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Presenting a regulatory governance model for the country's industrial development in medical equipment based on the Fuzzy Multi-Criteria Decision-Making Method (MCDM-Fuzzy)

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ABSTRACT

The present research studies and prioritizes the components of the country's industrial development regulatory governance in medical equipment. Given that the country's industrial development in medical equipment is used to ensure health and promote the general health of the society, therefore, to maintain national health and maintain social health in the domestic and foreign dimensions, determining a model for implementing regulatory governance and achieving these goals can be an effective step in achieving the country's industrial development regulatory governance in medical equipment. The statistical population of this study is managers and experts in the field of regulatory governance and medical equipment production and distribution industries in Tehran. The present study is a survey and applied type. The research method is a mixed method (quantitative-qualitative), in which 12 experts were identified in the qualitative section and interviews were conducted to identify effective components. In the quantitative part, using the fuzzy ANP technique, the identified components were prioritized based on the experts' views in two stages using pairwise comparisons. The results indicate that the most important factor affecting the governance of medical equipment regulation is political and legal factors, the most important component of which is transparency; in second place are social and technical factors, the most important component of which is culture and public customs; in third place is the structure of the regulatory system, the most important component of which is post-release monitoring and evaluation; in fourth place are structural and technical factors, the most important component of which is medical equipment life cycle management; and in last place are the economy and the market, the most important component of which is market diversity. Suggestions in this regard were presented below.

Keywords: Regulatory governance, medical equipment, industrial development of the country, approach ANP Fuzzy.

1. Introduction

In order to implement their policies and programs, governments are forced to use capacities and tools to intervene and control affairs and bring the existing situation into line with the desired situation. The scope of intervention and the type of capacities and tools that each government recognizes depend on its social structure and context. These interventions are referred to in the term regulation, where governments create the legal infrastructure for their implementation. In Iran, this tool has been used since the beginning of the organized administrative system, and it has undergone changes over time. The goal of governments is to provide public benefit, and this concept has a specific meaning in each government; but its ultimate result is the provision of public goods and services. According to research, there have been different views on this issue since the beginning of governments. Given the purpose of regulators, it is necessary to foresee all the structures and processes related to these institutions in such a way that they only aim to provide public benefit. Otherwise, a situation arises in which the so-called regulatory capture is called and subsequently the regulatory mechanisms become a tool for securing personal or group interests. In Iran, for many years, most regulatory tasks were carried out directly by the government and there was no clear separation between policymaking and regulation. But over time, organizations with a regulatory mission gradually emerged under the government. With the establishment of institutions such as the Bar Association and the Medical System Organization, sectoral and specialized regulation progressed, and gradually some relatively modern government regulatory institutions such as the Government Penal Organization, the Organization for the Protection of Producers and Consumers, and recently the Radio Regulatory Organization were also established with the aim of playing the government's regulatory role. With the announcement of the general policies of Article 44 of the Constitution and the approval of the law implementing these policies, which led to the formation of the Competition Council, a new stage in the establishment of the regulatory system in the country began, which, of course, has not been very successful so far.

Today, regulation has become intertwined with another concept called governance. Governance is a type of governance that is based on the perspective of distributed power and no longer considers the government as the only undisputed power in public control. According to this concept, power is not only in the hands of the government; rather, there are other powers, such as guilds, political and social groups, and the like, that can play a role in the main goal of government, which is to provide public benefit, and their position and influence cannot be ignored (Rasekh and Karabi Hosseini, 2016). Governance plays an important role in the growth and development of countries. Governance does not only include the government or state, but also the private sector and civil society (individuals and groups). Governance is manifested in different areas and societies and evaluates their performance, and it is obvious that the lack of tools and a comprehensive measure in the studies of governance of countries has led to the compilation of scattered research without theoretical support and cannot help develop governance literature in line with the requirements of countries (Amiri et al., 2018).

In this regard, health systems have played an important role in improving and increasing life expectancy. However, it can be assessed by examining specific functions or principles, including arrangements for stakeholder participation in health planning processes, mechanisms for accountability to local health services, availability of information on provider performance, clarity of health sector legislation, enforcement of health regulations, and availability of reporting mechanisms for resource abuse (Frayat et al., 2023). Therefore, it can be acknowledged that if industrial development departments in the medical industries can, by understanding the situation, provide appropriate environmental conditions for the development of their desired industry, they can, in a way, increase the growth of the industry and medical supplies in the country through their industrial development. Memarzadeh et al. (1400) state that in recent years, sustainable industrial development is one of the most important strategies of the regional planning system that has received much attention in recent decades. In accordance with the results of the evaluation of the three dimensions of sustainable industrial development, including economic, social and environmental sustainability; 63 percent of the regions of the entire country are in moderate deprivation and in general more than 77 percent of the regions of the

country are moderately to severely deprived (Atlas of Deprived Areas of the Country, 2017).

Given the problems in industrial development, especially in the medical industries, the governance and management system of industries, no matter how powerful and powerful, will be ineffective and powerless without the participation of the medical community and its stakeholders. In this regard, and in an era where we are witnessing the rapid growth of the human population and the aging of the population of the country and the world, exercising governance unilaterally, or merely having the government and government agents play a role in industrial management, the development of medical industries, etc., is not enough. Regulatory governance and sustainable industrial development share two key aspects in this regard: first, both aim to expand public participation; and second, both are both process-oriented and outcome-oriented. There is global consensus that governance, through the application of specific rules, leads to sustainable industrial development. The focus of this approach to industrial development management is on democratic and egalitarian development, to influence all interested and influential forces in the management of medical industries, and to respond to all the needs of these groups and their stakeholders. This new approach, with all its positive achievements in the development management of medical industries, is itself considered a missing principle in the industrial development management process of developing countries, especially our country, because its indicators and components and the need to institutionalize and create conditions for this new approach with respect to these indicators and components are still unknown and have been neglected.

So far, various solutions have been implemented to deal with industrial problems. For this purpose, regulatory governance can be used to help, which considers attitudes such as: behavior, manner, method, and method in which "power" serves the management of the economic and social resources of society for the growth and development of the country's people (Iftekhari, 2018). In 2007, the World Health Organization published the report "All Business: Strengthening Health Systems for Improved Health Outcomes," which defined the WHO framework for action, describing the architecture of the health system with six building blocks: leadership and governance; health workforce; information; medical products; vaccines and technology; financing and service delivery. Therefore, in this study, regulatory governance is presented as "ensuring the existence of strategic policy frameworks, accompanied by effective oversight, coalition building, regulation, attention to system design, and accountability." Therefore, the aim of the present research is to prioritize the components of digital financial literacy using the fuzzy ANP technique. But the main point is how to carry out the regulatory governance process in medical devices to have the necessary effectiveness? How can industrial development in medical devices be managed in this regard?

2- Theoretical foundations and review of research history

Theoretical developments in the concept of government and numerous international experiences, from welfare states to neoliberal or developmental states, have resulted in the emergence of a new concept called governance, which emphasizes the position of the government as the central axis of the governance system, while recognizing the presence of other stakeholders, such as private sector actors and civil society organizations at national and local levels, in the process of public policymaking and statecraft. Governance in its current reality is a much more complex and multifaceted concept. Going beyond the traditional circle of government, increasing the role of the private sector and civil society organizations in implementing government policies, vertical distribution of power in international supranational layers and local levels, along with horizontal distribution of power in various public and quasi-governmental organizations, shows a multilayered and interactive model of managing the affairs of modern societies.

Governance

With the increasing attention to regulation in academic circles and among policymakers, in the last two decades, the policymaking literature has witnessed a conceptual shift from focusing on the state as the sole source of national authority and the implementation of public policies to the concept of governance as a system of distributing power to exercise sovereignty and use all social capacities to advance public affairs.

This conceptual shift initially emerged from the growth of criticisms of the artificial and dichotomous distinction between the state and the market in political and social sciences, with many critics pointing to the analytical vacuum of social science disciplines in addressing intermediate levels and commonalities, including social institutions and non-governmental organizations (Strom, 1990). Various definitions of the concept of governance have been presented in the literature. For example, Scott (2003) defines governance as a broad set of capacities and resources used to exercise power over a wide range of state, non-state, and transnational actors. Also, governance, according to Benz (2011), is the guidance and coordination of interdependent entities, institutionalized within the framework of legal systems. Governance is a challenging, delicate, and complex concept that requires clarification and interpretation. Although governance is a concept related to sovereignty and the state, it is not synonymous with them. In the Heritage Dictionary, the word "governance" means the activity, practice, or power of governing; government. In the Oxford Political Dictionary, governance is defined as the activity or practice of exercising control or power over subordinates through the exercise of laws and regulations (Hedavand, 2005).

Necessity regulation

How do regulatory mechanisms improve governance? Do regulatory systems generally follow a uniform pattern in design and implementation? Have decades of implementation of regulatory tools in different countries yielded the same results? Answering questions such as these through numerous field studies has led to a wide range of theories that, on the one hand, consider regulation as an integral part of modern governance systems and, on the other hand, represent a strongly negative approach to the consequences of the creation of various types of regulatory institutions on the quality of public administration, and in particular the spread of corruption and monopoly in the field of governance. The diversity and range of these theories go back to the importance of governance as a contextual concept influenced by social construction as opposed to something technical and imitative. In simpler terms, when it comes to regulation, there are two conflicting theories. The first is the theory that considers regulation essential for creating an appropriate and efficient governance system and emphasizes the necessity of creating a governance system based on regulation. The second is the theory that considers the formation of regulation to have significant harms and damages and therefore opposes the formation of a regulatory system. The first theory emphasizes more on the benefits derived from the existence of regulatory institutions and, while listing them from different aspects, introduces the existence of regulatory institutions as a means of protecting the public interest. This group of theories is called public interest theories and the necessity of regulation is discussed and examined from aspects such as economic, political, governance system, technical expertise, political economy, and also complementing the judicial system. The second group of theories is more centered around the issue of capturing regulation. This group of theories states that rentiers and power holders have a high incentive to use the capacity of regulatory institutions, because these institutions have many and diverse powers and will greatly contribute to the realization of the interests of rentiers and power holders, and for this reason they will make every effort to conquer and influence the performance of regulators. Therefore, most regulators are influenced by the owners of rent and power and are so-called captured by them, and in such circumstances, they will function in a way that is contradictory to the purpose for which they were established. Of course, the first group of theories do not reject the criticism made by the second group of theories, but they believe that the solution to this problem is not to abandon regulatory institutions, but rather a mechanism should be designed to prevent the capture of regulatory institutions and for regulators to function independently and impartially (Adams et al., 2013).

The necessity of regulation from a technical-specialized perspective

The increasing complexity of policy areas and the government's technical inability to enter areas that are technically complex and the government does not have the necessary expertise to enter them are among the technical reasons for using self-regulatory mechanisms. In such areas, providing technical capability will be costly for the government. However, establishing a regulatory system and employing experts active in various sectors will enable the

government to exercise sovereignty in these sectors. In general, by establishing a regulatory system in its new sense, that is, by involving non-governmental actors in the regulatory process, the government will be able to benefit from the expertise of experts active in the sectors. This is an issue that is difficult to achieve without a regulatory system for two reasons: first, employing experts is costly for the government, and meeting this cost increases the government's financial burden, and second, many experts are unwilling to work in the government sector. But this purpose is achieved by establishing a regulatory system in its modern sense. On the other hand, the existence of such conditions greatly reduces the risk arising from non-specialist government decisions in relation to specialized areas (Scott, 2002).

Variety of control mechanisms

Unlike state-based theories of regulation, in which the use of formal mechanisms and hierarchical systems are considered one of the most important tools for exercising governance in the regulatory system, Scott's approach uses a diverse combination of the state, the market, and society to exert control (Offe, 2000; Santos, 2002). The central point in this theory is the abandonment of the monopoly of the hierarchical system stemming from the legitimacy of formal political positions such as courts and government departments, meaning that first, regulatory affairs are not necessarily implemented by the state, but by using the combined capacities of the state, the market, and society. Second, regulatory affairs are not implemented in the form of a top-down hierarchical system. In this theory, using the tool of institutional design, mechanisms are formed in which interactions between actors take place, the results of which will be in accordance with the intended goals of the regulator.

In fact, according to Scott, the mechanism for implementing governance goals for the government has shifted from focusing solely on hierarchical control based on the authority arising from formal laws, to a combination of social control mechanisms based on accepted norms of society, as well as the use of competitive mechanisms based on the design and formation of targeted markets, alongside technical mechanisms and designers that are based on the architecture of social and technical systems. In such a complex environment of combined mechanisms for implementing control, there is no need to use formal and legal authority, and the goals of the regulatory system are sometimes achieved in an imperceptible manner and as part of the organic structure of society (Scott, 2003).

Variety of regulators (controllers)

In the traditional model, the controllers were only government departments, courts, and official institutions. Modern societies have effectively distributed power to a wide and diverse range of non-governmental actors, granting them levels of regulatory authority. Therefore, in today's societies, various institutions such as guilds, non-governmental organizations, industry activists, international institutions, and even banks and credit institutions (as providers of financial resources), credit rating agencies, and insurance companies also have a controlling role, and each of them influences an aspect of the actors' activities (Scott, 2003).

Diversity of Regulated (Controlled)

The focus of state-centered and traditional approaches was usually limited to market regulation and economic businesses, but in the new approach, a wide range of market actors, from the government itself and government institutions to even social institutions, are regulated. By using intelligent regulatory mechanisms, it is possible to selectively regulate specific sectors, organizations, and even individuals in a completely targeted manner, which actually have a greater impact on the path to achieving the economic and social goals intended by the regulator. In Scott's model, the regulated and the manner and extent of applying control mechanisms are focused on a selection of key actors in an intelligent and targeted manner, replacing the general application of the same regulations to a wide range of actors with different importance and influence through traditional unintelligent formal and bureaucratic mechanisms. In fact, in the post-state regulatory approach, firstly, the scope under control increases and secondly, businesses are controlled through indirect methods. In the post-regulatory state era, control is exercised neither directly nor by a specific individual, but by the whole of society. In effect, the whole of society regulates the whole of society (Scott, 2003).

Regulation in Iran

In Iran, for many years, most regulatory tasks were performed directly by the government, and there was no clear separation between policymaking and regulation. However, over time, organizations with regulatory missions were gradually established under the government. With the establishment of institutions such as the Bar Association and the Medical System Organization, sectoral and specialized regulation has advanced, and over time, some relatively modern government regulatory institutions such as the Government Penal Code Organization, the Producers and Consumers Protection Organization, and recently the Radio Regulatory Organization have also been established with the aim of playing the government's regulatory role. With the promulgation of the general policies of Article 44 of the Constitution and the approval of the law implementing these policies, which led to the formation of the Competition Council, a new stage in the establishment of the regulatory system in the country began, which, of course, has not been very successful so far. With the passage of time and the changes in the concept and position of the government in Iran, organizations gradually emerged under the government that focused on regulatory tasks and were responsible for matters such as licensing, market regulation, and imposing certain penalties on violators. The history of the subject of regulation entered a new era with the establishment of some specialized and professional institutions that had regulatory powers. For example, the establishment of the Bar Association in 1920 and the Medical System Organization in the 1940s can be mentioned. Currently, there are institutions in the country that each perform some part of the regulatory tasks. It is noteworthy that currently in Iran there is no clear boundary between tasks and there are institutions that perform a combination of policy-making, regulatory, executive, and ... (Research Center of the Islamic Consultative Assembly, 2018).

Regulatory governance

Although the free market is the basis of a modern and free society, in some situations the market may not provide all the goods and services needed, or it may provide them in a way that has a negative impact on society as a whole. The market alone cannot perform all economic functions. In some situations, the market cannot allocate resources optimally and as it should, perhaps between sectors (Hughes, 2010). Ensuring social justice is another issue that can cast doubt on the idea of the free market even in the absence of market failure. In competitive markets, income may be distributed in unacceptable ways between groups. In these circumstances, people with little property or assets may not be able to access sufficient and necessary resources to provide for life, at an acceptable standard level, therefore, supporting vulnerable groups, guiding, correcting and completing market failures in some areas, justifies the principle of government intervention in the economy. The causes of market failures are numerous and may also have different degrees. Therefore, in each case, the consequences of the role of the government and the type and form of government interventions can be completely different from each other (Hughes, 2019). Regulatory governance is defined in the documents of the Organization for Economic Cooperation and Development as policies that are created with the aim of improving regulation (Dohler, 2011). Marian Dohler (2011) mentions the relationship between the term regulatory governance and the term meta-regulation, which refers to regulation within the regulation process itself. Emphasizing the relationship between political and economic theory, Levy Farr explains the “theory of regulatory capitalism” in which new regulatory approaches are integrated with “economic and political” theories. That is, regulatory governance is a new paradigm for sustainable human development with an interactive mechanism of the three sectors of the government, the private sector and civil society, whereby countries can use all their capabilities in all-round development. OECD (2023) pointed out that there are three characteristics of regulatory governance, such as regulatory policies, practices and institutions. However, the sound regulatory governance agenda is a very dynamic concept that emphasizes the continuous adoption of new tools, policies and institutions that need to be maintained and improved over time (Thomas and Zhang, 2020). The successful design and implementation of regulatory reforms should be linked to the concept of three mutually supportive elements of governance values, such as transparency, stability and accountability (Thomas and Zhang, 2020).

Goals of good regulatory governance

Governments can legitimately pursue limited or extensive regulatory reform, but ultimately, sustainable reform requires changes in institutions, capacities, incentives, and even the role of government. This understanding of the systemic nature of sustainable reform explains why many countries are moving toward a more comprehensive concept of regulatory governance. For the purposes of this study, the most common goals of regulatory governance are defined as achieving a regulatory system that is:

1) Impact: the relationship between public policy goals and regulatory outcomes. The closer the outcomes of regulation are to the stated goals, the more effective the regulation is.

2) Efficiency: a measure that reflects the relationship between benefits and costs at any given point in time. Regulations that are effective one day can be ineffective the next because their effectiveness, the assessment of benefits and opportunity costs, changes. Any reform that increases benefits while keeping costs constant, or reduces costs while keeping benefits constant, increases efficiency.

3) Transparency and accessibility: The capacity of stakeholders to understand the entire regulatory cycle through problem and objective definition, development, adoption, implementation, and adjudication. The more easily and fully a stakeholder can obtain information about a government's regulatory activities, the more transparent those activities are. Among the tools for transparency are consultation/engagement procedures that provide opportunities for stakeholders to participate in the development, monitoring, and review of regulations. The opportunities must be "meaningful." That is, stakeholder information and views must be obtained in a way that is relevant, timely, and responsive to policy development. The main goal is to ensure that regulations effectively deliver sustainable economic, social and environmental benefits, meaning that the benefits (broadly defined) justify the costs (broadly defined), that the minimum costs required for production at any level are met, and that resources are allocated to their highest value (Ribiru, 2018).

Regulatory governance and economic impacts

The overall objective of regulatory governance is to increase net social benefits, ensuring that both benefits and costs are considered in judging the effects of reforms. Cross-country reviews and assessments point to regulatory risks and costs as factors affecting firm performance and market incentives, operating through a wide range of influences such as potential returns on investment, cost of capital, incentives for innovation and market opportunities (OECD, 2005).

This section explores the evidence for regulatory governance initiatives across five categories or regulatory objectives: 1) sectoral liberalisation, with deregulation, re-regulation and the development of regulatory policies to address market failures; 2) broad regulatory reform initiatives focusing on market entry and competition; 3) reforms aimed at reducing regulatory and administrative compliance costs; 4) reforms aimed at improving regulatory quality tools, procedures and institutions; and 5) the impact of regulatory governance reforms on informal relations. The distinction between these five types of impacts is somewhat artificial because one type of reform, for example "cost reduction," can affect other areas, such as informal market entry. However, the distinction is important because each type of initiative has different overall effects, imposes constraints on some objectives and makes them difficult to achieve, and ultimately has different conditions and risks for the DP.

2. Research background

Safari Nasrani et al. (2024) studied the effect of supervisory governance on human resource development with the mediating role of political behavior of employees of the Ministry of Sports and Youth of the Islamic Republic of Iran. They showed that regulatory (supervisory) governance has an effect on human resource development, but the political behavior variable does not play a mediating role in this relationship.

Danaei Fard (2024) in her article entitled "Effectiveness Assessment of Regulators as a Tool for Eliminating Defects in the State Governance Process: Understanding the Rationale, Implementation Process, and Challenges Ahead" deals with understanding the nature, importance, and necessity of effectiveness assessment, the stages of its implementation, and the

challenges facing its implementation in the Iranian public sector.

Mousavi et al. (2024) in a study titled "The Relationship between Regulatory Governance and Public Administration Transformation in France; Moving from a State-Centered Order to Structured Pluralism" conclude that the four new tools for the transformation of French public administration are: 1. Budget reforms, 2. Simplification, 3. Contractualism, and 4. Effects of multi-level governance in interaction with the European Union, which are in a reciprocal relationship with regulatory governance and their concrete manifestations are crystallized in increasing participation, developing flexible rights, and the flexibility of the legal structure.

The Organisation for Economic Co-operation and Development (OECD) (2024) in a public governance policy document report entitled Regulatory Experiences: Advancing the Agile Regulatory Governance Agenda provides policy support to governments to develop constructive and appropriate regulatory experiences as part of implementing the 2021 Recommendation for Agile Regulatory Governance to Harness Innovation. Regulatory experiences can help promote adaptive learning and more innovative and informed regulatory policies and practices.

In their research work "Developing a Framework for Self-Regulatory Governance in Healthcare AI Research: Insights from South Korea," Kim et al. (2024) clarifies and rationalizes the ethical governance system for healthcare AI research. This paper expanded a four-step clinical trial process for healthcare AI research into six steps: preliminary ethics review (step 1); data set creation (step 2); model development (step 3); training, validation, and evaluation (step 4); application (step 5); and post-deployment monitoring (step 6). In articulating ethical requirements step by step, this analogy benefits from the reliable and flexible use of existing research ethics governance resources, research management, and regulatory functions.

Mishra (2023) in his article titled "Regulatory Governance Framework Profiling to Enhance Industry Performance: Application of Fuzzy Analytic Hierarchy Process" proposes a new regulatory governance profiling technique using a hybrid approach to enhance industry performance. Thus, equitable market access, market distortions, ecosystem, domestic production supported by R&D, and foreign direct investment are among the ranked sub-parameters, which constitute a combined weight of 60%. Greater focus by policymakers on these five regulatory governance sub-parameters may change the regulatory governance framework and enhance India's participation in the global value ecosystem.

Sangon (2023) in an article titled "Understanding Resilience in Sustainable Development: Alarm Bell or Public Information?" concludes that three approaches are crucial to regulatory governance. First, the lack of a coherent resilience paradigm (with common definitions, problems, and methods) in development studies. Second, its use, instead, by established development paradigms in a fragmented manner to expand and/or repackage pre-existing arguments. Third, the consequent possibilities of resilience as a wake-up call and siren song in sustainable development.

3. Research methodology

In this study, due to the novelty of the research topic and the use of 15 experts, the fuzzy Delphi method was used in order to achieve reliable results using this method. Since experts have different characteristics, they also have different mindsets, and if the options are answered based on different mindsets, the analysis of variables is worthless. Thus, by defining the range of qualitative variables, experts will answer the questions with the same mindset. Therefore, in this section, qualitative variables have been defined as trapezoidal fuzzy numbers. In measuring and ranking the main indicators effective in designing the regulatory governance model in the medical equipment sector, considering the two stages of distributing the questionnaire among the experts and selecting 12 healthy questionnaires from among the questionnaires distributed among the expert members, the results obtained are displayed in the following tables.

According to the results obtained from the qualitative fuzzy Delphi analysis in the above table, in measuring and evaluating the averages obtained from calculating the fuzzy values resulting from the distribution of the questionnaire among the experts in the 2 stages under study, the components with a final mean difference of less than or equal to 0.2 will be approved. Accordingly, according to the measurement of the final mean difference column, it is clear that only the first subcomponent of the main indicator of

organizational culture, which is the subcomponent of responsiveness, among all the subcomponents under study, did not have sufficient fit and validity from the point of view of the experts under study. Therefore, in concluding the qualitative analysis of the initial proposed model, we have reached a suitable and good consensus.

Table 1: The average difference between the experts' opinions in the first and second stages of completing the questionnaire

Final average difference		Fuzzy average of expert opinion(Second questionnaire)		Fuzzy average of experts' opinions (first questionnaire)		Component
2	1	2	1	2	1	Structure and Functioning of Regulatory Institutions
0.2	0.35	6,8,10,10	4/8.6/3,7/8,8/2	5/5,7/3,9/3,9/5	5/5,7/3,9/3,9/5	
4	3	4	3	4	3	
0.1	0	5/3,7,9,9/3	6,8,10,10	4/8.6/3,7/8,8/2	6,8,10,10	
2	1	2	1	2	1	Structural and technical factors
0	0.14	6,8,10,10	5/8,7/7,9/7,9/8	6,8,10,10	4/8.6/3,7/8,8/2	
4	3	4	3	4	3	
-	0.1	-	5/3,7,9,9/3	-	4/8.6/3,7/8,8/2	
2	1	2	1	2	1	Political and legal factors
0	0	5/5,7/3,9/3,9/5	5/8,7/7,9/7,9/8	5/5,7/3,9/3,9/5	5/8,7/7,9/7,9/8	
4	3	4	3	4	3	
-	0.2	-	6,8,10,10	-	5/5,7/3,9/3,9/5	
2	1	2	1	2	1	Economy and Market
0	0.2	5/8,7/7,9/7,9/8	6,8,10,10	5/8,7/7,9/7,9/8	5/5,7/3,9/3,9/5	
4	3	4	3	4	3	
-	0.2	-	6,8,10,10	-	(5/5,7/3,9/3,9/5)	
2	1	2	1	2	1	Social and technical
0	0.14	6,8,10,10	5/8,7/7,9/7,9/8	6,8,10,10	4/8.6/3,7/8,8/2	
4	3	4	3	4	3	
-	-	-	-	-	-	

Research findings and data analysis

The principles of quantitative analysis of the model presented in this article are based on the interpretation and analysis of data collected from the community of experts under study, in the form of analytical statistics in a combined quantitative and qualitative form. So that the data related to each of these variables, which were obtained from the experts' responses to the researcher-designed questionnaires, were analyzed using the qualitative fuzzy Delphi method in 2 stages, based on the principles of the quantitative research method of multi-criteria decision making (MCDM) and the fuzzy network analysis method (FANP).

Fuzzy Network Analysis (FANP):

In the fuzzy ANP method, the geometric mean of the experts' evaluation will be calculated first. Then, using the Googos and Boucher method, the consistency of the matrices at the level of each relationship between each component and the subcomponents related to that component will be calculated. For this purpose, according to the standard of the network analysis method, in order to achieve the goal of the present quantitative method, paired comparison questionnaires based on the proposed and approved model in the mentioned qualitative method were designed and distributed among the experts. Considering the fuzzy approach in this research, the verbal expressions and fuzzy numbers listed in the table below have been used.

According to the above table based on the components and subcomponents confirmed from the qualitative fuzzy Delphi method, in the first step, in the path to obtaining FANP results, the average of the pairwise comparisons of the studied criteria is displayed in the following table.

In the following table, in the first step, the main components of the regulatory governance model in medical devices have been examined and analyzed, and in accordance with the standard of the fuzzy network analysis method, the fuzzy geometric mean of these components has been calculated.

Table (2) Qualitative words and their corresponding fuzzy numbers in the fuzzy network analysis method (FANP)

NumberFari	PhrasesVerbal
(1,1,1)	Equal importance
(1,1.5,1.5)	Equal to weak importance
(1,2,2)	Weak importance
(3,3.5,4)	Weak to strong importance
(3,4,4.5)	Strong importance
(3,4.5,5)	Strong to very strong importance
(5,5.5,6)	Very strong importance
(5,6,7)	Very strong to absolute importance
(5,7,9)	Absolute importance

Table (3) Components and subcomponents studied[1]

Source	Symbol	Subcomponent	Symbol	Component
OECD, (2023); Fenwick; Kaal, and Vermeulen, (2017); Benner and Weiner, (2019); Shitkat and colleagues, (2021); Sunstein, (2022); Moss, David, and John Cisternino, (2009); Ranchordas and Van T Schip, (2019); Autry, Lesher and Lomax,(2020); Wisem,(2014)	a1	Regulators' experience	A	Structure and Functioning of Regulatory Institutions
BRAITHWAITE and DRAHOS, (2000); Shitkat and colleagues, (2021); Fatemi Amin and colleagues, (2013); Eftekhari, (2018); Correa et al., (2019);	a2	Independence and the regulatory framework		
Amiri et al., (2018); Glazer and Shleifer, (2003);Renda, Castro and Hernandez, 2022 Autry, Lesher and Lomax, (2020); Wisem, (2014); Moss, David and John Cisternino, (2009)	a3	Post-launch monitoring and evaluation		
OECD, (2021); Renda, Castro and Hernandez, (2022); Center of expertise for digital platform regulation, (2022);	a4	Registration and licensing		
Wiseman, (2014); Atery, Lesher and Lomax, (2020), World Health Organization (WHO), (2007)	b1	Quality technical standards	B	Structure factorsYand artY
Matrimony (1999); WhO, (2007)	b2	Medical equipment life cycle management		
Varazani and colleagues, (2023); WhO, (2007)	b3	Utilizing new technologies		
PORTER, (1999); Zarei, (2004); Global Governance Commission[2], (2004); Glaser and Shleifer, (2003); OECD, (2023); WhO, (2007); WhO, (2014)	c1	Globalization and international agreements	C	FactorsYSYAnd the lawY
Bright White and Routh, (2000); Momin, (2019); Group Bank Global (2019); Korea and Colleagues, (2019); Marquez and Pinto (2018); Mohair and Wagner (2013); Thomas and Zhang, (2020); Commission Europe,(2023);	c2	Accountability		
Bright White and Routh, (2000); Momen, (2019); World Bank Group (2019); Correa et al., (2019); Marquez and Pinto (2018); Mohr and Wagner, (2013); Thomas and Zhang, (2020)	c3	Transparency		
Amiri et al., (2018); AdineVand, (2013); Fatemi Amin and colleagues,2013 Honorary, (2018); United Nations[3], (1997); Parliamentary Research Center, (2018); Glazer and Shleifer, (2003); Peltzman (1976); Posner, (1971), (1974) and (1975); Becker, (1983);	d1	Macroeconomic stability	D	Economy and Market
Lobel, (2004); Lobel, (2007); DORFF (2003); Beck, (1992); AGELL, (1999); PORTER, (1999); Gairigia, (2011); Fright et al., (2017); Peykanpour et al., (2019); Alamdari et al., (2014)	d2	Diversity in the market		
Adams et al., (2013); Brightwhite and Routh, (2000); Dahler (2012); Salarianzadeh and Jaliseh, (1400); Freit et al., (2023); MohammadiHa	d3	Private sector and stakeholder		

[1] Objective: Identify and prioritize factors affecting the design of a regulatory governance model in the medical device sector.
[2] Unesco
[3] UNDP (United Nations Development Program)

Source	Symbol	Subcomponent	Symbol	Component
et al., (1400); Sunstein, (2022(2017); Fright et al. (2017); Mohammadiha et al. (1401)		participation		
Scott, (2002); Ranchordas, (2021); State Council, (2019); Innovative CenterYSupervisionY, (2021); Vahdani Nia, (2017); Roozbeh et al. (2023)	e1	Culture and public manners	E	CommunityYand artY
Jacobs, (2004); Salarianzadeh and Jalisa, (1400); World Health Organization, (2007); Organization Health Global (2014); Ministry of Health and Medical Education, (2010); Fifth Development Plan, (2006)	e2	Advertising monitoring and balanced stewardship		

Table (4) Average of pairwise comparisons of the main criteria of the regulatory governance model

Criteria	A			B			C				D		E			AverageGeometric		
	l	m	u	l	m	u	L	m	u	l	m	u	L	m	u	l	m	u
A	1	1	1	0.9	1.1	1.1	0.5	0.5	0.6	2.3	0.68	3.32	3.4	4.24	3.4	1.2672	1.08848	1.477
B	0.9	1	1.09	1	1	1	0.4	0.4	2.2	2.3	0.87	3.22	2.1	1.54	3.2	1.0921	0.87322	1.907
C	1.85	2.1	2.2	2.2	2.6	2.8	1	1	1	3.2	0.57	4.66	3.4	5.65	0.8	2.1497	1.77259	1.902
D	0.3	0.3	0.44	0.3	0.3	0.4	0.2	0.2	3.3	1	1	1	2.0	3.33	2.5	0.5261	0.61507	1.104
E	2.41	2.9	3.1	2.2	2.8	3	1.2	1.3	2.8	2.3	1.21	4.41	1	1	1	1.7115	1.66801	2.584
Total																6.7467	6.01739	8.976
	CRm =0.025 CRg =0.069 Compatible																	

Now, in the following table, we will examine the average comparisons in measuring the identified sub-criteria:

Table (5) Mean of pairwise comparisons of components and subcomponents of the regulatory governance model in medical devices

Compatibility status	Compatibility rate	Geometric mean			Symbol	Subcomponents	Component-(index)I see)
		U	m	l			
Compatible	CRm =0.010 CRg =0.019	1.56086	1.42655	1.24187	a1	Quality technical standards	Structure and Functioning of Regulatory Institutions (A)
		2.13092	1.61835	1.29986	a2	Medical equipment life cycle management	
		2.52291	2.37278	1.16818	a3	Utilizing new technologies	
		1.89823	1.97692	1.31125	a4	Quality technical standards	
		12.4858	11.1790	11.4635	A	Total	
Compatible	CRm =0.012 CRg =0.033	1.44802	0.93140	1.12065	b1	Quality technical standards	Structure factorsYand art(B)
		2.02821	1.01912	1.20235	b2	Medical equipment life cycle management	
		2.36785	1.47530	1.98606	b3	Utilizing new technologies	
		10.5177	8.05480	8.69328	B	Total	
Compatible	CRm =0.001 CRg =0.017	1.44802	0.93140	1.12065	c1	Globalization and international agreements	FactorsYSYAnd the lawY(C)
		2.02821	1.01912	1.20235	c2	Accountability	
		2.36785	1.47530	1.98606	c3	Transparency	
		10.5177	8.05480	8.69328	C	Total	
Compatible	CRm =0.008 CRg =0.055	1.53438	2.21316	2.14759	d1	Macroeconomic stability	Economy and Market(D)
		2.16871	2.07718	2.35967	d2	Diversity in the market	
		2.52786	2.14740	1.89013	d3	Private sector and stakeholder participation	
		13.3889	15.3835	12.7796	D	Total	
Compatible	CRm =0.010 CRg =0.023	1.39881	0.94039	1.13398	e1	Culture and public manners	CommunityYand art(E)
		1.40787	0.86425	1.16156	e2	Advertising monitoring and balanced stewardship	
		8.15275	7.61306	7.46229	E	Total	

In the third step, the geometric means calculated in the previous step are normalized. In this step, the values obtained from the second step are normalized. The values $\tilde{Z}_i$ for each matrix are normalized $\tilde{Z}_i$ by the sum will happen.

$$\tilde{r}_{ij} = \tilde{w}_i = \frac{\tilde{z}_i}{\sum_{i=1}^{n} \tilde{z}_i}$$

If these normalized weights are related to comparisonsOptionsbe $\tilde{r}_{ij}$(Option weightIMIn connection with Criteria jM) and if it is related to the comparison of criteria $\tilde{w}_i$ CalledIt will be. The table below shows these normalized values in the measurement of the five principal components.

Table6-Normalized geometric meanMain criteria

Criteria	Symbol	AverageNormalized geometry		
		l	M	u
Structure and Functioning of Regulatory Institutions	A	0.187835	0.18089	0.164538
Structure factorsYand artY	B	0.161872	0.145117	0.212523
FactorsYSYAnd the lawY	C	0.318631	0.294578	0.211967
Economy and Market	D	0.077979	0.102216	0.12309
CommunityYand artY	E	0.253683	0.2772	0.287881

Fourth stage: Defuzzification: In this stage, the obtained fuzzy weights will be defuzzified according to the following equation.

$$\boldsymbol{Crisp(\tilde{U}) = \frac{(u_l + 2 \times u_m + u_r)}{4}}$$

In this regard $\tilde{U} = (u_l, u_m, u_r)$ and $Crisp(\tilde{U})$ Day-Fuzzy $\tilde{U}$ It is.

By performing these calculations, the final weights will be obtained, respectively.

Accordingly, according to the results of the-Fuzzification of the output of the third stage in the calculation of the network analysis methodFuzzy (FANP), the main components and related subcomponents can be prioritized according to the following table:

PriorityClassification of criteria and sub-criteria of the research model:

According to the results of network analysis calculationsThe fuzzy logic and the output obtained in most of the aforementioned sections can be prioritized.General arrangement of the componentThe criteria in their main criterion group and at the overall level were displayed as follows (in order from highest priority to lowest):

Table 7 - Final weight matrix of criteria

Rank	WeightFinal determination of components	Component	
3	0.178538	A	Structure and Functioning of Regulatory Institutions
4	0.166157	B	Structure factorsYand artY
1	0.279939	C	FactorsYSYAnd the lawY
5	0.101375	D	Economy and Market
2	0.273991	E	CommunityYand artY

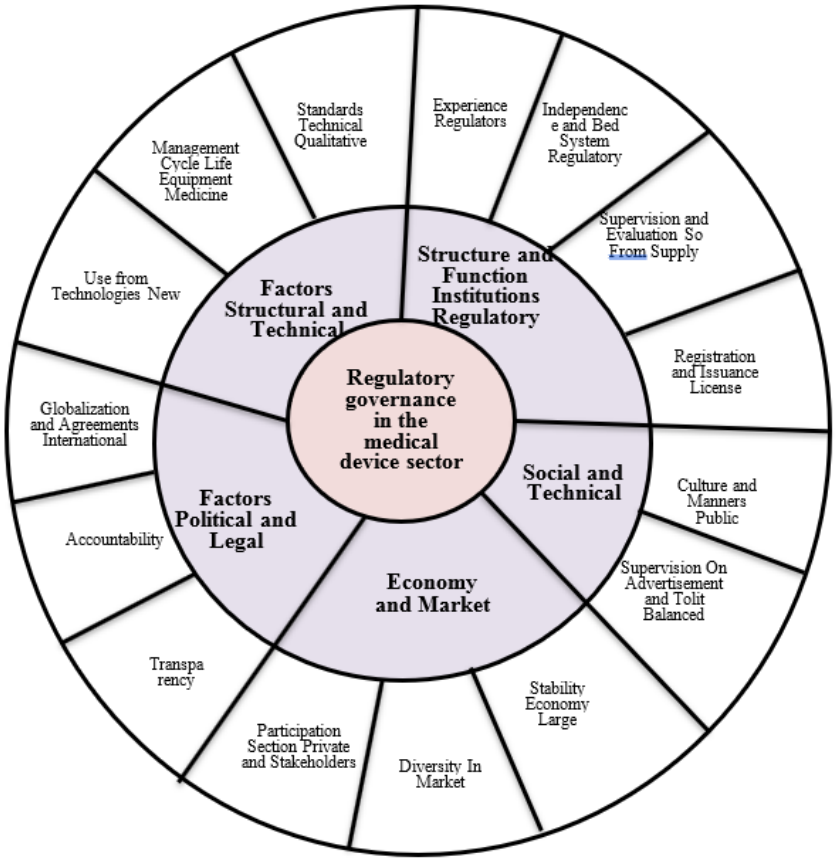
Table7The final weight matrix withShows the main characters.According to the results obtainedAbility to arrange and prioritizeThe classification of these criteria in influencing Roy designed a regulatory governance model for medical device development as follows (in order from highest to lowest priority):

1. Political and legal factors
2. Social and technical factors
3. Functional structure of the regulatory system
4. Structural and technical factors
5. Economy and Market

Now that the final weights of the main research criteria have been determined, we will measure and evaluate the final weights of the sub-criteria related to each of these 5 main components and criteria (Table 8):

Table 8 - Final weight of component sub-criteriaThe 5 main ones

Final internal ranking BelowComponentI see	Final weights of the day Fuzzy	Subcomponents	Abbreviation symbol	Criteria
4	0.122141	Regulators' experience	A1	Structure and Function Institutions Regulatory
3	0.143398	Independence and the regulatory framework	A2	
1	0.182118	Post-launch monitoring and evaluation	A3	
2	0.155025	Registration and licensing	A4	
2	0.124463	Quality technical standards	B1	Factors Structural and Technical
1	0.146048	Medical equipment life cycle management	B2	
3	0.204977	Utilizing new technologies	B3	
3	0.124463	Globalization and international agreements	C1	Factors Political and Legal
2	0.146048	Accountability	C2	
1	0.204977	Transparency	C3	
3	0.142595	Macroeconomic stability	D1	Economy and Market
1	0.154169	Diversity in the market	D2	
2	0.153972	Private sector and stakeholder participation	D3	
1	0.142646	Culture and public manners	F1	Social and Technical
2	0.138848	Advertising monitoring and balanced stewardship	F2	



Research model

As is clear from the research model, five components were identified from the perspective of the experts in the field of research in the direction of regulatory governance in medical devices, including: 1) the structure and function of regulatory institutions; 2) structural and technical factors; 3) political and legal factors; 4) economic and market; and 5) social and technical; which are from the perspective of the experts selected in this study, each of these factors also includes several sub-components, the extent of their influence has also been determined in previous discussions.

In the area of structure and functioning of regulatory bodies in line with the regulatory governance of medical devices, it is necessary and essential that regulatory bodies operate with a transparent, accountable, and expertise-based approach for regulatory governance in the field of medical devices. Risk-based regulation, continuous updating of standards, and effective supervision of the production, import, and distribution of devices are crucial. Continuous engagement with stakeholders, including manufacturers and healthcare providers, will ensure the effectiveness of regulations. Establishing digital systems for tracking and reporting increases transparency. The independence of the regulatory body from commercial and political interests guarantees public trust. Inter-institutional and international coordination is also essential for the integrity of regulations.

In the area of structural and technical factors, regulatory governance in medical devices should be able to consider the following six factors:

1) Establish an independent supervisory body structure with transparency of duties and effective accountability.
2) Develop and implement national and international technical standards as a mandatory reference.
3) Develop digital infrastructure to track, record, and evaluate equipment performance is mandatory.
4) Strengthen the technical qualification assessment system for manufacturers and importers.
5) Strengthen cooperation between executive, scientific, and professional bodies to align regulations. and
6) Use of new technologies such as artificial intelligence for continuous monitoring and supervision is recommended.

In the area of political and legal factors, in line with regulatory governance in medical devices, laws and regulations need to be aligned with international standards and up-to-date. Transparency and accountability of regulatory bodies need to be strengthened to gain public trust. Coordination between policy-making, regulatory, and executive bodies is also important. Licensing needs to be facilitated while maintaining safety and quality. Tackling corruption in the approval and distribution processes, as well as legal support for innovation and domestic production, are other necessities.

In the field of economics and markets, regulatory governance in medical devices needs to focus on transparency, healthy competition, and support for domestic production. It is essential to set fair pricing, facilitate market access for innovative companies, and promote quality through regulatory standards. Establishing integrated systems to track and monitor the supply of equipment prevents rents and monopolies. Close cooperation between the government, the private sector, and scientific institutions helps improve policymaking and the optimal allocation of resources. Ultimately, regulatory governance should be such that it simultaneously ensures the interests of patients, the sustainability of the health system, and the sustainable development of the industry.

In the social and technical domain, regulatory governance of medical devices requires an interdisciplinary approach. From a social perspective, strengthening transparency, stakeholder participation, and public education are essential to increase trust and awareness. From a technical perspective, establishing national and international standards, continuous quality monitoring, and employing new technologies for tracking and evaluating devices are important. Continuous interaction between governing bodies, manufacturers, and consumers will pave the way for effective and sustainable governance.

It is worth noting that the technique used in this study is the fuzzy ANP method, and since the priority of these factors has already been examined and identified, regulatory governance in medical equipment must be able to create this capability in

society so that individuals, policymakers, and stakeholders in the field of regulatory governance in medical equipment can overcome the inability and incompetence in the context of uniformity and homogeneity in medical equipment and the necessary standards, and with the same capabilities and approaches in the production and distribution of medical equipment, they can safely handle economic and commercial issues in medical equipment. Also, considering the comprehensive impact of the components in this model and this method, the accuracy of the dimensions and components identified is reliable and can be optimal solutions for regulatory governance in medical equipment in the future.

Discussion and Conclusion

In the current study, prioritizing effective components for regulatory governance in medical devices is important, considering the approach of strengthening regulatory governance in the development of production and distribution of medical devices and in order to create a culture of optimization for the production and development of medical devices in the context of supporting health and social hygiene. In this regard, regulatory governance in medical devices is a set of knowledge and skills necessary to make this important matter available to the target society in a healthy and practical manner.

The main objective of this research was to investigate and identify the components affecting regulatory governance in medical devices. According to the results of fuzzy network analysis calculations and the output obtained in most of the aforementioned sections, it is possible to prioritize the components in groups and main criteria, which at the overall level, the research identifies the relevant criteria. The final weight matrix shows the main criteria. According to the results, the order and prioritization of these criteria in influencing regulatory governance in medical devices can be shown as follows (in order from highest priority to lowest): 1) Political and legal factors; 2) Social and technical factors; 3) Functional structure of the regulatory system; 4) Structural and technical factors; and 5) Economy and market. From the discussion that was raised, it can be concluded that regulatory governance in medical devices and its strengthening in line with the practical goals used in this medical equipment production and distribution industry leads to the efficiency and effectiveness of health and social welfare. Regarding the comparison of the findings of the present study with other findings of researchers, it should be noted that this study is consistent with most of the effective components presented on the development of a regulatory governance model in medical devices by other researchers, including Yeganagi and Khodai 1403 in the components (modern and contemporary governance characteristics, basic dimensions of regulatory governance), Safari Nasrani et al. 1402 (organizational independence, culture, transparency), the Organization for Economic Cooperation and Development or OECD 2024 (regulatory experiences, comparative learning and innovative regulatory policies and practices), Kim et al. 2024 (creating data sets, training, validation and evaluation, requesting post-deployment monitoring, ethical requirements, research management and regulatory functions, governance of artificial intelligence research, creating a governance framework, ethical research, health care), who have tried to develop these models. Therefore, it can be said that an effective step has been taken towards better understanding the factors effective on the development of regulatory governance in medical devices. Therefore, the research suggests that in order to select the best regulatory body platform in the regulatory governance of medical devices, attention should be paid to several key aspects, including structure, processes, objectives, and interactions with stakeholders. Therefore, in this regard, we can consider a combination of international best practices and specific local needs. In this regard, the regulatory body should be able to use experts to achieve its regulatory goals and adapt itself by hiring experts with deep knowledge in the field of medical engineering, international regulations, and standards and update its processes. It is necessary that an optimal regulatory system can be established by establishing a "Medical Devices Regulatory Organization" as a subsidiary of the Ministry of Health or as an independent institution with the participation of the government, the private sector, and scientific institutions. This institution should help improve quality, safety, and innovation in the field of medical devices by utilizing information technology, developing transparent laws, and continuous monitoring. Ultimately, this model can serve as a model for increasing competitiveness and quality in the domestic and global medical equipment market.

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