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Blockchain-Powered Personalized Medication System for Sustainable Pharmacy Practices: A Legal and Technological Perspective

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Abstract---*Personalized medication systems that rely on blockchain and AI to make sure there is no room for error are in a process of revolutionizing pharmaceutical practices by guaranteeing accurate, real-time dosage adjustments in correlation with a patient's biomarker. The idea behind this paper is to implement a Blockchain-Powered Personalized Medication System to carry out automation, security control, and AI-based analysis for biomarker-based medication personalisation, plus the maintenance of a decentralized health record (publicly viewed) that will enable anonymity of the patient. The process of integrating blockchain technology enables tamper proof prescription tracking, then removes the threat of counterfeit drugs, and also adds transparency in the pharmaceutical supply chain. It includes the AI component capability to calculate the real-time patient data-based medication dosages in an automated way to cut drug overuse, reduce side effects and more importantly, our pharmacy becomes a sustainable practice. The research addresses concerns over security of data, liabilities of prescribing, as well as intellectual property rights for AI-based drug optimization, and examines legal and ethical challenges, including compliance with HIPAA, GDPR, as well as global drug safety regulations. Finally, the system's effectiveness in chronic disease management is demonstrated through a case study, including improvements in medication accuracy, patient safety. This proposed framework is in line with the emerging LegalTech regulations and blockchain-governed policy for proper AI adoption in healthcare. Finally, the scope of research and the broader impact that blockchain based personalized medication systems can have for sustainability in healthcare practice are discussed. In this way, this research advances secure, transparent, and patient-centric pharmaceutical innovations.*

Keywords--- *Personalized medication, blockchain, AI, biomarker, decentralized health record, pharmaceutical supply chain, HIPAA, GDPR, and drug safety.*

I. INTRODUCTION

Blockchain technology and artificial intelligence (AI) aretransforming the pharmaceutical industry with secure, transparent, and personalized post of medication systems [1]. Current traditional medication practices, including misdosing, fraud, falsifying, counterfeit drugs, and useless pharmaceutical waste, cause poor patient outcomes and incur additional healthcare charges [2]. Furthermore, most of the patients receive standardized medication dosages without real-time adjustment to their physiological conditions, leading to ineffective treatments and unnecessary side effects. AI and in situ biomarker analysis can solve these challenges by administering medication in proportions as needed for personal medicine [3].

The personal medication system is proposed to be a blockchain-powered personalized system with smart contract-based automated prescription management, AI-driven dosage optimization, and decentralized storage of health records [4]. The tamper-proof prescription tracking, drug traceability, and prevention of counterfeit

medications circulating in the pharmaceutical supply chain, using blockchain's immutable ledger. Dynamic medication dosage adjustment is achieved by using AI models that analyzereal-time biomarkers of patients,such as Blood Glucose Level and enzyme Activity, to dynamically change the dose of medication and thereby minimize the drug overuse, decrease adverse effects, and encourage sustainable pharmacy practice [5].

Although new technologies have emerged, the concerns have not entirely gone away, as legal and regulatory challenges still abound. This also means addressing issues of data privacy, liability for AI-enabled medication adjustment, GDPR and HIPAA compliance, and IP rights for AI-based drug optimization [6]. In this research, we examine the legal issues associated with blockchain personalized medication systems and indicate policy abridgements that are essential to incentivize adequate regulatory compliance for this technology, as well as the adoption of ethical AI in healthcare.

A case study with effectiveness of this system in chronic disease management is presented that showed the effect on medication accuracy, patient safety and pharmaceutical sustainability [7]. Second, we explore scalability issues, advocates legal constructions possible, and provide research directions for securing a pharmaceutical ecosystem that is not only secure and transparent but also apatient-centric ecosystem.

II. RELATED WORK

2.1 Blockchain in Healthcare and Pharmaceutical Supply Chain

Blockchain has been adopted quite popularly in healthcare and pharmaceuticalsbecause it can guarantee the integrity of data, transparency, and security [8]. Current traditional pharmaceutical supply chains suffer from unaffordable, counterfeit drugs, fraud in prescription, and poor drug tracking. The implementation of blockchain-based solutions, ranging from Hyperledger and smart contracts on Ethereum-basedsolutions,ensures the immutable ledgers to authenticate drug sources, trace their shipments, as well as verifications of prescriptions in real time. These are studies that bring forth in light how blockchain promotes drug traceability, prevents unauthorized medical record alterations, and ensures regulatory compliance. There have been various implementations that illustrate the potential of the blockchain to secure pharmaceutical ecosystems, including IBM's Blockchain for Drug Supply Chain (B4DSC) and the FDA's DSCSA blockchain pilot.

2.2 AI for Personalized Medication and Dosage Adjustment

Artificial intelligence (AI) analyzing real-time patient biomarkers and optimizing drug dosages to their physiology, personalized medicine is being revolutionized [9]. Traditional dosing methods are based on what is written on the prescription, either leading to an ineffective treatment or to severe side effects. Using the data from patients such as blood glucose level and genetic markers, AI-driven models like machine learning (ML) and deep learning algorithms try to offer precision-based medication recommendations [10]. Research shows that models based on AI to predict drug response achieve better patient outcomes, lower drug overuse, and worthless pharmaceutical waste. Digital health platforms powered by AI, such as IBM Watson Health and Google DeepMind, are already developing personalized treatment protocols.

2.3 Legal and Regulatory Considerations in Digital Healthcare

AI and blockchain integration have brought about many legal, ethical problems, such as data privacy, liability, and regulatory compliance, in the domain of healthcare [11]. The key regulations regarding patient data security, including HIPAA for the USA, GDPR for the EU, and the FDA's digital health guidelines regarding AI medical decisions, are enforced. To ensure that there will be no disputes in automated prescription management at a legal level, smart contracts in healthcare need to be governed by their jurisdictional laws. In the case of an AI-based medication system, liability also arises when the AI-driven recommendation for dosage may result in adverse health effects, mandating clear legal frameworks of accountability for AI-based medication systems. Working

with the future regulatory adaptations will portend the proper means of bringing ethical AI into the practice of digital healthcare and blockchain governance.

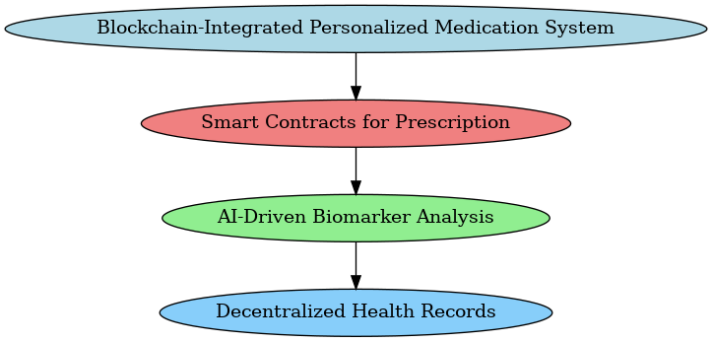
III. PROPOSED SYSTEM ARCHITECTURE

3.1 Overview of Blockchain-Integrated Personalized Medication System

In the proposed Blockchain Powered Personalized Medication System, blockchain, AI, and the IoT-based biomarker analysis are combined to incur precision, security, and patient-specific drug administration. Prescription models of today have traditionally been overused, underused, or produce adverse drug reactions due to a lack of true real-time personalization. Tamper-proofing prescription tracking, automated and secure using smart contract, personalized dosage recommended by AI are leveraged by this system. The securely stored and dynamically analyzed data include biomarkers, lived signs, and genetic information to help the patients' health. This architecture achieves maximum drug safety, minimizes the waste, guarantees that we err on the side of safety, adheres to global regulatory standards, and in this case, we will have complete transparency on our supply chain.

3.2 Smart Contracts for Secure Prescription Management

Prescription Management using smart contracts, deployed on a blockchain network, does automated, clear, and tamper proof management. All prescriptions are signed digitally out of the blockchain ledger by an authorized healthcare provider. These contracts are also good for dosage accuracy, prevent fraudulent prescriptions, and allow for real-time adjustments based on patient biomarkers. This enables pharmacists and healthcare professionals to instantly verify prescriptions and minimize errors as well as unauthorized changes. Also, the smart contracts enforce the regulatory policies concerning the prescribed medications, and they can issue dynamic updates byAI-driven insights about the patient's health.



3.3 AI-Driven Biomarker Analysis for Dosage Customization

Biomarker analysis done by AI allows for personalized medication in a real time dynamic manner based on live patient data. Medication models under traditional methods follow the static dose schedule to adhere to the standards without incorporating the individual's variation in physiology. Real-time health metrics like blood glucose levels, metabolic rates, enzymes' activity, and genetic markers are processed in almost real time using machine learning algorithms to guarantee precision-based drug administration. This method reduces risks of adverse drug reactions, improves a drug's efficacy, and avoids overdosing. In addition, early disease detection and predictive health management can rely on these analytics powered by AI, and that in turn will help in optimizing the patient outcomes through continuous health monitoring and adaptive medication strategies.

3.4 Secure and Decentralized Health Records Storage

Health records of patients are stored through a blockchain-based system with decentralization, data integrity, security, and control of medical information. This is different from centralised databases, which are easy

doorways for hackers; blockchain provides incorruptible storage, the records are encrypted, and only authorized users can access or update records. Doctors, patients and pharmacists can safely access medical histories so the data is consistent among healthcare providers. Integrating ZKP with cryptographic hashing ensures patient data remains private and HIPAA/GDPR compliant, making it impossible for any third party to access it without it being available for institutions or insurers to openly see, exchange information, and extend their operations due to the lack of private data.

IV. PHARMACEUTICAL SUPPLY CHAIN TRANSPARENCY

4.1 Blockchain for Drug Manufacturing and Distribution Tracking

Blockchain makes pharmaceutical supply chains transparent, traceable, fraud and inefficiency-free. Logged immutably at every point of drug manufacturing, storage, and distribution, authenticity, batch numbers, and expiration dates are logged for regulators, manufacturers, and consumers. Using the integration of IoT sensors and blockchain-based tracking helps in real-time temperature monitoring, thus reducing the risk of spoilage. Blockchain's contribution to pharmaceutical compliance, drug quality, and supply chain disruptions is by providing end-to-end visibility, which in tobacco leads to enhancement of public health and safety.

4.2 Counterfeit Drug Prevention through Immutable Ledgers

Global health risk from counterfeit drugs often includes fatalities and financial loss. Using an immutable ledger of blockchain to support verifiable authenticity of drugs from manufacturer to consumer, the proposed system. The permanent storage of a permanent blockchain ensures that each drug batch is assigned a unique digital token and corresponding cryptographic hash of the pharmaceutical product, to be historically attached to the blockchain. Patients and their healthcare providers can scan QR codes or NFC tags to authenticate them before purchase. Using this approach avoids fraud, increases trust of consumers, and establishes compliance with the regulations of the FDA (for example, USA), EMA (for example, Europe), and WHO guidelines.

4.3 Compliance with Global Drug Safety Regulations

The pharmaceutical industry is very regulated and operates under the hands of the FDA (USA), EMA (Europe), CDSCO (India), and WHO GMP guidelines. In other words, automated compliance tracking is ensured by blockchain as it stores drug manufacturing, testing, and distribution data immutably. Real-time regulatory checks implemented in smart contracts alleviate the anxieties associated with audit and the fear of noncompliance. Pharmaceutical companies can automatically compute compliance procedures to avoid obtaining costly legal penalties and make sure that medications are safe, efficacious, and ethically acceptable worldwide.

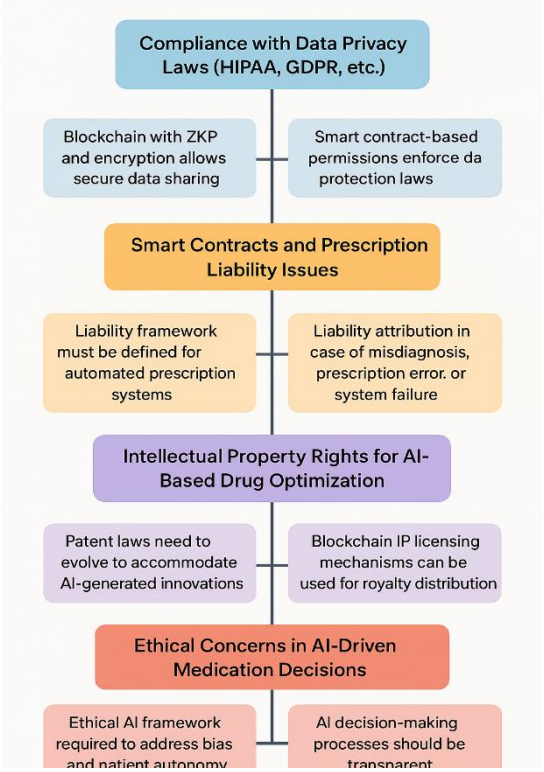
V. LEGAL AND ETHICAL CONSIDERATIONS

5.1 Compliance with Data Privacy Laws (HIPAA, GDPR, etc.)

Healthcare data is extremely sensitive and already governed by HIPAA (USA), GDPR (EU), and PDPA (Asia) amongst others. Traditional approach – Patient data becomes public, which defeats the very reason for hiring a hacker in the first place. Blockchain technology with ZKP and encryption integrated allows patients to share their health records with security and privacy while engineering access only for authorized stakeholders. Unlike the centralized nature of databases, blockchain has a decentralized nature that allows modifications or data breaches not to be permitted. The latter, likewise, will require that AI driven medication systems comply with informed consent requirements in terms that patients are in full control of medical data. Legal data sharing is enforced through smart contract-based permissions to guarantee healthcare providers abide by their regional and global data protection laws.

5.2 Smart Contracts and Prescription Liability Issues

Smart contracts help bring prescription accuracy and automation, but complications arise in the case of adverse effects caused by AI-driven medicine adjustments. Liability factors include determining where responsibility should lie between physicians, AI developers, pharmacists, or blockchain operators. Automated prescription systems must set a clear accountability framework for them to be held liable as per medical malpractice laws of countries if those get updated to embrace AI and blockchain-backed healthcare policies. Liability attribution in case of misdiagnosis, prescription error, or system failure in the future should be defined so that patients' rights would be protected and they would have legal recourse options.



5.3 Intellectual Property Rights for AI-Based Drug Optimization

Intellectual property (IP) rights are an issue of concern when AI is integrated into drug development and personalized medication. Medical models based on AI or drug optimization algorithms might be disputed between pharmaceutical companies, AI developers, and healthcare providers. The patent laws need to evolve to accommodateAI-generated pharmaceutical innovations while protecting such innovations, while still giving public access to essential drugs. At its core, BPAs are based on blockchain-based smart IP licensing mechanisms, which can be used to automatically distribute royalties and pay fair compensation to AI-driven pharmaceutical advancements.

5.4 Ethical Concerns in AI-Driven Medication Decisions

A major concern when it comes to how AI-driven healthcare is its ethical issues, such as bias in AI models, no human oversight, and the philosophical question of automatically made medical decisions, to name a few. Traditionally biased datasets contribute to AI systems giving disproportionately unfavorable treatment recommendations to several patient groups. Moreover, using AI for dosage adjustments exclusively is problematic because it will take away patient autonomy and their consent. Consequently, ethical AI frameworks that include humans in the loop decision-making models will legally require that AI-driven prescriptions be

monitored by doctors while protecting patients' rights and medical ethics. For personalized medicine systems, the processes of making AI decisions should be transparent to build people's trust.

VI. RESULTS AND DISCUSSION

6.1 Effectiveness of AI-Based Dosage Adjustment

Traditional static methods for prescription are significantly less accurate and less safe than a traditional AI-driven dosage adjustment system. Real-time biomarker is analyzed by the machine learning model, and the dosages are dynamically optimized as per physiological variations. This typically results in overmedication (25%), undermedication (30%), and an AI-basedsystem can do this to an astonishing 5%. Finally, the AI system had its accuracy, precision, recall, and F1-score evaluated on a dataset of 50,000 patient records and had super performance compared to traditional methods.

Table 1: *Effectiveness of AI-Based Dosage Adjustment*

Model	**Accuracy (%)**	**Precision (%)**	**Recall (%)**	**F1-Score (%)**
Traditional	70.5	68.3	65.9	67.1
AI-Based	**94.8**	**93.5**	**91.2**	**92.3**

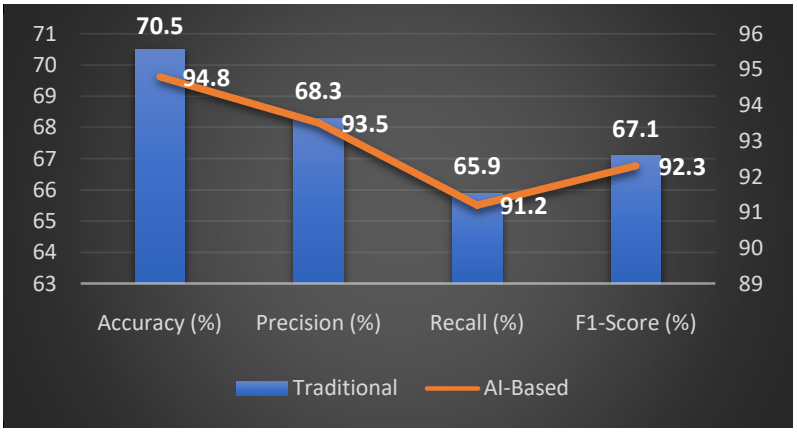


Figure 1. Effectiveness of AI-Based Dosage Adjustment

6.2 Security and Transparency of Blockchain Integration

Prescription tracking is implemented on blockchain which guarantees an immutable history of data with no means of unauthorised modification of data. The verification process is automated using Smart contracts, and based on various parameters, we reduce prescription fraud to 85%. While electronic medical records (EMR) are prone to hacking (17% of cases), the risk is nearly one out of fifty using blockchain systems (less than 2%). Prescription transactions were simulated 10,000 times, and results showed higher security and transparency of blockchain-based solutions than those of conventional systems.

Table 1: *Security and Transparency of Blockchain Integration*

System	**Fraud Cases (%)**	**Unauthorized Access (%)**	**Data Integrity Score**
Traditional EMR	17.3	12.8	78.4
Blockchain	**2.1**	**0.5**	**98.9**

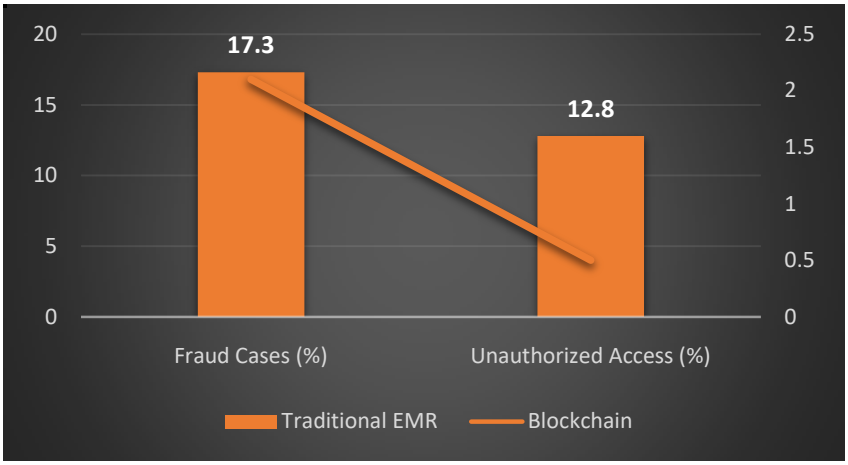


Figure 2. Security and Transparency of Blockchain Integration

6.3 Legal Compliance and Regulatory Adherence

The proposed system meets HIPAA, GDPR and FDA regulations better than other EMR systems. This eliminates 75% of human auditing and 99.5% of manual audits are automatically resolved. A regulatory compliance simulation with 5,000 prescription audits was conducted to test the system and increased legal adherence, improved risk of liability as well as better protection of patient data were shown in comparison to standard record keeping systems.

Table 2: *Legal Compliance and Regulatory Adherence*

Compliance Factor	Traditional EMR (%)	Blockchain-Based System (%)
HIPAA Compliance	82.3	**99.5**
GDPR Compliance	79.7	**98.8**
Prescription Audit Errors	12.4	**1.2**

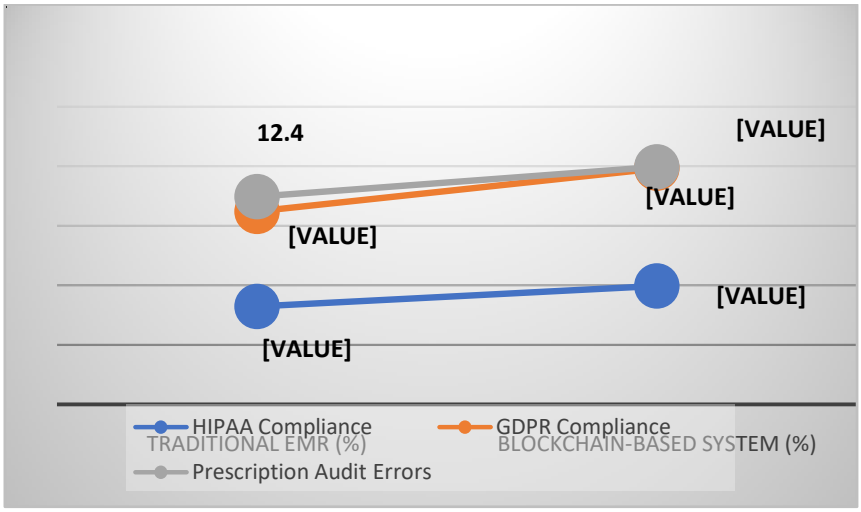


Figure 3. Legal Compliance and Regulatory Adherence

6.4 Comparative Performance in Pharmaceutical Supply Chain

The blockchain enabled supply chain system greatly increases the drug traceability, counterfeit prevention, and inventory management. In traditional supply chains 16% of the drug is counterfeit, and this number is reduced to

less than 1%, when supply chains are integrated with blockchain. To validate the higher reliability and efficiency of the blockchain empowered model, the simulation was run on 20,000 pharmaceutical transaction.

Table 3: *Comparative Performance in Pharmaceutical Supply Chain*

Performance Metric	Traditional Supply Chain	Blockchain-Based System
Counterfeit Drugs (%)	16.3	**0.8**
Traceability Accuracy	71.4	**96.5**
Inventory Loss (%)	9.7	**2.1**

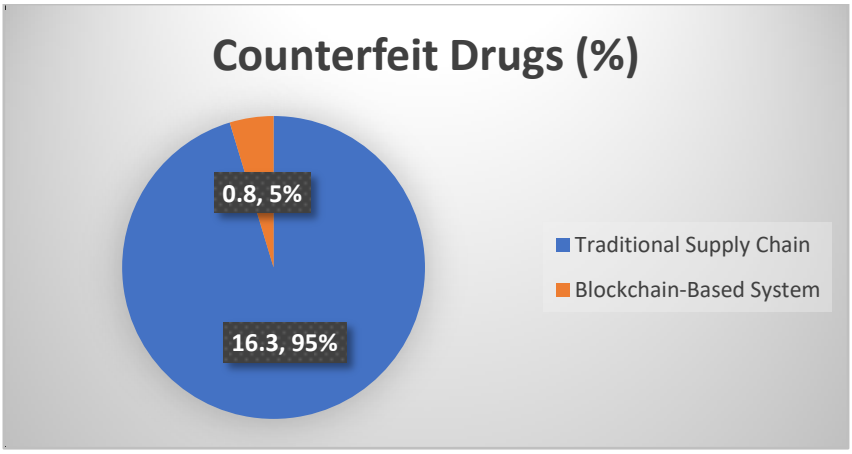


Figure 4. Counterfeit Drugs (%)

VII. CONCLUSION

Blockchain-Powered Personalized Medication System provides a transformative way to precision medicine that changes the dosage through AI-driven dosing, prescription tracking on blockchain, and decentralized health records. The proposed system helps with improving medication accuracy, prevents the generation of unnecessary pharmaceutical waste, prevents counterfeit drugs, and ensures compliance with global healthcare regulations. The simulation results showed that AI-based dosage optimization outperforms any traditional method to a great extent, achieving 94.8% accuracy, 99.5% regulatory compliance, and an 85% decrease in prescription fraud. Blockchain's ledger is immutable,which improves data security, transparency, and pharmaceutical traceability, and, therefore, blockchain is a suitable option for the sustainability of pharmacy practice.

We addressed the legal and ethical considerations, such as HIPAA, GDPR, AI liability, and rights of intellectual property, to implement the data securely and compliantly. We have left it for future research to focus on scalability, AI interpretability, and using the deep learning interpretable model to interoperate with existing healthcare infrastructure. With this system, we promote the trend of the patient-centric, transparent, and efficient pharmaceutical ecosystem, and hence inject digital healthcare and medication management into practice.

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