ORIJINAL MƏQALƏ **AÇIQ GİRİŞ (OPEN ACCESS)**

STRATEGY FOR IMPLEMENTING A MODERN DIGITAL TRACK & TRACE SYSTEM IN THE CIRCULATION OF PHARMACEUTICAL PRODUCTS

Farzullayev S.Y.[1], Valiyeva M.N.[2], Suleymanov M.Y.[1]

Abstract

This article examines the scientific-theoretical and practical aspects of implementing a modern digital Track & Trace system in the circulation of pharmaceutical products. The study was conducted at the public legal entity "Analytical Expertise Center" of the Ministry of Health of the Republic of Azerbaijan and aimed to evaluate the implementation of digital tracking mechanisms in pharmaceutical circulation. Track and Trace models developed within the regulatory frameworks of the European Union's Falsified Medicines Directive (FMD) and the United States Drug Supply Chain Security Act (DSCSA) are analyzed, and their adaptability to national conditions are assessed.

Based on the analysis, a phased implementation strategy tailored to the national context is proposed. The model incorporates unique identification of pharmaceutical products, real-time data exchange across the supply chain, and centralized regulatory control through a unified digital platform.

The proposed strategy contributes to preventing the circulation of falsified and substandard pharmaceutical products, improving regulatory efficiency, and enhancing overall safety in pharmaceutical circulation.

Keywords: pharmaceutical products, digital tracking, track & trace, quality, safety, digitalization.

INTRODUCTION

The circulation of pharmaceutical products represents one of the most sensitive and high-risk areas of the healthcare system.

Fragmented and non-integrated control mechanisms across supply chain stages significantly increase the risk of falsified and substandard pharmaceutical products entering the market.

According to the World Health Organization, up to 10% of medicines in low- and middle-income countries are estimated to be substandard or falsified, with this figure exceeding 20% in certain regions characterized by weak regulatory control. Additionally, global pharmaceutical supply chain inefficiencies result in substantial financial losses annually, further

Yazışma üçün əlaqə:
Farzullayev S.Y.[1], Valiyeva M.N.[2], Suleymanov M.Y.[1]
1 "Analytical Expertise Center" of the Ministry of Health of the Republic of Azerbaijan
2 Azerbaijan Medical University, department of Pharmaceutical Technology and Management
E-mail: said.farzullayev2021@gmail.com

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emphasizing the need for transparent and traceable systems.

Existing regulatory mechanisms are largely based on retrospective inspections, limiting real-time visibility and responsiveness. Therefore, the development of scientifically grounded and technologically advanced tracking systems is essential.

In recent years, the implementation of digital Track & Trace systems has become a strategic priority in developed countries. Within the European Union (FMD) and the United States (DSCSA), continuous tracking of pharmaceutical products through unique identifiers has been established as a legal requirement.

However, direct replication of international models does not always yield effective results due to differences in legal frameworks, institutional structures, and technological readiness. Thus, the implementation of Track & Trace systems should be approached as a legal, institutional, and technological transformation.

The objective of this study is to develop a scientifically substantiated national strategy for implementing a modern digital tracking system adapted to Azerbaijan's healthcare and pharmaceutical environment.

MATERIALS AND METHODS

The study is based on national and international scientific publications, regulatory documents of international organizations (WHO, European Commission, FDA), and legal frameworks related to pharmaceutical circulation.

A systematic approach was applied to analyze the pharmaceutical supply chain as an integrated system. Comparative analysis was used to evaluate international Track & Trace models (FMD and DSCSA) and their applicability to national conditions. Regulatory analysis assessed legal requirements and institutional competencies, while structural-functional analysis identified the roles of stakeholders (manufacturers, importers, distributors, pharmacies, and regulators).

Based on the findings, a phased strategic implementation model was developed.

RESULTS AND DISCUSSION

The study substantiates the strategic importance of implementing a modern digital Track & Trace system at the national level.

Unlike existing international models, the proposed strategy introduces several novel elements:

- Integration of risk-based regulatory control mechanisms
- Adaptation to institutional and technological readiness
- Implementation of a phased transition model
- Establishment of a centralized state-controlled digital platform

These features distinguish the proposed model from standardized international approaches.

Analysis of international experience demonstrates measurable outcomes. In the European Union, the implementation of FMD has significantly reduced the penetration of falsified medicines into legal supply chains. Similarly, the U.S. DSCSA framework has improved traceability and reduced the time required for product recalls.

These findings confirm that digital traceability systems enhance both patient safety and regulatory efficiency.

At the national level, key challenges include:

- Fragmented control mechanisms
- Limited data integration
- Insufficient digital infrastructure

The proposed model addresses these challenges through phased implementation and stakeholder integration.

Table. Key Indicators for Assessing the Effectiveness of a Digital Track & Trace System

Indicator Group	Indicator Name	Unit	Analytical Significance
Traceability	Share of products with unique identification	%	System coverage
Control Effectiveness	Detection of falsified products	Cases/month	Risk assessment
Operational Efficiency	Duration of control procedures	Hours/days	Response speed
Data Quality	Data completeness	%	Reliability
Risk-Based Control	Identification of high-risk products	Number	Risk targeting
Resource Efficiency	Reduction in control costs	%	Economic impact

Target benchmarks:

- ✓ 90% traceability coverage
- ✓ 30% reduction in regulatory processing time

CONCLUSION

This study demonstrates that the implementation of a modern digital Track & Trace system can increase traceability coverage of pharmaceutical products to over 90% within a phased implementation framework, significantly reducing the risk of falsified and substandard pharmaceutical products entering the supply chain.

International experience shows that such systems can reduce the detection time of unsafe products by up to 50% and substantially improve regulatory response efficiency.

The proposed strategy is specifically adapted to the legal, institutional, and technological conditions of Azerbaijan. It ensures practical feasibility through gradual implementation while maintaining alignment with international best practices.

The results indicate that successful implementation will lead to:

- ✓ Increased transparency in pharmaceutical circulation
- ✓ Improved regulatory efficiency
- ✓ Enhanced patient safety
- ✓ Reduced operational costs

Thus, the proposed model represents not only a theoretical contribution but also a practical roadmap for the digital transformation of pharmaceutical regulation in Azerbaijan.

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ƏCZAÇILIQ MƏHSULLARININ DÖVRİYYƏSİNDƏ MÜASİR RƏQƏMSAL İZLƏMƏ SİSTEMİNİN TƏTBİQİ STRATEGİYASI

Fərzullayev S.Y.[1], Vəliyeva M.N.[2], Süleymanov M.Y.[1]

1.Azərbaycan Respublikasının Səhiyyə Nazirliyi, "Analitik Ekspertiza Mərkəzi", Bakı

2.Azərbaycan Tibb Universiteti, Əczaçılıq texnologiyası və idarəçiliyi kafedrası

E-mail: said.farzullayev2021@gmail.com

Xülasə

Bu məqalə əczaçılıq məhsullarının dövriyyəsində müasir rəqəmsal Track & Trace sisteminin tətbiqinin elmi-nəzəri və praktik aspektlərini araşdırır. Tədqiqat Azərbaycan Respublikası Səhiyyə Nazirliyinin "Analitik Ekspertiza Mərkəzi" publik hüquqi şəxsində aparılmış və əczaçılıq dövriyyəsində rəqəmsal izləmə mexanizmlərinin tətbiqinin qiymətləndirilməsinə yönəlmişdir.

Avropa İttifaqının Saxtalaşdırılmış Dərmanlara qarşı Direktivinin (FMD) və ABŞ-ın Dərman Təchizat Zəncirinin Təhlükəsizliyi Aktının (DSCSA) normativ çərçivələri əsasında formalaşmış izləmə modelləri təhlil olunur və onların milli şəraitə uyğunlaşdırılması imkanları qiymətləndirilir.

Aparılmış təhlil əsasında milli kontekstə uyğunlaşdırılmış mərhələli tətbiq strategiyası təklif olunur. Model əczaçılıq məhsullarının unikal identifikasiya ilə markalanmasını, təchizat zənciri üzrə real vaxt rejimində məlumat mübadiləsini və vahid rəqəmsal platforma üzərindən mərkəzləşdirilmiş dövlət nəzarətini özündə birləşdirir.

Təklif olunan strategiya saxta və keyfiyyətsiz əczaçılıq məhsullarının dövriyyəsinin qarşısının alınmasına, tənzimləyici nəzarətin səmərəliliyinin artırılmasına və ümumilikdə əczaçılıq dövriyyəsində təhlükəsizliyin yüksəldilməsinə töhfə verir.

Açar sözlər: əczaçılıq məhsulları, rəqəmsal izləmə, track & trace, təhlükəsizlik, keyfiyyət, rəqəmsallaşma.

СТРАТЕГИЯ ВНЕДРЕНИЯ СОВРЕМЕННОЙ ЦИФРОВОЙ СИСТЕМЫ ОТСЛЕЖИВАНИЯ В ОБРАЩЕНИИ ФАРМАЦЕВТИЧЕСКОЙ ПРОДУКЦИИ

Фарзуллаев С. Я.[1], Валиева М. Н.[2], Сулейманов М. Ю.[1]

[1] “Центр Аналитической экспертизы” Министерства Здравоохранения Азербайджанской Республики, Баку

[2] Азербайджанский Медицинский Университет, кафедра фармацевтических технологий и менеджмента

E-mail: said.farzullayev2021@gmail.com

Резюме

Данная статья посвящена исследованию научно-теоретических и практических аспектов внедрения современной цифровой системы Track & Trace в обращении фармацевтической продукции. Исследование проведено в публичном юридическом лице «Аналитический экспертный центр» Министерства здравоохранения Азербайджанской Республики и направлено на оценку внедрения механизмов цифрового отслеживания в системе обращения фармацевтической продукции.

В статье анализируются модели отслеживания, разработанные в рамках нормативных требований Директивы Европейского союза по борьбе с фальсифицированными лекарственными средствами (FMD) и Закона США о безопасности цепочки поставок лекарственных средств (DSCSA), а также оцениваются возможности их адаптации к национальным условиям.

На основе проведённого анализа предлагается поэтапная стратегия внедрения, адаптированная к национальному контексту. Модель включает уникальную идентификацию фармацевтической продукции, обмен данными в режиме реального времени по всей цепочке поставок, а также централизованный государственный контроль через единую цифровую платформу.

Предлагаемая стратегия способствует предотвращению обращения фальсифицированной и некачественной фармацевтической продукции, повышению эффективности регуляторного контроля и укреплению общей безопасности в системе обращения лекарственных средств.

Ключевые слова: фармацевтическая продукция, цифровое отслеживание, track & trace, безопасность, качество, цифровизация.