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Policy Brief

Enhancing Transparency in the Public Pharmaceutical Sector to Reduce Corruption While Increasing Trust: A Policy Brief for a Developing Country

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Abstract

Transparency plays a pivotal role in good governance and is a key tool for achieving it. As the pharmaceutical sector is considered a critical component of the health governance framework, evaluating its performance and providing policy recommendations can remarkably contribute to this goal. Therefore, a policy brief was prepared using qualitative data from our previous study that evaluated transparency in Iran's pharmaceutical regulatory sector. Twenty-one semi-structured interviews were conducted in the mentioned study between November 2016 and July 2017, and its quantitative results have been published previously. To update the data, current laws and regulations were also reviewed to understand the context in 2024. In addition, the main findings and suggestions of Esfandiari et al (2021)were meticulously reviewed to help improve the recommendations. The policy recommendations derived from the interviewees' discussions confirmed the necessity of creating and implement more transparent guidelines, enhancing accountability mechanisms, mandating the transparency of clinical trials, establishing evidence-based selection processes, and implementing transparent procurement systems.

Keywords: Transparency, Pharmaceutical sector, Good governance, Policy recommendations, Developing countries

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Introduction

Governance refers to decision-making and policy implementation, and when aligned with core principles of good governance and ethical standards, it fosters social well-being and economic development across sectors like health, education, and the like (1). Transparency, which refers to openness about governmental structures, functions, policies and public sector accounts, is an essential element of good governance (2).

Consistent with this perspective, good governance in the pharmaceutical sector is enhanced by transparency, thereby helping in monitoring and evaluating the performance of pharmaceutical policies and practices (3). In fact, transparency measures help identify and reduce corruption at various decision points, ensuring that resources are used effectively and ethically (4). In addition, transparency is essential for building trust between pharmaceutical companies, healthcare providers, and patients by making processes and decisions clear and understandable (5). Therefore, implementing transparency is not just a regulatory requirement but a fundamental necessity for the pharmaceutical sector (6). Apparently, Iran has sufficient capacities to enhance transparency in its medicine regulatory sector (7). Accordingly, this policy brief synthesizes findings from the authors' previous research, with a focus on several key studies and reports regarding improving transparency in various countries (6-9). This policy brief aims to offer actionable recommendations to enhance transparency based on the evaluation of the pharmaceutical regulatory sector in Iran, which can also be utilized by other developing countries (7).

Methods

This policy brief is based on a comprehensive analysis of qualitative data from two previous studies conducted in Iran in 2020 and 2021 (7, 8). Data from these two existing studies, including surveys and interviews with key stakeholders in the relevant field, were utilized, and current laws and regulations were reviewed to understand the present context. The data were then analyzed by a thematic analysis using the MaXQDA version 2020. The analysis for this policy brief was conducted from January to March 2024. A set of proposed policies aimed at addressing the identified issues were developed based on the evaluation of the current situation and the findings from these studies.

Results

This policy brief offered actionable recommendations

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to enhance transparency based on the evaluation of the pharmaceutical regulatory sector in Iran (7). In this regard, the evaluation of transparency in the pharmaceutical system using the MeTA tool and method was conducted in eight pharmaceutical sectors in Iran (9), including the registration of medicines, licensing of pharmaceutical business, inspection of establishments, medicine promotion, clinical trials, selection of essential medicines, procurement of medicines, and distribution of medicines. Due to overlaps, they were grouped into five categories, for which specific recommendations were provided. The medicine promotion sector was not addressed, as a result of insufficient qualitative responses to open-ended questions in this domain.

- **In Registration and Licensing Sector**, there are significant gaps in transparency, with conflicting criteria and lack of public access to information (7). Thus, clear and publicly accessible guidelines and standards are necessary to prevent corruption, ensuring fair competition (8).
- **Inspection Processes** are frequently opaque, with limited accountability, leading to unchecked regulatory violations (7). Therefore, transparent inspection processes and regulation of promotional activities are crucial to prevent unethical practices and ensure compliance with standards (8).
- **Processes of Clinical Trials** and their reporting lack enough transparency, which can question their validity (7). Hence, the mandatory registration of clinical trials is necessary, as well as the publication of results, in order to enhance transparency and trust in clinical research (8).
- **Selection of Essential Medicines** is often influenced by non-scientific factors, resulting in less effective or more expensive medicines, impacting public health outcomes (7). Accordingly, it is recommended that clear, evidence-based criteria with stakeholder involvement and public disclosure be established for selecting essential medicines (8).
- **Lack of transparency** leads to corruption and inefficiencies in procurement and distribution systems, thereby raising the costs while reducing the availability of essential medicines (7). Thus, implementing transparent procurement processes, including e-procurement systems (e.g., tracing tracking and authentication control) can reduce corruption while improving efficiency (8, 9).

Discussion and Conclusion

The findings of this study highlight the necessity of transparency, clear guidelines, and accountability in regulatory processes for developing countries, including Iran. Therefore, policy recommendations will be discussed as follows:

Developing and Implementing Transparent Guidelines

Developing a more comprehensive guideline for the registration, licensing, and inspection of pharmaceutical products is highly recommended. These guidelines should be publicly accessible.

Action Steps

1. Representatives from the Ministry of Health, pharmaceutical companies, healthcare providers, and civil society organizations should form a task force. Moreover, members should be selected with impartiality and inclusion of key individuals.
2. International best practices should be used as a reference for drafting clear and comprehensive guidelines.
3. Public consultations as a feedback mechanism should be established for stakeholders to submit suggestions for improvements.
4. The guidelines should be published on official government websites and distributed through various media channels. In addition, it is important that these websites be completely user-friendly.
5. These guidelines should consistently be applied and regularly reviewed and updated considering the stakeholder feedback.

Enhancing Accountability Mechanisms

Robust mechanisms for accountability should be implemented for inspection activities, including regular audits and public reporting of findings. Meanwhile, the involvement of independent third parties in the inspection process would enhance its credibility.

Action Steps

1. Regular audits of pharmacies and companies should be performed based on a developed schedule. In this regard, one can use the successful experiences of the food and drug departments of different provinces.
2. The findings should be published on a publicly accessible platform.
3. Protections are necessary for encouraging the reporting of unethical practices.
4. Independent inspections should be conducted in partnership with reputable international and local organizations. These third-party inspectors should be trained to ensure they understand local regulations and standards.

Mandating Clinical Trial Transparency

The obligatory registration of all clinical trials in a publicly accessible database is necessary for both academic and non-academic cases. Naturally, the timely publication of positive and negative results is essential.

Action Steps

1. An enhanced database should be created. Of course, an experience of the Iranian Registry of Clinical Trials is highly valuable in this regard, but it can be improved to ensure that it is user-friendly and accessible.
2. Legislation should be passed, which obligates the registration of all clinical trials before they start.

3. Clear requirements should be set for the timely publication of trial results.
4. Compliance with publication requirements should be monitored, and penalties should be considered for non-compliance.

Establishing Evidence-Based Selection Processes

Current criteria for the selection of essential medicines should be improved in a clear, evidence-based manner, considering a diverse range of stakeholders. Moreover, decision-making processes should be transparent and publicly disclosed to raise trust.

Action Steps

1. An enhanced criterion should be developed based on cost-effectiveness and public health needs.
2. Healthcare professionals, patient NGOs, and industry experts should be involved in the criterion development process.
3. The decision-making process and criteria should be published on official and user-friendly platforms.
4. The list of essential medicines should be regularly updated based on new evidence and feedback.

Implementing Transparent Procurement Systems

Adopting e-procurement systems can reduce the risk of corruption in procurement processes. In addition, one should assure that all procurement decisions are based on clear, objective criteria and are publicly disclosed.

Action Steps

1. An e-procurement system tailored to the needs of the pharmaceutical sector of Iran should be developed and implemented.
2. Procurement officials and suppliers should be trained and supported on using the e-procurement system.
3. An enhanced criterion should be developed for procurement decisions, focusing on quality, cost, and supplier reliability.
4. Procurement decisions and criteria should be published on a publicly accessible and user-friendly platform.

Iran can significantly enhance transparency in its pharmaceutical sector by implementing these detailed and actionable recommendations that result in reducing corruption, improving efficiency, and increasing public trust (Table 1).

Monitoring the implementation of these policy options is crucial. Moreover, key indicators and targets should be established to track progress. Additionally, addressing potential barriers and facilitating factors is essential for successful implementation. Further research can fill the gaps in knowledge and update the policy brief.

Strengths and Limitations

A key strength of this study was the investigation of transparency in Iran's pharmaceutical sector since this issue, to the best of our knowledge, has not been sufficiently explored and no policy recommendations have so far been offered in this area. However, due to limited access to key informants, the number of interviews was restricted,

Table 1. Detailed Comparison of Policy Recommendations

Policy Recommendations	Description	Main Benefits	Main Risks	Cost and Feasibility of Implementation	Equity Consideration	Stakeholders' Responsibilities
1. Developing and implementing transparent guidelines	Establishing clear and publicly accessible guidelines for the registration, licensing, and inspection of pharmaceutical products	It enhances transparency, reduces corruption, and ensures fair competition.	Necessity of significant initial efforts to develop and implement guidelines	Moderate cost; feasible with regulatory support	Ensuring the equity of stakeholders to have access to the same information	Regulatory authorities and policymakers
2. Enhancing accountability mechanisms	- Implementing forceful accountability mechanisms for inspection and promotional activities - Involving independent third parties in the inspection process	It increases accountability and prevents unethical practices.	Potential resistance from stakeholders	Moderate cost; feasible with proper resources and training	Ensuring access to fair treatment across different socioeconomic groups	Regulatory authorities and independent auditors
3. Mandating clinical trial transparency	- Mandating the registration and publication of clinical trial results - Timely publishing the positive and negative results of clinical studies	It enhances transparency and trust in clinical research.	Potential resistance from entities concerned about negative results	Low to moderate cost; feasible with the improvement of existing digital infrastructure	Promoting equity by providing access to clinical trial data	Regulatory authorities and clinical researchers
4. Establishing evidence-based selection processes	- Developing evidence-based criteria for the selection of essential medicines - Publicly disclosing decision-making processes	It ensures selection of effective and cost-efficient medicines.	Necessity of comprehensive data collection and analysis	Moderate cost; feasible with involvement of experts and elites.	Improving access to essential medicines for all population groups	Health Ministry and pharmaceutical committees in the Food and Drug Organization
5. Implementing transparent procurement systems	- Adopting more transparent procurement processes, including up-to-date e-procurement systems - Assuring that procurement decisions are based on clear, objective criteria and are publicly disclosed	It reduces corruption while improving efficiency.	Initial setup costs and training requirements	High initial cost; feasible with long-term planning	Ensuring fair procurement practices benefiting all regions	Procurement agencies and the Food and Drug Organization

resulting in the exclusion of some expert perspectives.

Conclusion

In conclusion, enhancing transparency in the pharmaceutical sector of developing countries such as Iran requires a coherent set of policy actions. Key priorities include expanding the use of digital infrastructures across critical domains such as procurement and supply chains, and ensuring the meaningful engagement of a broad range of stakeholders in decision-making processes, particularly in the selection of essential medicines.

Equally important is the development of robust infrastructures for clinical trials to enable the comprehensive registration and reporting of all relevant data. Strengthening accountability mechanisms should also be emphasized through increased regulatory inspections of pharmaceutical companies and pharmacies, alongside the development and enforcement of more comprehensive and standardized guidelines for licensing and registration processes.

Taken together, these measures can improve transparency, reinforce public trust, and contribute to more transparent pharmaceutical governance.

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Competing Interests

The authors declare there is no conflict of interests.

Ethical Approval

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