



BRIEF COMMUNICATION

Approaches to the scientific production of National Regulatory Authorities of Regional Reference in Scopus

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ABSTRACT

Introduction: National Regulatory Authorities of Regional Reference are regulatory agencies recognized for their competence and efficiency in health regulation, standing out in the development of scientific research, personnel training and education, as well as the management of scientific knowledge and innovation.

Objective: to compare the scientific production of the National Regulatory Authorities of Regional Reference in Latin America.

Methods: a bibliometric study was conducted using institutional profiles of the National Regulatory Authorities of Regional Reference in the Scopus database. Basic indicators of productivity and citation were applied, along with a review of institutional research and innovation policies. Search strategies were standardized to minimize data dispersion, and publication and citation patterns were evaluated for the period 2004–2024.

Results: Public Health Institute of Chile leads productivity, growth, and regional performance, followed by the Brazilian National Health Surveillance Agency and the Cuban Center for State Control of Medicines, Equipment, and Medical Devices. The most frequently addressed topics are related to Medical Sciences, Pharmaceutical Sciences, and Biological Sciences. The research and innovation policies of the agencies contribute to the development of scientific activity and the quality of research to support regulatory work.

Conclusions: the scientific production of the studied regulatory agencies shows different behavioral patterns associated with institutional scientific policies, with positive growth confirmed over the last 20 years.

Keywords: Bibliometrics; Health Information Management; Information Products and Services; Health Surveillance Services.

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INTRODUCTION

National Regulatory Authorities of Regional Reference (NRAr) are national regulatory agencies recognized for their competence and efficiency in health regulation, especially in guaranteeing the safety, efficacy, and quality of medicines and biological products. These authorities act as a model for other regulatory authorities in the region, supporting their strengthening and the development of better regulatory practices.^(1,2)

In the Region of the Americas, regulatory authorities are evaluated and certified to become regional reference authorities for medicines and biological products. This process, supported by the Pan American Health Organization, aims to strengthen health regulation, promote regulatory convergence, and facilitate information exchange.⁽²⁾

Specifically in Latin America, these include the National Administration of Drugs, Food and Medical Technology (ANMAT) of Argentina, the National Health Surveillance Agency (ANVISA) of Brazil, the Public Health Institute of Chile (ISP), the National Agency for Health Regulation (CECMED), and the Federal Commission for Protection against Health Risks (COFEPRIS). NRAr promote the development of effective health policies aimed at contributing to access to medicines, optimizing the regulation of innovative, competitive, quality, and safe medicines, as well as reducing inequalities in direct information to the population.^(2,3)

NRAr must rely on scientific research, specialized training, and expert knowledge to streamline the implementation of new technologies and demonstrate their capacity for adaptation. The use of innovation and scientific knowledge is crucial for these agencies to work effectively and strengthen health regulation, cooperation at the regional and global levels. In this way, the importance of strengthening technical and investigative capabilities to provide quality services is manifested.⁽⁴⁾

Studying the scientific output of these agencies allows us to determine the degree of importance of the link between technical processes and scientific research. In this sense, bibliometric analysis constitutes a robust methodological tool for evaluating institutional scientific performance. Its application contributes not only to quantifying scientific output, but also to a much broader spectrum that includes mapping cognitive domains, detecting emerging research areas, examining inter-institutional collaboration networks, and evaluating scientific impact and influence through indicators standardized by areas of knowledge. This multidimensional approach allows for the development of precise diagnoses of internal capabilities and shortcomings, as well as identifying areas of specialization. Consequently, bibliometric analysis not only enhances strategic positioning and institutional visibility, but also provides managers with solid and contextualized empirical evidence for decision-making and the dynamic reorientation of Science and Technology policies.⁽⁵⁾

Several studies have explored the scientific output of regulatory agencies in the region and internationally, allowing the present research to be situated within a broader comparative framework. In Latin America, bibliometric analyses have been published on the research activity of institutions such as ANVISA in Brazil and the ISP in Chile, highlighting their role in generating knowledge related to health regulation. Likewise, recent research in Cuba has examined the scientific output of entities linked to biotechnology and drug regulation, providing evidence on the relationship between institutional policies and research performance.⁽⁶⁾

In this sense, the present study does not arise in isolation, but rather complements and engages with previous findings, contributing to a broader understanding of the role of regulatory authorities in scientific production and its impact on public health. Given that scientific output is an indicator of an institution's technical and innovative capacity, it is imperative to determine whether significant differences exist among these agencies, which could translate into inequalities in health decision-making. Without this evidence, regional strengthening policies lack an objective diagnosis. This led to the present study, which aimed to compare the scientific output of the leading regional regulatory authorities in Latin America.

METHODS

Design and approach

A retrospective and comparative bibliometric study was conducted to analyze the scientific output of Latin American rRNAs. The approach was quantitative, based on productivity and citation indicators, complemented by a qualitative analysis of institutional research and innovation policies.

Data source and search strategy

The primary source of information was the Scopus database, selected for its international coverage and its ability to provide consolidated institutional profiles. Standardized search strategies were employed, using the official names of each rRNA and their institutional affiliation variants. Filters were applied by publication period (2004–2024), and documents not indexed in Scopus were excluded. To minimize data dispersion, multiple affiliations were checked, and duplicate records were removed. The strategy was designed to ensure comprehensiveness and consistency in information retrieval, allowing the procedure to be replicated in future research.

Selection criteria

Only documents published in Scopus-indexed journals explicitly linked to the institutions under study were included. Original articles, reviews, brief communications, and conference papers were considered, provided they reflected institutional scientific output. Publications without clear institutional affiliation, documents unrelated to health regulation, and those with indexing errors were excluded. This selection criterion aimed to ensure that the results accurately reflected the scientific activity of regulatory agencies, avoiding biases arising from external collaborations not directly attributable to the regulatory agencies.

Bibliometric indicators and study variables

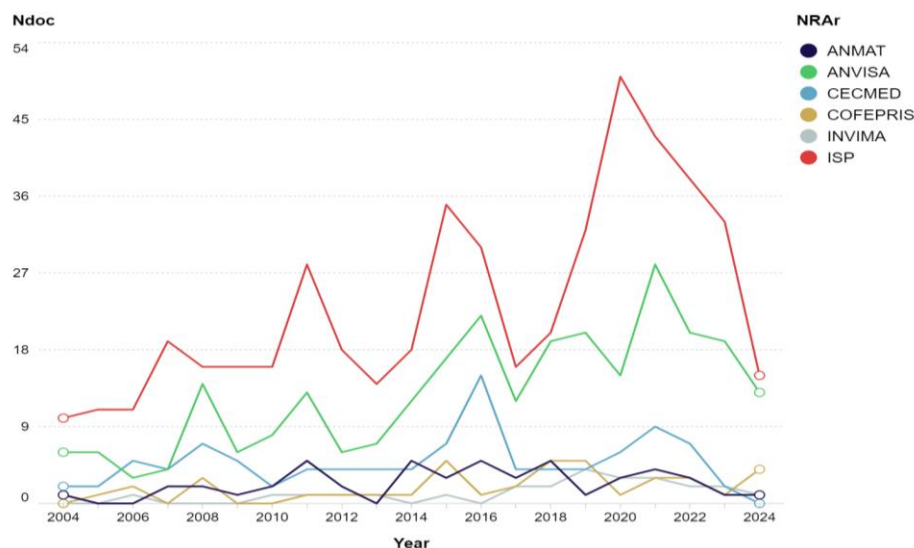
Basic indicators of productivity (number of annual publications) and impact (total citations) were applied. The combination of these quantitative and qualitative indicators made it possible to evaluate not only the volume and visibility of the output, but also its strategic orientation and thematic relevance.

Data processing, analysis, and ethical considerations

The data were exported from Scopus and processed using spreadsheets and specialized statistical software (SPSS). Descriptive and comparative analyses were performed, presented in tables and graphs to facilitate the interpretation of trends. Normalization techniques were applied to avoid bias due to differences in institutional size. Regarding ethical considerations, the study relied exclusively on publicly available information, without involving personal or confidential data. International standards of scientific integrity were respected, and methodological transparency was ensured, guaranteeing that the results can be replicated and verified by other researchers.

RESULTS

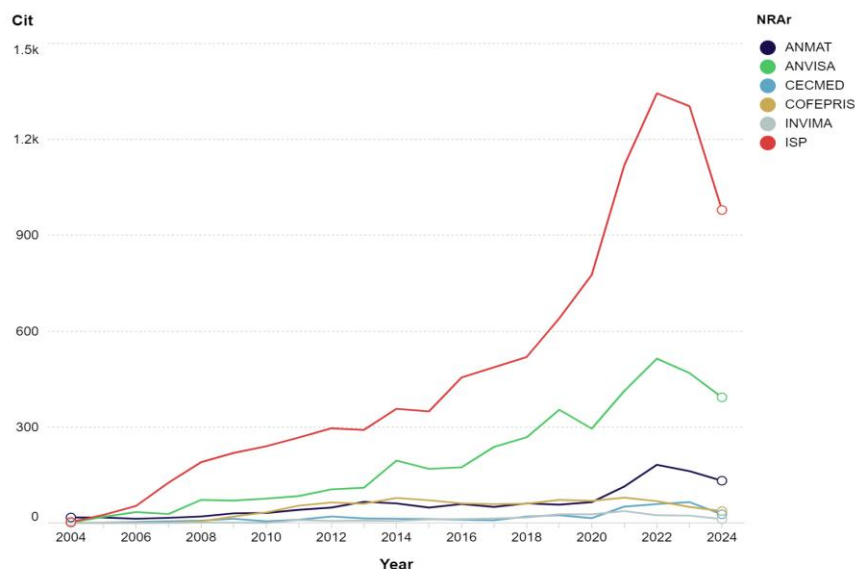
Figure 1 shows the behavioral patterns of the scientific production of NRARs and the comparative flow between the different institutions, where ISP leads the production of articles, followed by ANVISA and CECMED. With a lower range of publication are ANMAT, COFEPRIS, and INVIMA.



Grades: ANMAT (National Administration of Drugs, Food and Medical Technology); ANVISA (National Health Surveillance Agency); CECMED (National Health Regulation Agency); COFEPRIS (Federal Commission for Protection against Health Risks); INVIMA (National Institute for Drug and Food Surveillance); ISP (Public Health Institute)

Fig. 1 Comparison of the annual volume of publications of NRARs in the last 20 years.

The values associated with citation patterns are shown in Figure 2, where the leadership of ISP again stands out, followed by ANVISA and ANMAT. The figure also exposes the growth of citation levels, mainly in the case of the three agencies mentioned above.



Grades: ANMAT (National Administration of Drugs, Food and Medical Technology); ANVISA (National Health Surveillance Agency); CECMED (National Health Regulation Agency); COFEPRIS (Federal Commission for Protection against Health Risks); INVIMA (National Institute for Drug and Food Surveillance); ISP (Public Health Institute)

Fig. 2 Comparison of the annual volume of citations received by NRARs in the last 20 years.

NRARs addressed different themes in their publications with varying patterns and with a majority predominance of ISP in almost all areas analyzed, as presented in Figure 3.

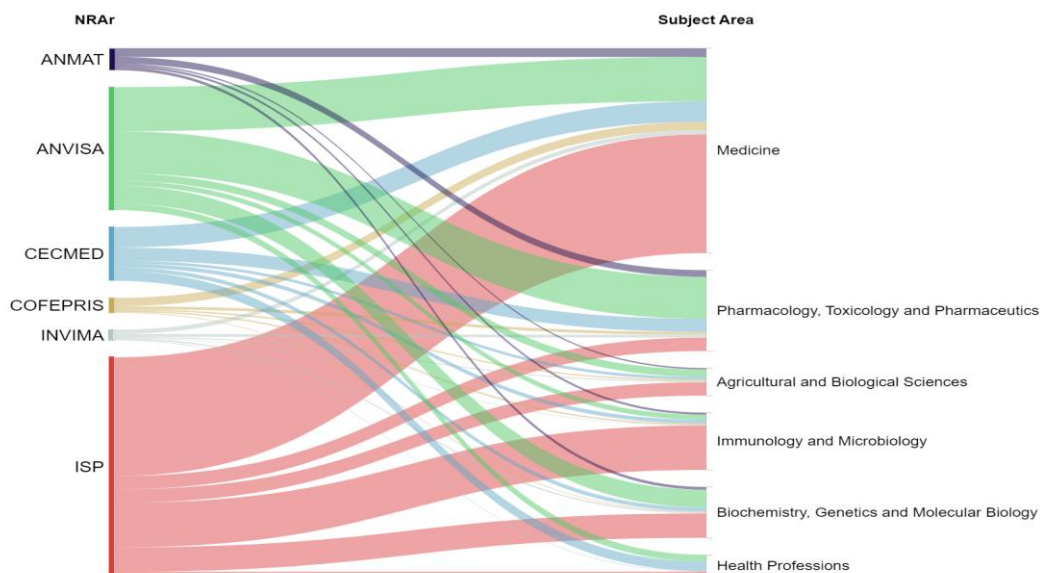


Fig. 3 Distribution of documents by Scopus thematic area.

DISCUSSION

The regional regulatory agencies (RNAr) exhibit distinct patterns of scientific productivity, with the ISP (Public Health Institute) leading the way in article production. Following closely behind are ANVISA (Health Regulatory Agency) and CECMED (Center for Scientific and Medical Research). ANMAT (National Administration of Drugs, Food and Medical Technology), COFEPRIS (Federal Commission for Protection against Sanitary Risks), and INVIMA (National Institute for Food and Drug Surveillance) have lower publication rates. The annual growth of these agencies is also noteworthy, reflecting the aforementioned trends.

The results show marked heterogeneity in the scientific output of the Regional Reference National Regulatory Authorities (ARNr), with sustained leadership from the Public Health Institute of Chile (ISP), followed by ANVISA and CECMED. This behavior is consistent with the general pattern of Latin American scientific output in public health, characterized by sustained growth, but accompanied by significant inequalities between countries and institutions. A bibliometric analysis of Latin American public health output indexed in Scopus showed that Brazil concentrated the largest regional output and that quantitative growth did not always correspond to greater international visibility, while scientific collaboration was a determining factor in strengthening the impact of research.⁽⁷⁾

Similarly, Chinchilla-Rodríguez et al.,⁽⁸⁾ observed that scientific systems with greater production capacity did not necessarily exhibit balanced performance in terms of volume, visibility, collaboration, and knowledge transfer to healthcare practice. In this context, the leadership of the ISP and ANVISA identified in this study can be interpreted not only as a difference in institutional productivity, but also as an expression of more developed scientific and organizational capacities within national research systems. The comparison is particularly relevant because the National Research Authorities (NRAs) are not conventional academic institutions: their scientific output is linked to surveillance, technology assessment, health control, and the generation of evidence for regulatory decisions.

The patterns of the two most productive rRNAs show different stages with production peaks that exhibit an incremental trend. The period with the greatest increase was identified between 2020 and 2022, years that coincide with the beginning and peak of the COVID-19 pandemic. However, these patterns differ from the rest of the rRNAs. For example, in the Cuban case, while a higher concentration of publications is observed during the pandemic period, the peak publication rate was reached in 2016. Another example is the Mexican institution, whose behavior is the opposite, showing low values during the pandemic period.

The magnitude of the observed differences is also supported by specific studies from regulatory agencies. In Cuba, Velázquez-Soto et al. conducted a bibliometric analysis of CECMED's scientific output over 25 years and identified 107 articles, 458 citations, and an h-index of 12, with a predominance of original articles and a high level of international collaboration. The authors also concluded that insufficient integration persisted between scientific activity and technical-regulatory work, an aspect that may limit the dissemination and utilization of research results.⁽⁶⁾

This background is especially relevant for interpreting our results, since CECMED occupies an intermediate position in productivity, with an annual average of 4,8 documents, well below the ISP (23,2) and ANVISA (12,8). Therefore, the volume of publications should not be interpreted in isolation as an indicator of regulatory capacity: an agency can generate scientifically relevant knowledge without achieving large publication volumes, while high productivity requires mechanisms capable of transferring evidence to procedures, standards, guidelines, and regulatory decisions. This consideration coincides with the experience of agencies such as the Food and Drug Administration (FDA), whose institutional policy explicitly states that the results of regulatory research can inform policies, guidance documents, analytical methods, and the evaluation of regulatory applications.⁽⁹⁾

One finding that deserves special consideration is the concentration of the largest productivity increases at the ISP and ANVISA between 2020 and 2022, coinciding with the COVID-19 pandemic. This behavior is plausible considering that health emergencies simultaneously increase the demand for scientific evidence, the need for surveillance, the accelerated evaluation of products, and risk communication. International experience demonstrates that regulatory agencies actively participate in the generation and use of evidence during emergencies; furthermore, the EMA has incorporated bibliometric trend surveillance tools to identify emerging scientific and technological signals that may have regulatory implications.⁽¹⁰⁾

However, the results of this study show that this response was not uniform. While ISP and ANVISA experienced an increase during the pandemic period, CECMED reached its historical peak in 2016, and COFEPRIS showed relatively low values during 2020–2022. These discrepancies suggest that the health emergency alone does not fully explain the dynamics of institutional publications. Factors related to each agency's scientific priorities, installed research capacity, collaboration mechanisms, availability of human and financial resources, and the structure of their research programs likely played a role. Nevertheless, due to the bibliometric design of this study, it is not possible to causally attribute the peaks or declines to changes in leadership, graduate programs, or specific alliances without further document analysis; therefore, these explanations should be considered hypotheses for future research.

The particular behavior of CECMED thus constitutes a phenomenon that requires a differentiated interpretation. The production peak observed in 2016 does not coincide with the regional maximum recorded during the pandemic and could reflect a temporary concentration of certain lines of research, collaborative projects, or institutional publication policies. This possibility is compatible with previous evidence from CECMED, where more than half of the analyzed works were developed through international collaboration and the predominant areas were Pharmacology and Medicine.⁽⁶⁾

Relevant to this analysis is the study of the scientific research policies and standards adopted by the regulatory bodies (RNRs), which methodologically govern these processes in each entity. This analysis reveals notable differences in how the processes associated with scientific activity supporting regulatory activity should be developed. Although these policies can positively impact the outcomes of the activities carried out, they also face common challenges related to funding and government support for scientific research. The RNRs share a common institutional interest in promoting research, innovation, and training through various strategies, including scientific publications, virtual classrooms, innovation labs, and strategic alliances, with the aim of improving health regulation and public health in their respective countries and the region.

Another relevant aspect is that the predominance of Medical, Pharmaceutical, and Biological Sciences is consistent with the nature of these agencies' functions, but it also reveals an opportunity to broaden the concept of regulatory scientific production. In the present study, ISP stood out particularly in Medicine and Immunology and Microbiology, ANVISA in Pharmacology and Toxicology, and CECMED in Medical Professions. This profile coincides with the international literature on regulatory science, in which research is increasingly oriented toward drug evaluation, safety, pharmacovigilance, emerging technologies, and the generation of evidence to support regulatory decisions. Bibliometric studies on pharmacovigilance precisely demonstrate the participation of regulatory authorities such as the FDA and other agencies in the construction of this scientific field.⁽¹¹⁾

Consequently, the value of rRNA scientific output should not be judged solely by the number of documents or citations, but also by its regulatory relevance, understood as the capacity to transform scientific knowledge into tools applicable to health surveillance, technology assessment, risk management, and regulation. This perspective would overcome one of the main limitations of traditional bibliometric indicators: a highly cited publication does not necessarily represent a regulatory outcome of greater utility for the population.

The results of this study therefore suggest that strengthening regulatory agencies should include not only incentives for publication, but also mechanisms to link research, innovation, and regulatory decision-making. In practical terms, future research should link institutional scientific output with indicators such as the number and timeliness of health alerts, risk assessments, evidence-based regulatory changes, guidelines and standards developed with agency participation, health technology assessments, and emergency response times. In this way, bibliometrics would shift from describing the scientific capacity of the authorities to evaluating their effective contribution to health regulation and, ultimately, to the protection of public health.

This study has some methodological and design limitations that should be considered when interpreting the results. First, the analysis was restricted to a single database (Scopus), which may introduce coverage bias by not including other relevant sources of scientific output. Furthermore, the reliance on institutional profiles may have led to dispersion or underreporting of publications, especially those linked to international collaborations or multiple affiliations, which is an area for improvement in future research.

CONCLUSION

It can be concluded that the scientific production of the studied NRAs presents different patterns of behavior influenced also by the science policies and regulations implemented in the institutions. In general, it was verified that there has been a growth in productivity and impact over these last 20 years. An expected tendency towards publications related to Biomedical and Pharmaceutical Sciences was also identified. It is the ISP of Chile the leading institution in terms of production, growth, and impact, so it represents a strength in the region.

Conflict of interest

The authors declare that there are no conflicts of interest.

Authors' contributions

OEVS: Conceptualization; formal analysis; research; methodology; visualization; drafting of the original draft; revision, writing and editing.

IRAS: Formal analysis; research; drafting of the original draft; revision, writing and editing.

LCCB: Formal analysis; research; drafting of the original draft; revision, writing and editing.

OLJC: Conceptualization, supervision, review, writing and editing.

All authors participated in the discussion of the results and have read, reviewed and approved the text

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