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A comparative analysis of Namibia's medicines regulatory authority with regulatory authorities of South Africa, the United States of America, and the United Kingdom

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Abstract

Background: Little attention has been paid to the principle of the independence of medicine regulatory authorities, agencies, or boards, especially in Africa, despite their role in ensuring the availability of safe, effective, and affordable pharmaceuticals to society.

Methods: Data was collected using information from the Acts, Laws, legislation, and regulations available in the public domain. Standard Gilardi and INDREG questionnaires were used to collect data to assess the legal status, adequacy of human and financial resources, role clarity, transparency, and accountability of regulators, which could be answered through desk research.

Findings: The average overall independence for all four agencies is 59%, with a standard deviation of 10%. The study results further revealed that the national regulatory authorities have significant protection above average from external influence though they are not entirely independent.

Conclusion: The four agencies have comparable regulatory independence and similar protection from undue external influence. Namibia's medicines regulatory independence level is not significantly different from that of South Africa, the United Kingdom (UK), and the United States of America (U.S.A).

Keywords: Regulatory Authorities; Governance; Independence; Global Benchmarking Tool; Regulatory Independence; Independent Regulatory Authorities

1. Introduction

The law permits regulators to make decisions within their scope of expertise without seeking approval from other government officials, parent ministries, or departments within the government. They must be sufficiently shielded from short-term government pressure and other external stakeholders. Rangoni and Thatcher [1] highlight that there has been a significant expansion in the delegation of authority to independent regulatory agencies. Regulatory freedom allows decision-making bodies to address issues on their precise terms. Furthermore, it ensures that the agency bases its decisions on scientific evidence rather than extraneous considerations, including fear, self-interest, or prejudice [1].

Independence allows regulators to conduct themselves and act in an impartial, equitable, and consistent manner without any personal interest, prejudice, or inappropriate influence [2]

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No entity other than a court or a pre-established appellate panel should overrule the regulator's decisions [3]. Regulatory independence offers a solid foundation for consistent and impartial decision-making in complex matters, guided by the opinions of experts and compatible with core principles for effective, efficient, and fair judgment [4]

Medicine Regulatory Authorities are the gatekeepers in the supply chain of medicines and related products. They work within a legal framework and a set of regulatory functions that cover the entire lifecycle of a medicine, including clinical trial oversight, product marketing authorization, registration, licensing regulatory inspections, and product testing [5]. Independent medicine regulators can protect the public against manufacturers' requests to lower or raise drug prices depending on demand or shortage. It also ensures the safety of all registered medicines due to the absence or limited influence of government, health professionals, pressure groups, or pharmaceutical companies on the medicines registration process.

Most governments and regional bodies are giving more prominence to the independence of regulators [6]. The OECD has conducted several studies, including independence from government, politicians, firms in the regulated sectors, and other interest groups, such as consumer and environmental groups [7]. Medicine regulators operate in a complex environment with public authorities, the private sector, human rights organizations, and the public. There are very few studies published on the autonomy of medicines regulatory authorities despite the WHO Global Benchmarking Tool (GBT) for assessing the level of regulatory maturity encouraging regulatory independence [8]. Therefore, the motivation of the study was to evaluate and compare the level of formal independence of medicine authorities in advanced nations to that in Namibia.

Some studies reveal that strong formal independence leads to substantial de facto autonomy with better regulatory outcomes [9]. The level of de-jure independence will help evaluate the general assumptions on the medicines regulatory authorities' freedom level. Several theories have been proposed to evaluate the level of independence in various sectors focusing on both de jure and de facto independence of regulatory authorities [8,10,11]. Most previous studies in various sectors agree that institutional building blocks for the decision-making of freedom are the legal provisions of space, financial independence, the head of the regulator of human resources, and accountability [11,12].

1.1. Development of Independent Regulators

The concept of formal independence was initially developed in the literature on central banks in the 1980s [10]. Over the years, various public utility markets such as energy, telecommunications, audio-visual services, railway, competition protection, and consumer protection authorities, have advanced into independent authorities and bodies [13]. Liberalization of regulatory authorities was established in multiple sectors where the states ceased to operate. Independent Regulatory Authority (IRA) was once confined to specific industries such as financial markets or countries like the United States. However, it has become common in many policy areas and countries [14].

1.2. Benchmarking in Regulatory Independence

There is no commonly accepted catalog of regulatory agencies and a minimum standard of independence. However, many legal tools exist to safeguard regulators' freedom from the government and the industry [13]. These commonly include, among other things, statutory provisions governing the election and removal of regulatory officials, conflict of interest rules, clear roles for the regulator and the sector ministry, and dedicated funding sources [15].

An expanding body of literature shows that identifying the critical components of the regulators' independence is more challenging than creating their catalog [10]. Benchmarks of evaluating a regulatory system provide coherence, discipline, and meaning by comparing with a standard. The governance benchmarks of independent regulators have been used in many evaluations in various sectors [3]. The defining characteristic of independent regulators is the decision-making independence achieved by several institutional and legal principles common in IRAs.

Ranking Tool has been used to integrate techniques, measuring the threat of influence from outside parties rather than the degree of independence of regulators [11] Some authors follow a more generalized approach by developing universal independence indices [16,17]. Although many undisputed statutory independence standards exist, authors recognize a general blueprint for what constitutes an independent regulator. Hanretty et al. [17], for example, observe that their index needs to correctly reflect the distinctive governance structure of some of the regulators examined. A standard deposit indicator would profit from a study strategy that allows for contextual interpretation of the findings [11].

1.3. Benefits of Regulatory Independence

Many scholars agree that providing regulatory agencies with adequate independence is necessary for designing effective regulatory systems [9,11]. Studies show that independent regulatory authorities were justified as a measure of regulatory activities [13]. The cost of clinical testing of pharmaceuticals has raised inconsistency in the authorization process [18]. The regulators usually experience pressure from the product producers who might depend on the approval of a particular product, from patients, and from public health pressure groups eagerly waiting for product authorization, for critical conditions. Therefore, there is a high probability that pressure groups or applicants may influence decision-makers to decide according to demand.

It may be expected that the independent regulation of essential products according to dependable and relatively stringent criteria is in the long-term interest of society since both consumers and producers profit from a well-functioning market [19]. Overall, evidence indicates that providing regulatory authorities with unique guarantees of independence enhances quality by entrusting decision-making powers to experts insulated from direct external influence [13]. Credible assurances that the government is committed to impartial and open governance and rule enforcement can be communicated to regulated organizations by establishing a more independent regulator. Regulatory decision-making will become more consistent and reliable as politically biased effects are reduced and regulatory interest choices that could result in conflicts of interest must be made impartially concerning government and non-government organizations [20].

An independent regulator can stand up to pressure to lower or raise prices in the regulated industry if that would hurt cost recovery, long-term maintenance, and service quality. When staff is chosen based on merit, independence encourages professionalism, clear roles, accountability, and expertise. It also promotes competitive neutrality by ensuring that all providers are on the same playing field and that the regulators are independent of and not answerable to any supplier. Independence improves market participants' confidence that they will be handled relatively fairly, promoting the industry's growth and vitality [15].

A review of the relevant literature by the European Commission et al. [21] shows that independent regulators are necessary to preserve the stability and continuity of rules, avoid political interference in business decisions and regulatory risks, and maintain high standards of expertise and professionalism. Regulatory autonomy guarantees that all relevant parties are consulted throughout a product's approval lifecycle. The outcome of a regulatory decision is likely to be affected by several factors, including the interests of various political players, regulators, regulated entities, and more significant social and economic actors [9].

This can lead to better regulatory decisions and, above all, innovative policies at the macro level. Autonomy is not meant to remove the regulator from the decision-making process. Instead, the objective is to ensure the regulatory body is sufficiently shielded from excessive influence and short-term political concerns, to maintain a stable and trustworthy regulatory environment. Stability permits a long-term view of the provision and operation of the network market, including concerning investment [2].

Aim

The study aimed to determine the influence of politics, industry, and other stakeholders in decision-making during the manufacture and registration of medicines and related substances in Namibia compared to selected stringent authorities of South Africa, the United States of America, and the United Kingdom.

2. Methodology

2.1. Study Design

A desk review of regulations and governing acts was conducted to identify and analyze the legal framework concerning NRA independence in the selected countries. The academic literature has built several independence indices to evaluate regulatory independence in various sectors [7]. The technique chosen to categorize National Regulatory Authority (NRA) independence involved the creation of a table in which several relevant questions from Gilardi and INDREG indices were answered [10,12,16]. The indices have been used in literature to identify relative levels of autonomy based on objective and comparable indicators. Formal independence was coded with indicators clustered around dimensions and weighted according to their presumed influence [11].

2.2. Study Sources

Data was collected using information from the Acts, Laws, legislation, and regulations available in the public domain. The Medicines and Related Substances Control Act 13 of 2003 regulates the Namibia Medicines Regulatory Council (NMRC). Medicines and Related Substances Act no. 101 of 1965 regulates the South Africa Health Products Regulatory Authority (SAHPRA) Furthermore, the SAHPRA website has several reports that foster regulatory independence. The Medicines and Health Products Regulatory Agency (MHRA) of U.K has a rich website that provides regulatory guidelines and is regulated by the Human Medicines Regulations 2012.

Some parliamentary calls and publications for MHRA to be independent were also used as sources of information to compile data. The federal regulation of food, drugs, cosmetics, biologics, medical products, and tobacco is legally mandated by acts of the United States Congress and constitutional design. Two main statutes regulate the Food and Drug Administration (FDA): the Federal Food, Drug, and Cosmetic (FD & C) Act, and the Public Health Service (PHS) Act. Several studies and publications also provided information on the challenges and weaknesses of the regulatory independence of the FDA [22,23,24,25,26].

2.3. Data collection

This study used two standard questionnaires employed in many studies to evaluate NRA independence in various sectors, the INDREG ranking tool and the Gilardi indices [2,11,16]. Formal independence was coded using indicators grouped around dimensions and weighted by influence. The ranking tool has been developed specifically to measure the risk of influence by external players, whereas the Gilardi indices measure the level of independence of the regulators themselves [10,11]. Gilardi indices were therefore used to evaluate the NRAs' degree of independence compared to the NMRC. At the same time, the ranking was also applied to explore the possible undue influence from authorities and industry.

Each indicator has several questions describing the NRA's structure or operation. The response to each question was given some weight based on the influence of the parameter on regulatory independence. Using the information of each regulator available in the public domain, the ranking tool and the Gilardi index questionnaire were completed to evaluate the independent regulator parameters. The responses were collected and fed to an Excel spreadsheet. The average of all questions in each dimension was used to determine each parameter's independence.

2.4. Data Analysis

Every conceivable response was given a Gilardi score between 0 and 1, with 0 denoting a high probability of the exercise of influence and 1 denoting a high degree of protection against possible impacts. Findings on the questionnaires were fed into narrative comparisons, bar graphs, and tables. The average level of independence of the NRA was obtained by taking the average of the five dimensions. Descriptive statistics were conducted using Excel to determine the average mean NRA Independence. Inferential statistics were performed using Excel. The statistical significance of the difference between NMRC and the other NRAs was determined using the t-test and p-value.

3. Results

3.1. Comparison of formal status regulatory independence level

Gillard's score results for each factor were plotted on a bar graph to compare the formal regulatory independence level. The graph in Figure 1 compares the Formal regulatory independence of the four agencies on all Gilad score indicators on each status. The graph in Figure 2 compares the overall formal regulatory independence of the four agencies. The graph in Figure 3 compares formal independence from risk potential external influence for all indicators on each status. Figure 4 represents the overall formal independence from the external influence of the four countries.

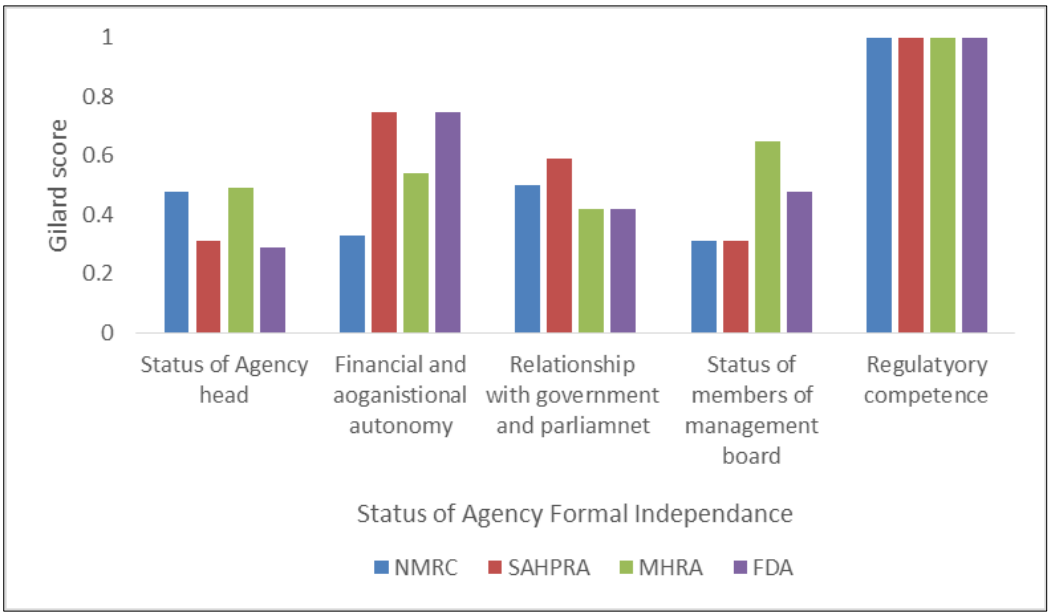

Figure 1 The formal independence of NRAs

The RANKING tool score results for each factor were plotted on a bar graph to compare the level of formal regulatory independence from external influence.

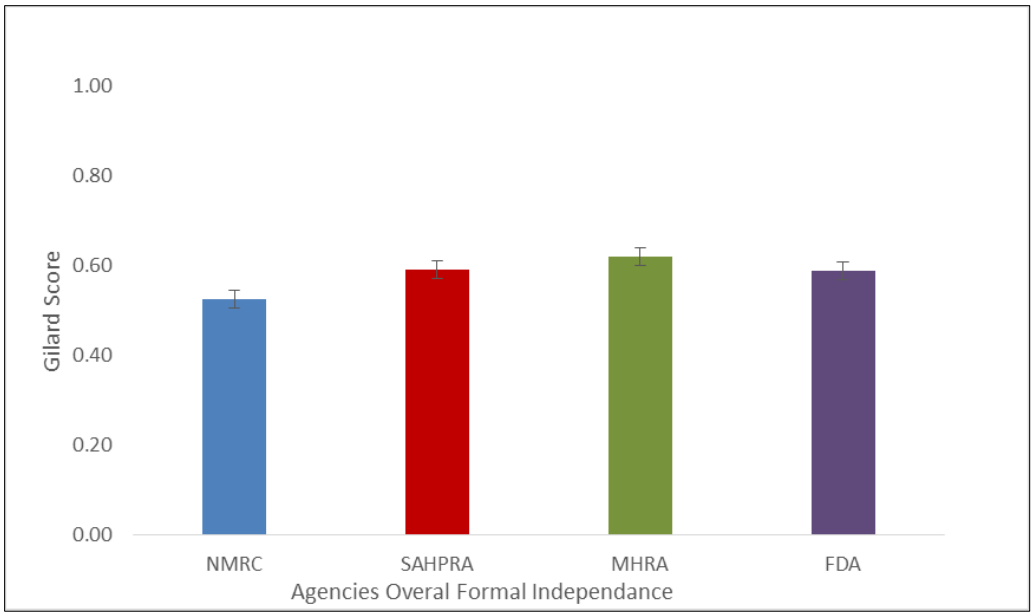

Figure 2 Overall formal regulatory independence of the four agencies

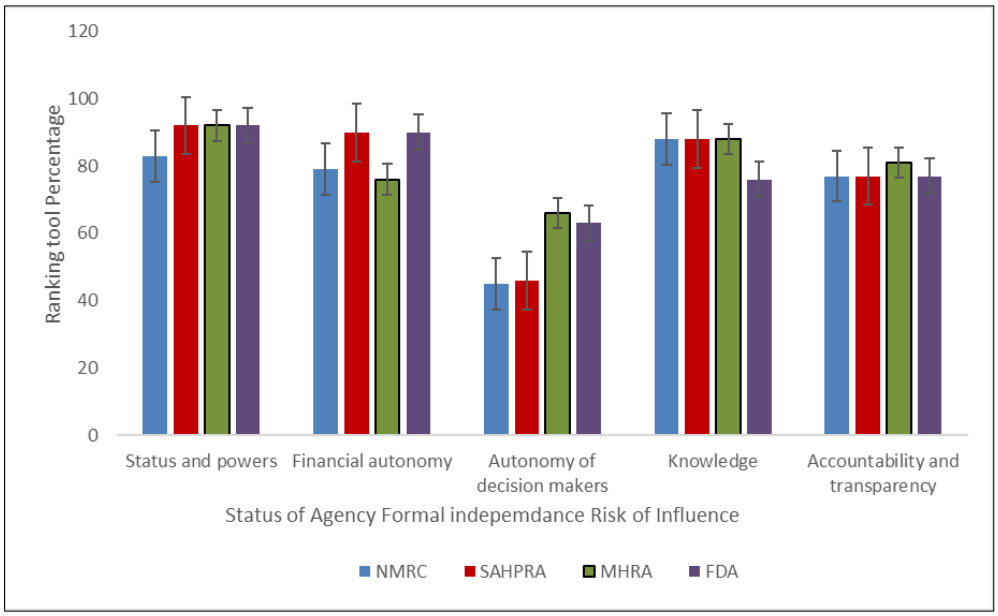

Figure 3 Formal independence from risk potential external influence

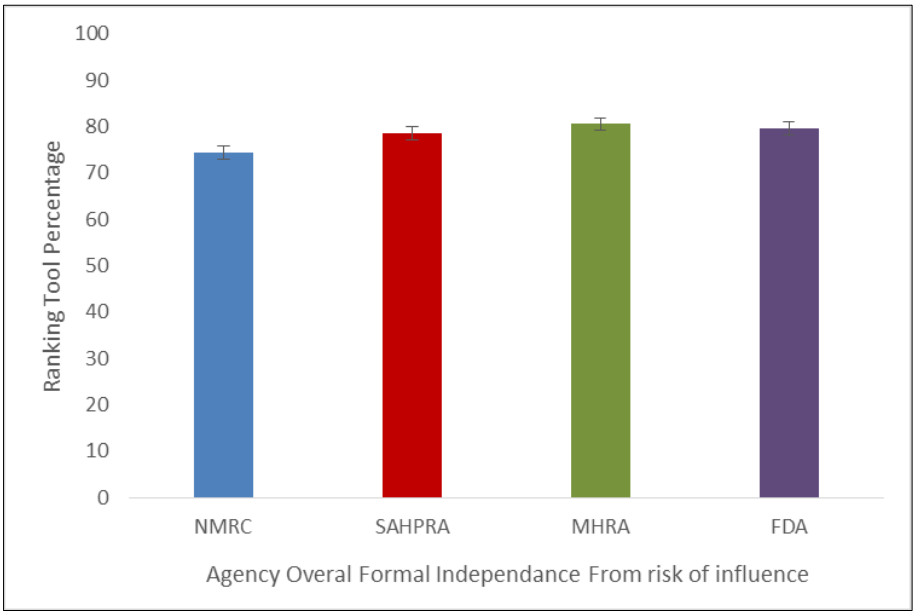

Figure 4 The overall formal independence from the external influence of the four countries

Table 1 Descriptive statistics of the formal independence from external influence

	NMRC	SAHPRA	MHRA	FDA
Mean	74.4	78.6	80.6	79.6
Median	79	88	81	77
Standard Deviation	16.96	19.12	10.23	11.80
Sample Variance	287.8	365.8	104.8	139.3
Range	43	46	26	29
Minimum	45	46	66	63

4. Discussion

The comparative analysis of the independence of national medicine regulatory authorities (NMRA) in Namibia, South Africa, the United States of America, and the United Kingdom reveals several insights into regulating medicines globally. The results of this study highlight the varying levels of independence of NMRA in different countries. The differences in organizational structure, funding mechanisms, transparency and accountability measures, industry influence, and political autonomy affect the regulatory process and public trust. Despite different structures and systems among countries, Badran [9] asserts that the boundaries between the regulator and the parent ministry should be distinct. However, there is a lack of agreement on how the notion of autonomy should be implemented although some regulators appear less impenetrable to external effects [10].

Based on the findings of this research, the four agencies enjoy similar degrees of regulatory independence and close relative protection against undue external influence. Despite the four NRA independence being significantly lower than IRAs, all agencies show high protection from undue external influence. Rangoni and Thatcher [1] found that governments persistently politicized IRAs which presents problems to the current delegation of power and has led to numerous efforts to withdraw or limit delegation. Typically, the procedure of task delegation implies a conflict between autonomous decision-making and constant scrutiny [19].

All four agencies are not formally distinct and functionally independent from the government or parliament. NMRC and SAHPRA score over 50% on this criterion since they need to be fully accountable to Parliament. MHRA and FDA are below 50% because both are fully accountable to parliament. NMRC must only present a report for approval. However, SAHPRA is only responsible for giving information reports. All the agencies have independence clearly stated in the law. Complete control of the regulator by the parliament could lead to never-ending political discussions on purely administrative, legal, and management matters, which do not encourage solid regulatory processes and evaluations.

In comparison, it can be concluded that the level of formal regulatory autonomy of the NMRC is like the other regulatory agencies despite the different levels of economic development. Overall, the findings suggest that there is no one-size-fits-all approach to ensuring the independence of the NMRA. Concerning relationships with political players, Sześciło and Jakubowski [13] observe that complete autonomy is unattainable as regulators are still part of the government and political choices may still influence them. However, the study highlights some best practices and areas for improvement that could be implemented globally, such as greater transparency and accountability in decision-making, a dedicated budget for the NMRA, and protection against political interference

5. Conclusion

Based on the findings of this research, the four agencies enjoy similar degrees of regulatory independence and close relative protection against undue external influence. The goal of autonomy is not to remove the regulator from the governing process but rather to shield the regulator from undue influence and short-term political considerations so that a dependable and credible environment can flourish. Despite the four NRA independence being significantly lower than IRAs, all agencies show high protection from undue external influence. In comparison, it can be concluded that the level of regulatory autonomy of the NMRC is similar to the other regulatory agencies despite the level of economic development. Studies have revealed that formal regulatory independence is necessary but more is needed to guarantee the effectiveness of the regulatory system and better outcomes.

Recommendations

The study suggests that there are several areas for improvement in the regulation of medicines globally. All four countries could benefit from strengthening their relationship with government, robust organizational structures, and autonomy in decision-making and funding. There is a clear indication of the importance of ensuring that NMRA operates with high independence from external pressures. Formal independence is required from an institutional standpoint to ensure the effectiveness of the regulatory system.

Limitations

The study's findings are limited to the four countries for which data was collected and can therefore not be generalized to regulators outside these countries.

Compliance with ethical standards

Disclosure of conflict of interest

The author reports no conflicts of interest in this work.

Statement of ethical approval

This research did not deal directly with human subjects. Issues relating to informed consent and ethical approval do not apply.

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