number of inspection visits | Total visits (%) |
|---|---|---|
| Pharmacies | 2,465 | 75.5% |
| Private wholesale drug stores | 562 | 17.2% |
| Scientific bureaus | 236 | 7.2% |
| Total | 3,263 | 100.0% |

Note: Percentages were calculated using the total number of inspection visits classified by institution type (n = 3,263).

## DISCUSSION

This study provides one of the first descriptive accounts of the implementation status, operational workflow, administrative outputs, and implementation challenges of the Gudea system. The findings show that the Gudea system is not merely a price medicine label or a verification application, but an integrated national digital regulatory platform linking medicine serialization, official price control, laboratory testing, customs-related information, field inspection, and public verification. The administrative indicators showed substantial system activity, including more than 1.8 billion official electronic labels, product registration and pricing, batch testing, import-related procedures, and inspection visits. Qualitative findings indicated a shift from paper-based regulation to electronic verification, especially in field inspection. However, implementation remains incomplete due to partial coverage, stakeholder cooperation issues, customs-release gaps, laboratory delays, and the need for wider integration with national digital systems. This role is consistent with international experiences showing that pharmaceutical track-and-trace systems are most effective when they function as integrated regulatory infrastructures across the medicine supply chain. Türkiye's Pharmaceutical Track and Trace System represents one of the most mature examples, with reported contributions to a cleaner, more regulated supply chain, reduced reimbursement fraud, rapid market recalls, and identification of potential medicine shortages [14]. Saudi Arabia's RSD system provides a relevant regional comparator, as it was introduced to monitor pharmaceutical products manufactured in or imported into Saudi Arabia, prevent counterfeit medicines, support drug availability, and improve drug safety and recall management [15]. However, recent stakeholder-based evidence from Saudi Arabia suggests that implementation outcomes may remain variable, with perceived improvements in traceability, inventory management, operational efficiency, and product safety, alongside technical, financial, and organizational challenges [16]. Therefore, the Iraqi experience may be interpreted as an emerging national digital regulatory model that shares the integrated regulatory logic of mature systems such as Türkiye's, while facing implementation challenges similar to those reported in the regional Saudi experience [14–16]. The Gudea system represents an important shift in pharmaceutical governance in Iraq by bringing previously fragmented regulatory procedures into a centralized digital framework, including product registration, import approvals, customs release, laboratory testing results, label delivery, official pricing, and field inspection. This integration may help the Ministry of Health monitor medicine movement, identify irregularities, and support regulatory enforcement more systematically. The centralized data generated through Gudea may also provide more accurate information on national medicine consumption patterns, supporting future planning, pharmaceutical supply management, and the development of the local pharmaceutical industry. This aligns with the global recommendations and emphasizes that medical-product traceability systems should be adapted to national regulatory and supply-chain needs while supporting interoperability and regulatory oversight. It is also consistent with international healthcare traceability standards, which highlight the role of structured data exchange in improving supply-chain visibility and inventory management [17,18]. The quantitative indicators show that serialization and official medicine labeling are central to Gudea implementation. More than 1.8 billion official medicine labels were supplied, including approximately 1.45 billion for imported products and 362.5 million for nationally manufactured medicines. In addition, 12,076 products were priced, and 10,044 active products were monitored with labels, indicating substantial regulatory coverage within the private pharmaceutical sector. The Gudea system also supports product authentication and price control by linking each labeled medicine to official pricing and product-specific regulatory data. The identification of more than 18.5 million irregular or suspected counterfeit labels suggests that the system contributes to detecting duplication, damage, price alteration, mismatch, and other forms of non-compliance. This finding is consistent with anti-counterfeiting literature showing that package-level labeling and verification technologies can support routine pharmaceutical authentication and field detection of suspected irregularities, particularly in resource-limited settings where complex analytical detection technologies may be difficult to implement at scale. However, such labeling should complement, not replace, laboratory quality testing [19,20]. The predominance of imported-product labels also provides insight into Iraq's private pharmaceutical market and the degree of reliance on imported medicines. Similar regulatory frameworks, such as the U.S. Drug Supply Chain Security Act and the European Union Falsified Medicines Framework, emphasize package-level identification and verification to strengthen supply-chain security. Therefore, Gudea may serve not only as an authentication and price-control tool but also as a national data source for pharmaceutical planning, supply management, and future support of local pharmaceutical manufacturing [21,22]. The Gudea system integrates laboratory testing, customs-related

information, label release, and field inspection within a single regulatory workflow. Official medicine labels are delivered only after the required laboratory and regulatory conditions are fulfilled, which may reduce unauthorized label use and strengthen pre-market control. The system recorded 78,817 tested batches and 3,263 inspection visits, indicating its role in both pre-market verification and post-market monitoring. Field inspectors reported that tablet-based access to customs release documents, laboratory results, label status, and official prices improved electronic verification and supported faster regulatory action. This aligns with evidence that effective track-and-trace implementation depends on regulatory coordination, stakeholder participation, and integration across the pharmaceutical supply chain [23]. Despite its substantial activity, the Gudea system remains partially implemented, with estimated coverage of 50–60% of private-sector imported and locally manufactured medicines. Main challenges include limited stakeholder cooperation, customs-release gaps, absence of pharmacists at some border points, and laboratory delays causing label accumulation, as reported in the key-informant interview. These barriers show that Gudea's effectiveness depends on institutional coordination, not only on the digital platform itself. Future priorities include expanding coverage, strengthening linkage with customs and ASYCUDA, improving inter-ministerial data exchange, and implementing the planned electronic prescription system. This is in line with what studies on drug traceability systems have found: that successful implementation depends on the readiness of the organization, the ability of the technology, the support of the regulations, the sharing of information, and the involvement of stakeholders across the pharmaceutical supply chain [24].

## Strengths and Limitations

To the best of our knowledge, this is the first study to describe the implementation status, operational workflow, administrative outputs, and implementation challenges of Gudea. A key strength is that the study draws on information from Ministry of Health personnel directly involved in the system's implementation and regulatory use. The integration of key-informant interviews with administrative quantitative indicators allowed the study to describe Gudea from both practical and administrative perspectives. This study also has limitations. The qualitative component was based on two key-informant interviews and may not capture the views of all relevant stakeholders, such as pharmacists, scientific bureaus, national manufacturers, customs personnel, and patients. The quantitative data were administrative and descriptive; therefore, they cannot establish causal effects or directly measure the impact of the Gudea on medicine availability, falsified medicines, price compliance, or patient outcomes. Because implementation is ongoing, the findings reflect the status of the system during the study period and may change as coverage and technical integration expand.

## Conclusion

This study described the implementation status, operational workflow, administrative outputs, and challenges of the Gudea system. The findings show that Gudea has developed beyond an official medicine label or verification application into a national regulatory platform that links medicine serialization, official pricing, laboratory testing, customs-related information, field inspection, and public verification. The qualitative and administrative findings indicate substantial system activity and a clear shift from paper-based procedures toward electronic regulatory verification, particularly in field inspection. However, implementation remains incomplete, with challenges related to partial coverage, stakeholder cooperation, customs-clearance gaps, laboratory delays, and the need for broader technical integration. Overall, the Gudea system represents an important national step toward strengthening medicine authentication, price transparency, and pharmaceutical regulatory oversight in Iraq. Future work should focus on expanding system coverage, improving institutional coordination, completing technical integration, and evaluating its impact on medicine safety, price compliance, and market regulation.

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### Conflict of interests

The authors declare no conflict of interest.

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### Data sharing statement

All data used in this systematic review were obtained from publicly available sources and are included in the references cited in this article. No new datasets were generated or analyzed beyond the published literature included in the review.

## REFERENCES


1. A study on the public health and socioeconomic impact of substandard and falsified medical products n.d. https://www.who.int/publications/i/item/9789241513432 (accessed April 28, 2026).
2. Iraq n.d. https://data.who.int/countries/368 (accessed May 18, 2026).
3. Iraqi Ministry of Health. Iraq pharmaceutical country profile 2020. Baghdad: 2020. Available at: https://moh.gov.iq/upload/1375.pdf
4. Al-Sudani: Iraq spends $3 billion dollars on imported medications - Shafaq News n.d. https://shafaq.com/en/Iraq/Al-Sudani-Iraq-spends-3-billion-dollars-on-imported-medications (accessed March 25, 2026).
5. Ahmed KK, Al-Jumaili AA, Aladul MI, Farhan MS, Al-Ghuraibawi FH, Al-Sayegh HF. Pharmacy education and practice in Iraq: expanding roles and fostering research. Int J Pharmacy Pract. 2026. doi: 10.1093/ijpp/riag072.
6. Kulkarni SR. Implementation of track and trace systems at pharmaceuticals industry Ltd. J Inform Syst Engineer Manag. 2025;10:834–841. doi: 10.52783/jisem.v10i19s.3120.
7. Rached S. Barriers to the implementation of a unique identifier and a track and trace system in the Lebanese pharmaceutical sector Lebanese American University. Thesis, 2022. doi: 10.26756/th.2022.427.
8. Al-Jumaili AA, Sameer HN. View of the insights of experienced pharmacists regarding the Iraqi health insurance program: A qualitative study. Iraqi J Pharm Sci. 2022;31(Suppl.):131-140. doi: 10.31351/vol31issSuppl.pp131-140.
9. Anonymous. Pharmaceutical Drug Regulatory Affairs Journal Challenges of Iraq Pharmaceutical Market Post-2003. n.d. Available at: https://www.researchgate.net/publication/338013459_Pharmaceutical_Drug_Regulatory_Affairs_Journal_Challenges_of_Iraq_Pharmaceutical_Market_Post-2003 (accessed May 24, 2026).
10. Al-Jumaili AA, Younus MM, Kannan YJA, Nooruldeen ZE, Al-Nuseirat A. Pharmaceutical regulations in Iraq: from medicine approval to postmarketing. *East Mediterr Health J*. 2021;27(10):1007-1015. doi: 10.26719/emhj.21.025.
11. Al-Jumaili AA, Younus MM, Saleh MZ. The epidemic of substandard and falsified medications in Iraq: Evaluating the effectiveness of national pharmacovigilance alerts to community pharmacies. *Pharm Med*. 2021;35:169–186. doi: 10.1007/s40290-021-00386-9.
12. Gudea. Gudea National Pharmaceutical Verification System: Official Website. Available at: https://gudea.gov.iq/ (accessed March 26, 2026).
13. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3:77–101. doi: 10.1191/1478088706qp063oa.
14. Parmaksiz K, Pisani E, Kok MO. What makes a national pharmaceutical track and trace system succeed? lessons from turkey. *Glob Health Sci Pract*. 2020;8:431–441. doi: 10.9745/GHSP-D-20-00084.
15. Drug Track and Trace System (RSD). The official website of the Saudi Food and Drug Authority. Available at: https://www.sfda.gov.sa/en/eservices/65904 (accessed May 17, 2026).
16. Almutairi M, Alyousef A, Alduraywish W, Hafiz R, Almutairi K, Alturki M. The impact of implementing the drug-tracking system on operational efficiency in the Saudi healthcare supply chain. *Saudi J Health Syst Res*. 2026:1–13. doi: 10.1159/000551453.
17. Anonymous. Policy paper on traceability of medical products. Available at: https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products (accessed May 17, 2026).
18. Anonymous. Healthcare traceability and GS1 standards. Available at: https://www.gs1.org/industries/healthcare/traceability (accessed May 17, 2026).
19. Zhang H, Hua D, Huang C, Samal SK, Xiong R, Sauvage F, et al. Materials and technologies to combat counterfeiting of pharmaceuticals: Current and future Problem tackling. *Adv Mater*. 2020;32. doi: 10.1002/adma.201905486.
20. Bolla AS, Patel AR, Priefer R. The silent development of counterfeit medications in developing countries – A systematic review of detection technologies. *Int J Pharm*. 2020;587. doi: 10.1016/j.ijpharm.2020.119702.
21. FDA. Drug Supply Chain Security Act (DSCSA). Available at: https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa (accessed May 17, 2026).
22. European Commission. Falsified medicines - Public Health - European Commission. Available at: https://health.ec.europa.eu/medicinal-products/falsified-medicines_en (accessed May 17, 2026).
23. Kootstra J, Kleinhout-Vliek T. Implementing pharmaceutical track-and-trace systems: a realist review. *BMJ Glob Health*. 2021;6:3755. doi: 10.1136/bmjgh-2020-003755.
24. Da Silva RB, de Mattos CA. Critical success factors of a drug traceability system for creating value in a pharmaceutical supply chain (PSC). *Int J Environ Res Public Health*. 2019;16:1972. doi: 10.3390/ijerph16111972.