Original Article

Evaluating the Role of the Strategic Level of the National Drug Regulatory Authority in Enhancing Medication Adherence in Cardiovascular Patients: An Importance–Performance Analysis Approach

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Highlights

- Eight strategic tasks (28.6%) fell into the "Concentrate Here" quadrant, with 50.7% of the weight and a gap of 2.69.
- The largest gaps were in research and innovation (3.54), production/import planning (2.88), and quality monitoring (2.79).
- Drug supply and distribution performed well, but innovation, financial planning, quality monitoring, and patient education were deficient.

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ABSTRACT

Introduction: Medication adherence in patients with cardiovascular disease remains a significant challenge and directly affects treatment success, morbidity, and healthcare costs. Although many studies have examined clinical and individual factors that influence adherence, the role of regulatory agencies has received less attention. The Iranian Food and Drug Administration (IFDA) is the leading authority responsible for regulating drugs, Understanding the strategic functions of this agency, and aligning them with adherence factors can be crucial for improving patient outcomes and maintaining the sustainability of the healthcare system.

Methods: This study was conducted in 3 stages. First, regulatory activities of the IFDA were gathered from regulations, policy documents, organizational reports, and semistructured interviews. Second, the identified factors were validated by clinical and pharmaceutical experts, and monitoring activities were matched with medication adherence through a mapping matrix approach. Third, the importance-performance analysis (IPA) method was applied to evaluate systematic strengths and weaknesses, and the performance gap and normal weight were calculated.

Results: Twenty-eight strategic-level tasks of the organization were classified into 4 IPA quadrants. The “Immediate Focus” quadrant consisted of 8 tasks (28.6%) with the highest normal weight (50.7%) and an average performance gap of 2.69, indicating serious weaknesses in the areas of innovation and research, strategic planning of production/imports, quality monitoring, and currency policies. The “Continuing the Good” quadrant encompassed 6 tasks (21.4%, 25.1% weight) reflecting strengths in drug supply, continuous access, equitable distribution, drug information systems, and communications. The “Low Priority” (5 tasks, 17.9%) and “Overfocus” (9 tasks, 32.1%) quadrants reflected administrative or ineffective activities that allocated disproportionate resources.

Conclusion: The findings of this study suggest that the strategic-level tasks of the IFDA play a crucial role in promoting adherence to cardiovascular medication for patients. While good performance was observed in the areas of drug supply and access, significant deficiencies were identified in innovation, financial planning, quality monitoring, and patient education.

Keywords: Medication Adherence; Cardiovascular Disease; Iranian Food and Drug Administration (IFDA); Health Policy; Importance-Performance Analysis

Introduction

The healthcare system constitutes a critical components of the public sector in every nation, with health policy making occupying a uniquely sensitive position due to its direct implications for human life.[1]

Decisions made by health policy makers fundamentally influence the survival and well-being of populations, distinguishing this sector from other social domains.[2] The World Health Organization (WHO) affirms that governments bear primary responsibility for ensuring the health of their populations.[3]

Regulatory pharmaceutical institutions play a pivotal role in enhancing healthcare quality through comprehensive oversight of drug quality, acceptability, availability, accessibility, affordability, pharmacovigilance, rational use, and adherence to regulatory standards. By ensuring the safety and efficacy of medications, these entities directly impact public health outcomes and service quality. Their efforts encompass equitable drug distribution, cost reduction, and continuous monitoring of adverse effects to build and maintain public trust. Furthermore, improving regulatory standards through technological advancement and policy development remains essential for advancing healthcare outcomes.[4]

Global public health reforms increasingly aim to reduce unnecessary healthcare costs while optimizing clinical outcomes, with medication adherence emerging as a critical priority. The WHO notes that only 50% of patients with chronic diseases in developed countries adhere to treatments, leading to poor health outcomes and higher costs. Effective interventions to improve adherence require reliable measurement tools that appropriately balance subjective and objective methods. Currently, a multimethod approach represents the most effective for assessing and addressing nonadherence.[5]

Chronic disease treatment typically involves long-term pharmacotherapy, yet approximately half of all patients fail to adhere to prescribed regimens, limiting therapeutic benefits. Nonadherence stems from multiple sources: patient-related issues (eg, low health literacy), physician-related factors (eg, complex prescriptions), and systemic barriers (eg, limited care access). These multifaceted challenges necessitate comprehensive, multilevel strategies to enhance adherence. Effective provider-patient communication and simplified medication regimens are crucial for strengthening patient compliance.[6]

Regulatory interventions in developed nations demonstrate the potential of national agencies to shape medication adherence through targeted policies. In the United States, the Food and Drug Administration (FDA) has aligned its regulatory strategies with clinical practice to improve adherence, particularly for cardiovascular disease (CVD), with the explicit goal of reducing mortality and disability.[7,8] Research emphasizes the importance of improving labeling and patient education to enhance adherence, initiatives actively supported by the FDA. Collaborative efforts in monitoring, evidence-based strategy development, and reducing health disparities remain essential. These interventions collectively aim to improve clinical outcomes and reduce mortality.[7] As part of a broader healthcare ecosystem, the FDA collaborates with diverse stakeholders to address issues related to medical practice and access to care. Key factors influencing adherence include socioeconomic conditions, healthcare system characteristics, and patient engagement levels. Multifaceted approaches involving government agencies and academic institutions are crucial for successful outcomes.[8] The American College of Preventive Medicine (2011) identified socioeconomic, healthcare system, medical condition, treatment, and patient-related factors as key domains requiring focused research and regulatory attention. Addressing these factors requires targeted, evidence-based interventions to improve adherence rates. Understanding the complex interplay among these determinants is essential for developing practical, effective solutions.[9] Promoting generic medications addresses socioeconomic barriers to adherence by offering affordable therapeutic alternatives and increasing access across diverse populations. The FDA facilitates timely approval of generic drugs and, thus, reduces the need for costly duplicative clinical studies. Improved health literacy, supported by initiatives from the United States Department of Health and Human Services (HHS),

empowers patients to make informed decisions regarding their healthcare. Clear communication and accessible healthcare services are vital for enhancing adherence.[10] The FDA Plan 443 for CVD specifically aims to improve adherence through patient-friendly product labeling, ensuring clarity and compliance with clinical guidelines. The FDA labeling team ensures that prescribing information serves as a practical, accessible tool for healthcare providers. This approach facilitates safe and effective medication use, which is critical for treatment success. Simplified, accurate labeling represents a key strategy for supporting patient adherence.[11] Compounded medications play an essential role for patients with specific clinical needs, addressing drug shortages and promoting adherence when commercial medications are unavailable. Customization enhances patient trust and engagement, potentially leading to improved treatment compliance. In pediatric populations, adjustments to taste and dosage form are particularly critical for adherence, especially for oral liquid formulations. Compounding addresses otherwise unmet patient needs, thereby reducing barriers to effective treatment.[12] These examples from developed nations illustrate that regulatory agencies can extend their influence beyond traditional quality control to actively shape the conditions that enable better medication adherence.

Economic factors such as poverty, inadequate insurance, and high medication costs significantly contribute to nonadherence. Healthcare system issues, such as poor access, unclear prescribing information, and weak provider-patient communication, exacerbate the problem. These systemic barriers highlight the need for improved healthcare delivery models and enhanced follow-up mechanisms. Addressing access and communication gaps is crucial for enhancing adherence outcomes.[13]

Medication adherence refers to the alignment of patient behavior with healthcare provider recommendations, nonadherence results in suboptimal outcomes and increased costs. Systemic barriers, including financial and geographic inaccessibility, medication shortages, and adverse drug effects, drive nonadherence. Tailored, multifaceted interventions are necessary to address patient-specific factors effectively. Continuous monitoring and individualized strategies are crucial for enhancing adherence.[14] Nonadherence, affecting 50% of patients in developed countries, results in significant healthcare costs, including $100 billion annually in the United States and €1.25 billion in Europe. Failure to follow treatment plans leads to preventable hospitalizations and complications. Effective interventions are critical to reducing these costs and improving outcomes. Addressing nonadherence requires both systemic and patient-focused strategies.[15]

Nonadherence in patients with CVD leads to poor outcomes, including rehospitalization and increased mortality, driven by such factors as fear of side effects and economic constraints. Clinicians must adopt multifaceted, straightforward strategies to enhance both short- and long-term adherence to medication. Education and clear communication regarding treatments are essential. Addressing patient concerns can substantially improve compliance.[16] The organization of the healthcare system meaningfully influences medication adherence, with pharmacists playing a critical role in post-hospital care. Nonadherence increases hospitalization and costs and, thus, strains healthcare resources. Factors like disease, treatment, patience, provider, and socioeconomic issues all impact adherences. Collaborative, systemic interventions are necessary to address these challenges effectively.[17]

Regulatory interventions positively impact medication adherence, as demonstrated in studies focusing on high-burden diseases selected via clustering techniques. These diseases, selected for their prevalence and impact on quality of life, enable the generation of generalizable findings. Targeted interventions improve health outcomes and quality of life. Analyzing homogeneous patient groups enhances the applicability of results.[18] CVD is a leading cause of premature death, with 17.9 million deaths in 2012 and a significant burden in low- and middle-income countries. Iran faces a high CVD burden, driven by hypertension and socioeconomic factors. Improved healthcare access and early detection have increased not only life expectancy but also CVD prevalence. Systemic reforms are critical to addressing this growing epidemic.[19]

In Iran, CVD represents a major public health

concern in that it accounts for 46% of all deaths and 20% to 23% of the total disease burden, with projections indicating a steep rise due to aging populations and epidemiological transitions.[20] The prevalence of CVD risk factors, such as hypertension, has exceeded 25% among Iranian adults, exacerbated by urbanization, socioeconomic challenges, and limited access to preventive care. Studies on medication adherence among Iranian patients with CVD reveal rates varying from 38% to 57%, influenced by factors including health literacy, economic barriers, and patient-provider relationships.[21,22] These low adherence levels both amplify morbidity and mortality and impose significant financial strain on the healthcare system, with annual costs for preventable CVD-related hospitalizations estimated in the billions. Addressing this gap requires evaluating the effectiveness of regulatory frameworks in promoting adherence.[23]

Nonadherence to medications, with rates as low as 38% to 57% in older populations, contributes to adverse outcomes and increased healthcare costs. Accurate measurement is vital for research and clinical practice, yet no single method is comprehensive. Factors such as access to healthcare, quality of physician-patient relationships, and economic considerations all contribute to nonadherence. A multidimensional approach is needed to address these complex, interrelated issues effectively.[24]

While previous research has focused on clinical interventions, the strategic role of national drug regulatory authorities in shaping adherence remains underexplored. Therefore, this study aimed to identify the strategic-level activities of the Iranian Food and Drug Administration (IFDA) that are relevant to medication adherence, map these activities to established adherence frameworks and validate them through expert consensus, and evaluate the importance and performance of these activities from the perspective of key stakeholders using the importance-performance analysis (IPA) method. The findings will provide evidence-based guidance for regulatory reform to enhance medication adherence among Iranian patients with CVD and offer a methodological framework applicable to other settings seeking to integrate regulatory strategy with patient-centered outcomes.

Methods

Study Design

The methodology is divided into 3 sequential steps that integrate qualitative and quantitative methods, including literature reviews, expert consultations, and IPA. Data collection was conducted in accordance with ethical guidelines so as to ensure that informed consent and confidentiality were maintained for all participants. The following steps outline the research process, which is supported by valid methods and robust analytical frameworks.

Step 1: Identifying Monitoring Activities

Drug-related activities in the IFDA at strategic levels were extracted using grey texts (eg, guidelines, regulations, policy documents, and organization website) and semistructured interviews with 18 experts recruited through snowball sampling.[25,26] The semistructured interview guide was developed through a review of the literature, including the WHO multidimensional adherence model,[27] and an initial analysis of the grey literature. The questions were designed to explore experts' perceptions of the IFDA strategic role, the mechanisms by which regulatory activities might influence adherence, and the challenges in implementing these activities. A pilot interview was conducted with an expert to refine the wording and flow of the questions.[28] Each interview lasted between 45 and 70 minutes, depending on the expert's depth of knowledge and availability. All interviews were audio-recorded, transcribed verbatim, and subsequently imported into the MAXQDA 2020[29] software for systematic data management, coding, and thematic analysis. The principle of thematic saturation guided the number of interviews. Saturation was defined as the point at which no new themes, concepts, or insights related to the IFDA strategic role in medication adherence emerged from three consecutive interviews. Recruitment was continued until this criterion was met, which occurred after the 15th interview.[30] Three additional interviews were conducted to ensure confidence; the results confirmed that saturation had been achieved, as no novel information was added. The 28 strategic tasks identified in this step

were then subjected to a structured mapping and validation process to ensure their relevance to medication adherence.

Step 2: Mapping Activities to Adherence

The identified strategic-level activities were mapped to medication adherence in patients with CVD via a matrix approach. The identified strategic-level activities were mapped to the dimensions of medication adherence using the WHO multidimensional adherence model as a guiding framework.[27] A mapping matrix was created, and through an expert consensus process, the activities most directly associated with the "healthcare system/team factors" influencing adherence in patients with CVD were extracted and prioritized for further analysis A matrix was created with the 28 strategic tasks on 1 axis and the 5 dimensions of the WHO adherence model (patient-related, condition-related, therapy-related, health system/team-related, and social/economic) on the other. Two researchers independently mapped each task to the most relevant dimension(s). Discrepancies were resolved through discussion.

To validate the mapping of activities and prioritize them for the IPA questionnaire, we employed a formal consensus-building process. This process, resembling a modified Delphi method,[31,32] involved a panel of 15 experts from the initial interviewee pool (including policy makers, senior cardiologists, and clinical pharmacists). The process was conducted in 2 rounds:

• **Round 1:** Experts were presented with the initial list of 28 mapped strategic activities and asked to rate the strength of each activity's impact on improving medication adherence in patients with CVD on a 5-point Likert scale (1=no impact and 5=extremely high impact). They were also invited to provide qualitative feedback and suggest modifications or additions.

• **Consensus Threshold:** Consensus was defined a priori as at least 80% of panel members[31] rating an activity as having a "high" or "very high" impact (a score of 4 or 5). Activities that did not meet this threshold were either revised based on expert feedback and carried forward to a second round or were excluded if they were deemed irrelevant by the majority.

• **Round 2:** In the second round, experts were provided with a summary of the Round 1 ratings and their anonymized comments. They were subsequently asked to re-rate the revised list of activities. All 28 activities presented in the final questionnaire achieved the 80% consensus threshold after this second round, confirming their relevance to the study objectives.

Through expert consensus, the activities most associated with improving adherence in cardiovascular patients were extracted and prioritized.[32,33] Following validation through the consensus process, the final set of 28 tasks was used to develop the instrument for the IPA method in Step 3.

Step 3: Tool and IPA Development

Based on the 28 validated strategic activities from Step 2, a questionnaire was developed. Its content was validated by experts (Table 1), and its reliability was assessed using Cronbach's α and the content validity index (CVI).[34] The tool was administered to 80 experts, and responses were collected on a 7-point Likert scale. The importance and performance scores were analyzed using the IPA matrix[35] to identify strengths, weaknesses, and critical gaps.[35] All statistical analyses, including the calculation of geometric means, standard deviations (SDs), grand mean thresholds, and normalized weights for the 28 strategic tasks, were performed using Microsoft Excel 2019.[36] The IPA quadrant diagram (Diagram 1) was generated using the Excel scatter plot function, with performance plotted on the X axis and importance on the Y axis. The grand means of importance (5.81) and performance (4.27) were employed as the intersection points to delineate the 4 quadrants. Policy recommendations were formulated to enhance regulatory functions that are important but perform sub optimally, thereby supporting improved medication adherence among patients with CVD.

Table 1. Cronbach's α and content validity index (CVI)

	Questions	Average
Cronbach's α	28	0.890
CVI	28	0.845

The IPA method was drawn upon to assess the adherence, based on stakeholder ratings of importance and performance for tasks at the strategic level. Importance ratings (geometric means) were used to prioritize tasks, with thresholds calculated as grand means for each level. Functions with high importance (above the threshold) were analyzed for performance gaps, revealing priorities for improvement. Weights were normalized to percentages to quantify relative importance.

Results

The IPA method was conducted to evaluate the performance of the IFDA at a strategic level in relation to medication adherence. The analysis utilized geometric means of importance and performance ratings from stakeholder perspective (experts) to categorize tasks into 4 quadrants: Quadrant I (Concentrate Here: high importance, low performance), Quadrant II (Keep Up the Good Work: high importance, high performance), Quadrant III (Low Priority: low importance, low performance), and Quadrant IV (Possible Overkill: low importance, high performance). Thresholds were calculated as grand means for each level: strategic (importance: 5.81, performance: 4.27). Tasks were weighted, normalized, and expressed as percentages to reflect their relative importance and significance. The following results highlight the importance-driven analysis across each level, prioritizing tasks based on their contribution to organizational goals and stakeholder expectations.

Demographic Characteristics of Respondents

A total of 120 questionnaires (Table 2) were distributed to experts in various fields relevant to pharmaceutical regulation and CVD management. Of these, 80 completed responses were received, yielding a response rate of 66.7%. Participants included specialists in pharmaceutical sciences, cardiology, health policy, and health administration, with representation from academia, clinical practice, and regulatory bodies such as the IFDA.

Table 2. Demographic characteristics of respondents

Specialization	Number Invited	Number Responded	% Of Respondents	% Of Total Invited
University Professor in Pharmaceutical Sciences	20	15	18.75	16.67
Cardiologist	15	5	6.25	12.50
Provincial Deputy Head of the Food and Drug Administration	7	5	6.25	5.83
Health Policy Specialist	6	4	5.00	5.00
Pharmacist (10+ years of experience)	20	15	18.75	16.67
Nurse (10+ years of experience)	13	9	11.25	10.83
Medical Science Specialist with Prior IFDA Experience	15	10	12.50	12.50
Medical Science Specialist, Current IFDA Member	12	7	8.75	10.00
Pharmacy Specialization Student	12	10	12.50	10.00
Total	120	80	100.00	100.00

IPA For the Strategic Level of The Drug Regulatory Authority

In this report, IPA was conducted based on the data below. IPA, first introduced by Martilla and James (1977), is a managerial tool used to evaluate organizational performance against stakeholder (expert) expectations. This method (Figure 1) categorizes tasks into a 2D matrix based on the dimensions of importance and performance.

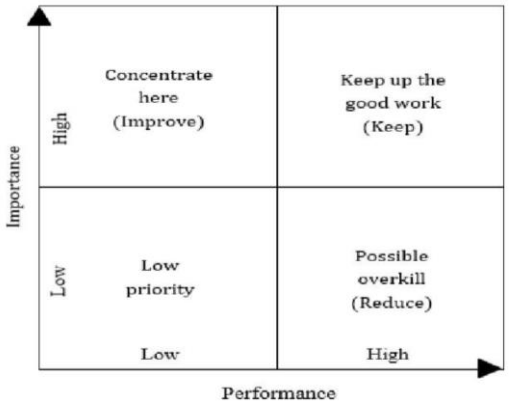

Figure 1. A Cartesian diagram illustrating the importance-performance analysis matrix

Quadrant Distribution

Duties were categorized into 4 IPA quadrants (Table 3 and Diagram 1), revealing systemic strengths and weaknesses in the IFDA operations pertinent to CVD medication adherence.

Table 3: Strategic level analysis (IPA)

	Code	Importance (SD)	Performance (SD)	Raw Weight	Normalized Weight	Gap	IPA Quadrant	
Medicine supply policy (domestic, import, and contract manufacturing)	C1	6.18 (0.92)	5.14 (0.87)	6.386	0.023	1.03	Keep Up the Good Work	II
Medicine availability policy for continuous access	C2	6.30 (0.83)	4.62 (0.89)	10.616	0.039	1.68	Keep Up the Good Work	II
Equitable distribution policy across regions	C3	6.78 (0.87)	4.49 (0.81)	15.523	0.057	2.29	Keep Up the Good Work	II
Quality and effectiveness monitoring policy	C4	6.93 (0.79)	4.14 (0.87)	19.361	0.071	2.79	Concentra te Here	I
Currency policy for medicines	C5	6.55 (0.85)	3.95 (0.88)	16.999	0.062	2.59	Concentra te Here	I
Macro policy for organizational management improvement	C6	5.55 (0.87)	4.68 (0.84)	4.839	0.018	0.87	Possible Overkill	IV
Performance evaluation system design	C7	5.51 (0.78)	5.20 (0.81)	1.698	0.006	0.31	Possible Overkill	IV
Development of pharmaceutical information systems	C8	6.76 (0.79)	4.61 (0.88)	14.54	0.053	2.15	Keep Up the Good Work	II
Organizational culture and management enhancement	C9	5.25 (0.93)	3.90 (0.86)	7.083	0.026	1.35	Low Priority	III
Financial data analysis for budget allocation	C10	5.21 (0.81)	5.23 (0.90)	0.103	0	– 0.02	Possible Overkill	IV
Budget planning to reduce medicine costs	C11	6.27 (0.82)	4.14 (0.79)	13.362	0.049	2.13	Concentra te Here	I
Budget agreements with pharmaceutical centers	C12	5.52 (0.79)	4.51 (0.82)	5.575	0.02	1.01	Possible Overkill	IV
Coordination with academia for budget allocation	C13	5.39 (0.92)	4.21 (0.83)	6.345	0.023	1.18	Low Priority	III
Annual planning for drug information centers	C14	5.97 (0.82)	3.28 (0.86)	16.085	0.059	2.69	Concentra te Here	I
Annual budgeting for pharmaceutical centers and committees	C15	5.90 (0.87)	4.36 (0.79)	9.14	0.033	1.55	Keep Up the Good Work	II
Financial resource allocation to pharmaceutical centers	C16	4.59 (0.75)	4.08 (0.81)	2.336	0.009	0.51	Low Priority	III
Strategic planning for the production/import of medicines	C17	6.35 (0.78)	3.48 (0.82)	18.277	0.067	2.88	Concentra te Here	I

Supervision of health technology assessment (HTA)	C18	5.75 (0.88)	4.35 (0.74)	8.109	0.03	1.41	Possible Overkill	IV
Supervision of strategic pharmaceutical programs	C19	3.40 (0.89)	4.20 (0.92)	2.714	0.01	–0.80	Low Priority	III
Supervision of evidence-based cost policies	C20	5.55 (0.87)	4.53 (0.77)	5.719	0.021	1.03	Possible Overkill	IV
Media communication policy for patients	C21	6.51 (0.87)	4.55 (0.81)	12.737	0.046	1.96	Keep Up the Good Work	II
Establishment of an electronic policy database	C22	5.28 (0.76)	4.59 (0.81)	3.623	0.013	0.69	Possible Overkill	IV
Research and innovation development policy	C23	6.41 (0.82)	2.88 (0.88)	22.704	0.083	3.54	Concentrate Here	I
Coordination with the Ministry of Health and insurers to reduce costs	C24	5.33 (0.72)	4.45 (0.79)	4.739	0.017	0.89	Possible Overkill	IV
Enhancement of pharmaceutical regulatory standards	C25	6.53 (0.92)	4.19 (0.89)	15.318	0.056	2.34	Concentrate Here	I
Anti-smuggling and counterfeit prevention policy	C26	5.12 (0.79)	3.59 (0.85)	7.82	0.029	1.53	Low Priority	III
Public awareness policy for rational medicine use	C27	6.42 (0.91)	3.87 (0.87)	16.353	0.06	2.55	Concentrate Here	I
Staff welfare and cultural services policy	C28	5.48 (0.87)	4.38 (0.90)	6.053	0.022	1.1	Possible Overkill	IV
	Threshold	5.818	4.275					
				274.15	1			

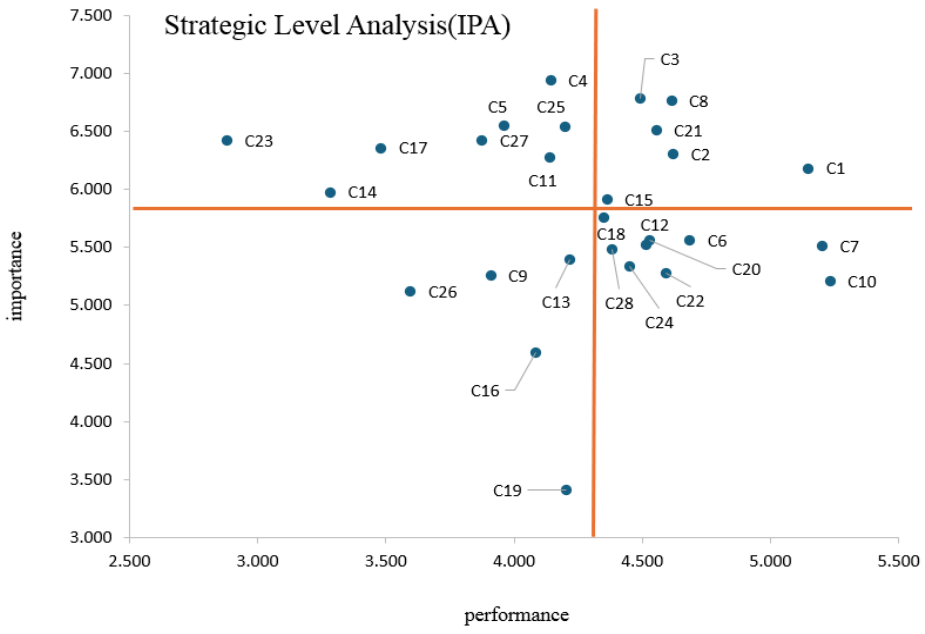

Diagram 1: Strategic level analysis (IPA)

Concentrate here: This quadrant encompasses 8 duties (28.6% of total), accounting for 50.7% of the total normalized weight. These duties exhibited a mean performance gap of 2.69 (SD=0.42), indicating substantial underperformance in high-impact areas. Key duties included quality and effectiveness monitoring policy, currency policy for medicines, budget planning to reduce medicine costs, annual planning for drug information centers, strategic

planning for production/import of medicines, research and innovation development policy, enhancement of pharmaceutical regulatory standards, and public awareness policy for rational medicine use. The high normalized weight in this quadrant highlights urgent priorities for innovation, supply chain reliability, quality assurance, cost management, information planning, regulatory enhancement, and patient education to improve CVD adherence.

Keep Up the Good Work: Six duties (21.4% of total) were classified here, representing 25.1% of the normalized weight, with a mean gap of 1.78 (SD=0.46). These organizational strengths comprised medicine supply policy (domestic, import, contract manufacturing, medicine availability policy for continuous access, equitable distribution policy across regions, development of pharmaceutical information systems, annual budgeting for pharmaceutical centers and committees, and media communication policy for patients). These duties demonstrate effective performance in foundational aspects of supply, accessibility, distribution, information systems, budgeting, and communication.

Low Priority: This quadrant featured 5 duties (17.9% of total), contributing 9.7% of the normalized weight, with a mean gap of 0.75 (SD=0.95). Duties were organizational culture and management enhancement, coordination with academia for budget allocation, financial resource allocation to pharmaceutical centers, supervision of strategic pharmaceutical programs, and antismuggling and counterfeit prevention policy. The inclusion of a negative gap suggests a minor overallocation in supervision; however, these duties have limited strategic relevance to adherence and should be deprioritized.

Possible Overkill: Nine duties (32.1% of total) fell into this quadrant, accounting for 14.7% of the normalized weight, with a mean gap of 0.81 (SD=0.43). These included macro policy for organizational management improvement, performance evaluation system design, financial data analysis for budget allocation, budget agreements with pharmaceutical centers, supervision of health technology assessment, supervision of evidence-based cost policies, establishment of electronic policy database, coordination with the Ministry of Health and insurers to reduce costs and staff welfare, and cultural services policy. Negative gaps (eg, in C10) point to potential resource overcommitment in administrative functions.

Gap and Weight Analysis

Across all 28 duties (Table 4), the overall mean gap was 1.54 (SD=0.98), with positive gaps predominant (n=26; mean=1.69; SD=0.84), signifying widespread underperformance relative to perceived importance. The most significant gaps were observed in research and innovation development policy (C23; gap=3.54; n-w=0.083), strategic planning for production/import of medicines (C17; gap=2.88; n-w=0.067), quality and effectiveness monitoring policy (C4; gap=2.79; n-w=0.071), annual planning for drug information centers (C14; gap= 2.69; n-w = 0.059), currency policy for medicines (C5; gap=2.59; n-w=0.062), and public awareness policy for rational medicine use (C27; gap=2.55; n-w=0.060). These underscore critical deficiencies in innovation, planning, quality control, and education. In contrast, negative gaps in financial data analysis for budget allocation (C10; gap=–0.02; n-w=0.000) and supervision of strategic pharmaceutical programs (C19; gap=–0.80; n-w=0.010) indicate areas of possible overinvestment.

Normalized weights further emphasized the dominance of the “Concentrate Here” quadrant (50.7% of total n-w), substantially outweighing “Keep Up the Good Work” (25.1%), “Low Priority” (9.7%), and “Possible Overkill” (14.7%). These findings suggest that targeted improvements in the former could yield the most significant impact on CVD adherence.

Table 4: Classification of the IFDA duties by IPA quadrants and performance gap

Quadrant	Number of Duties	% Duties	% Normalized Weight	Mean Gap	Gap SD
Concentrate Here	8	28.6	50.7	2.69	0.39
Keep Up the Good Work	6	21.4	25.1	1.78	0.42
Low Priority	5	17.9	9.7	0.75	0.85
Possible Overkill	9	32.1	14.7	0.81	0.41

IFDA: The Iranian Food and Drug administration; IPA: importance-performance analysis

The IPA results highlight the IFDA strengths in maintaining high-importance duties related to medicine supply, availability, equitable distribution, pharmaceutical information systems, annual budgeting, and media communication. These efforts collectively facilitate reliable access and patient engagement for CVD adherence. Still, the "Concentrate Here" quadrant's substantial weight (50.7% n-w) reveals significant weaknesses in research and innovation, strategic planning for production/import, quality monitoring, currency policies, cost-reduction budgeting, information center planning, regulatory standards, and public awareness. These areas, characterized by significant gaps and high weighted impact, represent systemic barriers that necessitate immediate managerial attention and resource reallocation. Opportunities for efficiency exist in the "Possible Overkill" quadrant (14.7% n-w) through reduced focus on lower-importance administrative tasks, while "Low Priority" duties (9.7% n-w) can be further de-emphasized. Addressing these priorities could significantly enhance the IFDA role in promoting CVD medication adherence by mitigating gaps in innovation, quality, and education.

Discussion

This study analyzed the strategic-level duties of the IFDA using the IPA framework, revealing systemic strengths and weaknesses in relation to medication adherence for CVD. The findings indicate that the IFDA strategic policies significantly shape patient access, affordability, and trust in the pharmaceutical system, which in turn affects adherence outcomes.

The "Concentrate Here" quadrant, representing 28.6% of duties but accounting for more than half of the total normalized weight (50.7%), highlights fundamental deficiencies in the IFDA policies. Notably, the most substantial performance gaps were observed in research and innovation development (C23), strategic planning for production/import (C17), and quality and effectiveness monitoring (C4). These findings align with the broader literature, which indicates that insufficient investment in pharmaceutical innovation, regulatory oversight, and long-term planning are systemic barriers in developing countries, leading to poor drug accessibility and limited adherence support.[37,38] Moreover, currency policy (C5) and budget planning to reduce medicine costs (C11) emerged as highly weighted gaps, underscoring the financial barriers that patients in low- and middle-income countries (LMICs) frequently encounter.[39] Because affordability and stable financing mechanisms are recognized as key determinants of adherence in CVD,[27,40] targeted reform in these domains is critical.

The "Keep Up the Good Work" quadrant demonstrates the IFDA relative success in foundational operations. Duties related to medicine supply (C1), availability (C2), and equitable distribution (C3) align with the WHO recommendation that uninterrupted supply chains are prerequisites for ensuring adherence to chronic diseases.[41] The development of pharmaceutical information systems (C8) and effective media communication policies (C21) further strengthen patient engagement and support informed medication use, both of which are essential for sustained adherence in patients with CVD.[12] These results suggest that the IFDA has established a baseline infrastructure for medicine access but must extend its focus toward innovation and quality enhancement.

The "Possible Overkill" quadrant (32.1% of duties, 14.7% n-w) signals potential inefficiency in overemphasizing administrative tasks, such as financial data analysis (C10) or budget agreements with pharmaceutical centers (C12). Although administrative accountability is essential, excessive allocation of resources to lower-priority functions risks diverting capacity from higher-impact duties. This inefficiency aligns with previous critiques that health authorities in LMICs often overprioritize bureaucratic structures at the expense of patient-centered outcomes.[42] Optimizing these areas could free resources for urgent priorities in research, planning, and cost reduction.

The "Low Priority" quadrant (17.9% of duties, 9.7% n-w) highlights duties such as organizational culture improvement (C9) and academic coordination (C13). While these may contribute indirectly to adherence, their limited strategic relevance indicates that they should remain secondary to the critical gaps in innovation, affordability, and patient education.

Taken together, the results emphasize that systemic barriers in innovation, planning, and

financial policy are the dominant obstacles preventing the IFDA from maximizing its impact on CVD adherence. These findings are consistent with global evidence showing that medication adherence in chronic diseases is a multidimensional issue, shaped not only by patient-level factors but also by system-level determinants, such as regulatory performance, cost management, and health information structures.[43] For the IFDA, this implies that managerial attention and resource reallocation must prioritize the "Concentrate Here" quadrant to achieve measurable improvements in adherence.

From a policy perspective, several strategies emerge, as follows:

1. Strengthening research and innovation capacity through partnerships with academia and industry to ensure evidence-based, context-specific solutions.[44]

2. Reinforcing quality and effectiveness monitoring to align with international pharmacovigilance standards.[41]

3. Exploring multicurrency pricing agreements or regional procurement pools to buffer the pharmaceutical market against currency fluctuations.[45]

4. Enhancing patient education and awareness campaigns to address knowledge-related drivers of nonadherence in CVD.[40]

A deeper examination of the strategic-level responsibilities of the IFDA indicates that challenges related to medication adherence among patients with CVD are not confined to operational or clinical domains but are rooted in high-level policy and structural decisions. This observation aligns with the WHO Health System Building Blocks framework, which emphasizes that pharmaceutical policies exert a chain of direct and indirect effects on access, quality, and ultimately, medication adherence.[46]

A critical issue concerns dependency on imports and currency fluctuations. Iran's experience in recent years demonstrates that international sanctions and economic instability have hindered patients' access to essential medicines.[47] Similar dynamics have been observed in Venezuela and Zimbabwe, where macroeconomic crises triggered severe drug shortages and dramatically reduced adherence among patients with chronic diseases.[48] These examples highlight that pharmaceutical strategies without financial protection mechanisms are unlikely to generate sustainable improvements in adherence.

Another dimension is quality assurance and patient trust. Evidence suggests that in contexts with weak regulatory oversight, patients may perceive generic medicines as less effective, resulting in nonadherence.[49] In Iran, concerns about variability in the quality of locally produced vs imported medicines can undermine patient confidence. Strengthening laboratory capacities, coupled with transparent disclosure of quality monitoring results, may increase trust in medicines and thus improve adherence.

Regarding patient education and awareness, although specific communication policies scored relatively well, the absence of a national adherence education strategy remains evident. In Turkey, for example, nationwide awareness campaigns resulted in a 15% improvement in adherence among patients with CVD.[50] Similarly, community-based education interventions in India have shown measurable improvements in treatment adherence.[51] These cases illustrate the importance of developing high-level, cross-sectoral strategies that extend beyond fragmented or short-term interventions.

Investment in research and pharmaceutical innovation is another critical strategic gap. While OECD countries typically allocate 10% to 15% of their health expenditure to R&D, Iran invests less than 1%.[52] Structured partnerships between academia, industry, and the IFDA could foster context-specific innovations, enhance the domestic production of high-quality medicines, and strengthen public trust in the pharmaceutical industry. Comparable initiatives in South Korea and India have successfully established pharmaceutical innovation ecosystems that not only stimulate local R&D but also indirectly support patient adherence through improved access to effective medicines.[53]

Finally, issues of equity in access require sustained attention. Although equitable distribution policies in Iran were rated relatively positively, geographic disparities persist, particularly in rural and underserved regions.[54] Brazil's experience with nationwide zero-cost drug

programs illustrate that expanding public pharmaceutical coverage can substantially improve adherence among high-risk populations.[55]

Taken together, this extended analysis underscores that improving adherence among patients with CVD in Iran requires not only clinical or behavioral interventions but also comprehensive reforms at the strategic policy level. Economic stabilization, quality assurance, innovation, patient education, and equitable access must be addressed simultaneously to generate sustainable improvements in medication adherence.

In conclusion, while the IFDA achievements in supply and communication provide a solid foundation, the identified systemic weaknesses necessitate urgent reform in innovation, cost management, and regulatory oversight. Addressing these priorities will not only improve adherence outcomes among patients with CVD but also strengthen the overall resilience of Iran's pharmaceutical system.

Limitations

This study has several limitations that should be acknowledged. First, IPA relies on stakeholder perceptions rather than objective performance metrics, introducing potential subjectivity into the assessment of IFDA strategic functions. Second, the cross-sectional design captures only a single point in time and cannot account for how regulatory performance or stakeholder priorities may evolve. Third, while the findings offer valuable insights for the Iranian context, they may not be directly generalizable to other countries with different regulatory structures, healthcare systems, or socioeconomic conditions. Finally, despite efforts to assemble a diverse expert panel through snowball sampling, the possibility of selection bias remains, and the views expressed may not fully represent all relevant stakeholder perspectives.

Conclusion

This study indicates that the IFDA strategic-level duties play an important role in shaping CVD medication adherence. While strong performance was noted in ensuring supply, access, and equitable distribution, substantial deficiencies were observed in innovation, strategic planning, quality monitoring, and financial policy making. The disproportionate weight of the "Concentrate Here" quadrant underscores the urgent need for targeted reforms and reallocation of resources. Addressing these systemic barriers will not only strengthen medication adherence but also contribute to improved public health outcomes and a more resilient pharmaceutical governance system in Iran.

Declarations:

Ethical Approval

This study was approved by the Ethics Committee of Tehran University of Medical Sciences (No: IR.TUMS.TIPS.REC.1403.053). The study was conducted as part of an approved academic thesis, and all procedures were performed in accordance with the ethical standards of the institutional research committee and the Declaration of Helsinki. Informed consent was obtained from all participating experts prior to data collection.

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Conflict of Interest

The authors declare no competing interests. However, for transparency, we disclose that Dr. Akbar Abdollhiasl is the General Director of the Iran Food and Drug Administration (IFDA). This affiliation did not influence the study design, analysis, or conclusions.

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References

1. Collins C, Green A, Hunter D. Health sector reform and the interpretation of policy context. Health policy. 1999;47(1):69-83.
2. Buse K, Mays N, Walt G. Making health policy: McGraw-hill education (UK); 2012.
3. Shahri S, Tabibi SJ, Nasiripour AA, Ghaffari F. Effect functions on goals of health system in Iran. Payavard salamat. 2017;11(3):247-58.
4. McCarthy S, O'Raghallaigh P, Woodworth S, Lim YL, Kenny LC, Adam F. An integrated patient journey mapping tool for embedding quality in healthcare service reform. Journal of Decision Systems. 2016;25(sup1):354-68.
5. Lam WY, Fresco P. Medication adherence measures: an overview. BioMed research international. 2015;2015.
6. Brown MT, Bussell JK, editors. Medication adherence: WHO cares? Mayo clinic proceedings; 2011: Elsevier.
7. Ferdinand KC, Senatore FF, Clayton-Jeter H, Cryer DR, Lewin JC, Nasser SA, et al. Improving medication adherence in cardiometabolic disease: practical and regulatory implications. Journal of the American College of Cardiology. 2017;69(4):437-51.
8. Kini V, Ho PM. Interventions to improve medication adherence: a review. Jama. 2018;320(23):2461-73.
9. Baur C. The national action plan to improve health literacy. US Department of Health and Human Services, Office of Disease Prevention and Health Promotion. 2010.
10. https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/labeling-policy-team. https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/labeling-policy-team 2022.
11. Carvalho M, Almeida IF. The role of pharmaceutical compounding in promoting medication adherence. Pharmaceuticals. 2022;15(9):1091.
12. Kardas P, Lewek P, Matyjaszczyk M. Determinants of patient adherence: a review of systematic reviews. Frontiers in pharmacology. 2013;4:91.
13. Zeković M, Krajnović D, Marinković V, Tasić L. The Complexity of Adherence Issue: A Review of its scope and determinants. Acta Medica Medianae. 2016;55(1):51-8.
14. Kılıç H, Güneş ED. Patient adherence in healthcare operations: A narrative review. Socio-Economic Planning Sciences. 2023:101795.
15. Baroletti S, Dell'Orfano H. Medication adherence in cardiovascular disease. Circulation. 2010;121(12):1455-8.
16. Pietrzykowski Ł, Michalski P, Kosobucka A, Kasprzak M, Fabiszak T, Stolarek W, et al. Medication adherence and its determinants in patients after myocardial infarction. Scientific reports. 2020;10(1):12028.
17. Pettinati HM, Volpicelli JR, Pierce Jr JD, O'brien CP. Improving naltrexone response: an intervention for medical practitioners to enhance medication compliance in alcohol dependent patients. Journal of Addictive Diseases. 2000;19(1):71-83.
18. Rb H. Can simple clinical measurements detect patient noncompliance? Hypertension. 1980;2:757-64.
19. Walsh JC, Mandalia S, Gazzard BG. Responses to a 1-month self-report on adherence to antiretroviral therapy are consistent with electronic data and virological treatment outcome. Aids. 2002;16(2):269-77.
20. Tasavon Gholamhoseini M, Arjomand Kermani S, Yazdi-Feyzabadi V, Goudarzi R. Economic burden of cardiovascular diseases among elderly patients in Iran: a case from a developing country. BMC Health Services Research. 2024;24(1):1355.
21. Rezaei S, Vaezi F, Afzal G, Naderi N, Mehralian G. Medication adherence and health literacy in patients with heart failure: a cross-sectional survey in Iran. HLRP: Health Literacy Research and Practice. 2022;6(3):e191-e9.
22. Saki N, Karandish M, Cheraghian B, Heybar H, Hashemi SJ, Azhdari M. Prevalence of cardiovascular diseases and associated factors among adults from southwest Iran: Baseline data from Hoveyzeh Cohort Study. BMC cardiovascular disorders. 2022;22(1):309.
23. Behnoush AH, Younesian S, Mousavi SM, Khanmohammadi S, Golestani A, Rashidi M-M, et al. Temporal trends in cardiovascular disease risk factors attributed burden in Iran, 1990–2021. Scientific Reports. 2025;15(1):14279.
24. Piña IL, Di Palo KE, Brown MT, Choudhry NK, Cvengros J, Whalen D, et al. Medication adherence: importance, issues and policy: a policy statement from the American Heart Association. Progress in cardiovascular diseases. 2021;64:111-20.
25. Adams J, Hillier-Brown FC, Moore HJ, Lake AA, Araujo-Soares V, White M, Summerbell C. Searching and synthesising 'grey literature'and 'grey information'in public health: critical reflections on three case studies. Systematic reviews. 2016;5(1):164.

26. Noy C. Sampling knowledge: The hermeneutics of snowball sampling in qualitative research. International Journal of social research methodology. 2008;11(4):327-44.

27. Sabaté E. Adherence to long-term therapies: evidence for action: World health organization; 2003.

28. Chenail RJ. Interviewing the investigator: Strategies for addressing instrumentation and researcher bias concerns in qualitative research. Qualitative report. 2011;16(1):255-62.

29. VERBI Software. MAXQDA 2020. Berlin, Germany 2020.

30. Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. Field methods. 2006;18(1):59-82.

31. Limotai C, Boonyapisit K, Suwanpakdee P, Jirasakuldej S, Wangponpattanasiri K, Wongwiangiunt S, et al. From international guidelines to real-world practice consensus on investigations and management of status epilepticus in adults: a modified Delphi approach. Journal of Clinical Neuroscience. 2020;72:84-92.

32. Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR. The RAND/UCLA appropriateness method user's manual. 2001.

33. Walt G, Shiffman J, Schneider H, Murray SF, Brugha R, Gilson L. 'Doing'health policy analysis: methodological and conceptual reflections and challenges. Health policy and planning. 2008;23(5):308-17.

34. Polit DF, Beck CT. The content validity index: are you sure you know what's being reported? Critique and recommendations. Research in nursing & health. 2006;29(5):489-97.

35. Martilla JA, James JC. Importance-performance analysis. Journal of marketing. 1977;41(1):77-9.

36. Incerti D, Thom H, Baio G, Jansen JP. R you still using excel? The advantages of modern software tools for health technology assessment. Value in Health. 2019;22(5):575-9.

37. Godman B, Fadare J, Kwon H-Y, Dias CZ, Kurdi A, Dias Godoi IP, et al. Evidence-based public policy making for medicines across countries: findings and implications for the future. Journal of comparative effectiveness research. 2021;10(12):1019-52.

38. Wirtz VJ, Hogerzeil HV, Gray AL, Bigdeli M, de Joncheere CP, Ewen MA, et al. Essential medicines for universal health coverage. The Lancet. 2017;389(10067):403-76.

39. Ewen M, Zweekhorst M, Regeer B, Laing R. Baseline assessment of WHO's target for both availability and affordability of essential medicines to treat non-communicable diseases. PloS one. 2017;12(2):e0171284.

40. Nieuwlaat R, Wilczynski N, Navarro T, Hobson N, Jeffery R, Keepanasseril A, et al. Interventions for enhancing medication adherence. Cochrane database of systematic reviews. 2014(11).

41. Organization WH. Global report on effective access to assistive technology. who https://apps? who. int/iris/handle/10665/341978; 2021.

42. Bigdeli M, Peters DH, Wagner AK, Organization WH. Medicines in health systems: advancing access, affordability and appropriate use. Medicines in health systems: advancing access, affordability and appropriate use2014.

43. Vrijens B, De Geest S, Hughes DA, Przemyslaw K, Demonceau J, Ruppar T, et al. A new taxonomy for describing and defining adherence to medications. British journal of clinical pharmacology. 2012;73(5):691-705.

44. Ma Z, Augustijn K, de Esch IJ, Bossink B. Collaborative university–industry R&D practices supporting the pharmaceutical innovation process: Insights from a bibliometric review. Drug Discovery Today. 2022;27(8):2333-41.

45. Davari M, Walley T, Haycox A. Pharmaceutical policy and market in Iran: past experiences and future challenges. Journal of Pharmaceutical Health Services Research. 2011;2(1):47-52.

46. Indicators AHO. Monitoring the building blocks of health systems. Geneva, Switzerland: WHO Document Production Services. 2010.

47. Cheraghali AM. Impacts of international sanctions on Iranian pharmaceutical market. DARU Journal of Pharmaceutical Sciences. 2013;21(1):64.

48. Kheirandish M, Rashidian A, Kebriaeezade A, Cheraghali AM, Soleymani F. A review of pharmaceutical policies in response to economic crises and sanctions. Journal of Research in Pharmacy Practice. 2015;4(3):115-22.

49. Godman B, Hill A, Simoens S, Kurdi A, Gulbinovič J, Martin A, et al. Pricing of oral generic cancer medicines in 25 European countries; findings and implications. Generics and Biosimilars Initiative Journal. 2019;8(2):49-70.

50. Karakurt P, Kaşikçi M. Factors affecting medication adherence in patients with hypertension. Journal of vascular nursing. 2012;30(4):118-26.

51. Bana A, Sharma KK, Guptha S, Gupta R. Adherence to pharmacotherapy for secondary prevention of coronary heart disease: A registry-based prospective study. Indian Heart Journal. 2025.

52. Systems EOoH, Policies. State of Health in the EU Austria: Country Health Profile 2021: OECD Publishing; 2021.

53. Gerybadze A, Reger G. Globalization of R&D: recent changes in the management of innovation in transnational corporations. Research policy. 1999;28(2-3):251-74.

54. AKHMAD AD, KRISTINA SA, Endarti D. A Systematic review of pharmaceutical situation on access, quality, and rational drug use. International Journal of Pharmaceutical Research (09752366). 2021;13(2).

55. Luiza VL, Chaves LA, Campos MR, Bertoldi AD, Silva RM, Bigdeli M, et al. Applying a health system perspective to the evolving Farmácia Popular medicines access programme in Brazil. BMJ Global Health. 2018;2.