ARTICLE
https://doi.org/10.22239/2317-269x.01271

Strategic objectives of Health Regulatory Agencies: an international comparative study

Objetivos estratégicos de Agências Reguladoras em Saúde: um estudo comparativo internacional

Rodrigo Lino de Brito[I,*]

Raquel Gonçalves Coimbra Flexa[II]

[I] Ministério da Economia, Brasília, DF, Brasil

[II] Centro Federal de Educação Tecnológica Celso Suckow da Fonseca (Cefet), Rio de Janeiro, RJ, Brasil

***** **E-mail:** rodrigolbrito@yahoo.com.br

Received: Feb 21, 2019
Approved: Jul 11, 2019

ABSTRACT

Introduction: This article presents a comparative panorama between the current strategic maps of three of the world's major regulatory agencies, in order to allow the analysis of the future objectives of these entities, as well as to understand the alignments and particularities of each organization. **Objective:** To analyze and compare the strategic maps of the National Health Regulatory Agency in Brazil (Anvisa); the US Food and Drug Administration (FDA) in the United States; and the European Medicines Agency (EMA) in the European Union. **Method:** This is a qualitative research which used the content analysis method and the technique of meaning condensation to structure and interpret findings. **Results:** It can be seen that all the analyzed entities have, in the organization of their management, the definition of planning processes, with the design of strategic objectives in synthetic maps and focused on problems, declaring their strategy with clarity, conciseness and objectivity. In addition, the degree of homogeneity of issues, as well as a text that is coherent with the state of the art of the regulatory field, favor the alignment between such agencies, making possible a greater international regulatory convergence. **Conclusions:** Explaining the strategy in the right way helps to provide organizational management with systemic analysis, focus, direction and intentionality, which certainly influences the achievement of the expected results.

KEYWORDS: Strategic Planning; Strategic Objectives; Health Regulation; Regulatory Agencies

RESUMO

Introdução: Esse artigo apresenta um panorama comparativo entre os mapas estratégicos atualmente vigentes de três das grandes agências reguladoras de peso mundial, de modo a possibilitar a análise dos objetivos de futuro desses entes, assim como entender alinhamentos e particularidades de cada organização. **Objetivo:** Analisar e comparar os mapas estratégicos da Agência Nacional de Vigilância Sanitária (Anvisa), no Brasil; do *US Food and Drug Administration* (FDA), nos Estados Unidos; e da *European Medicines Agency* (EMA), da União Europeia. **Método:** Trata-se de uma pesquisa qualitativa, que utilizou o método de análise de conteúdo e a técnica de condensação de significados para estruturar e interpretar os achados. **Resultados:** Percebe-se que todas as entidades analisadas têm, na organização de sua gestão, a definição de processos de planejamento, com o desenho de objetivos estratégicos em mapas sintéticos e focados em problemas, declarando a estratégia com clareza, concisão e objetividade. Além disso, o grau de homogeneidade de temas, assim como a redação coerente com o estado da arte do campo regulatório favorecem o alinhamento entre tais agências, possibilitando maior convergência regulatória internacional. **Conclusões:** Explicitar a estratégia da maneira correta ajuda a dotar a gestão organizacional de análise sistêmica, foco, direção e intencionalidade, o que certamente influi no atingimento dos resultados esperados.

PALAVRAS-CHAVE: Planejamento Estratégico; Objetivos Estratégicos; Regulação Sanitária; Agências Reguladoras

INTRODUCTION

Some authors define strategies as the specific choices that enable success in the context of the work done by the organization, emphasizing that choices imply prioritizing certain actions over others[1]. Mintzberg[2] conceptualizes strategic planning as the "organizational process aimed at defining the strategy or direction and the decisions about resource allocation in order to work out the strategy."

In this sense, the strategic planning of regulatory agencies in the field of health surveillance (Visa) stands out as a powerful management tool that is live, dynamic, fluid, and enables the achievement of their core objectives of protection and promotion of collective health.

Dealing with health risks is not a simple task: the problems that health surveillance addresses are intricate, with multiple objects and also multiple interventions to be considered[3]. This context requires different approaches and interdependencies among various fields of knowledge.

From this perspective, it should be noted that the current shaping of the regulatory system is not restricted to economic regulation. This regulatory system acts at both social and administrative regulation, under different organizational formats and perspectives.

Health Regulation

It can be said that models of regulation have always been adopted over time, although this term is relatively new. There are authors who claim that, for centuries, regulatory functions have been performed by various countries as a particular type of State intervention in society life. Others point out that regulation is a contemporary form of State action and refers to the set of legal-normative instruments (laws, decrees, regulations and other rules) available to the government to establish obligations that must be fulfilled by the private sector, by the citizens and by the government itself. Classically, the term regulation has a conceptual meaning based on economic and governmental restructuring processes, led by the State reforms of the last decades. Based on this concept, the role of the State in the process of production and consumption of goods, products and services is limited to that of "regulator" of the market[4,5,6].

Overall, regulation aims to ensure the proper functioning of the market, with a view to achieving optimal efficiency in the pursuit of social welfare, making use of architectures, mechanisms, instruments and institutional designs capable of establishing and inducing certain behavioral patterns, detecting variations and correcting any deviations, according to the characteristics, particularities and needs of each sector. State intervention, therefore, replaces or limits private choices in sectors considered relevant by the society, for the protection of public interest and the benefit of the community[7,8].

For Jordana and Levi-Faur[9], the term regulation can have many meanings. Among them, the authors highlight the definition of Baldwin, Scott and Hood[10], in which three main approaches stand out: i) as specific rules; ii) as all forms of economic and social intervention, from the State point of view; and iii) as all forms of interaction and influence of economic and social behavior, acting as agents beyond the State. However, for Lodge and Wegrich[11], regulation is at the heart of State action, in combination with redistributive and productive activities. These authors point out that even if the boundaries of specific regulatory activities are questioned, certain aspects of the market require regulation because of information asymmetries and inherent monopolistic characteristics.

From this perspective, while on the one hand there is economic pressure on governments for less regulation, on the other, State intervention in new social issues is increasingly required, which reflects the dilemma and constant tension between liberalism and democracy. As a result, recent discussions have put regulation quality improvement at the heart of this debate, expressed internationally by terms like "smart regulation", "better regulation" or "regulatory quality and performance".

Far from the sufficiency of the minimal State and simple regulation by the market, today's reality demands a new type of State intervention that is more effective and efficient in the face of risks and threats that are also quickly becoming global issues. This reinforces the shift in the political and academic debate from the notion of "less regulation" or mere "deregulation" to the focus on what has been called "better regulation" or "high-performance regulation"[12,6].

Because of this movement, international organizations, particularly the Organization for Economic Co-operation and Development (OECD), are urging national governments to evaluate and review their national regulatory regimes in the light of their experience and inspired by peer-review exercises and benchmarking[11].

In this scenario, regulatory agencies have played a prominent role in the political and academic debate over the last decades, especially regarding the terms of institutional design of the State administrative apparatus, seeking a balance between the interests of consumers, companies and governments and to offer society better living and development conditions[6,13].

When moving the regulatory debate into the field of health surveillance, we find a huge amount of products and services that make life easier and extend human survival in such a way that could not have been imagined a few decades ago. However, these products and services also have a great potential to cause harm, raising concerns about quality, efficacy, health safety and rational use and consumption of these products[14].

Therefore, State health regulation seeks to cover sectors characterized by several market failures, that is, cases and situations where market forces are not enough to ensure efficient resource allocation and other desired outcomes, such as gaps in access to essential goods, quality and safety shortcomings in production and consumption, imperfect competition, information asymmetry and various externalities[12,7].

In this context, it can be stated that the increased use of health services and technologies by the population and the increase in people's purchasing power in recent decades has led health surveillance and its regulatory structure to acquire a new status and understanding of its contribution to the social right to health[15].

Health surveillance is an area of public health that addresses the health threats posed by the contemporary way of life, the use and consumption of new materials, new products, new technologies, new needs, i.e., by the habits and complex forms of collective life. Therefore, it is a collective action in health that characterizes the industrial society and can be seen as a requirement of the contemporary civilizing process. In this sense, health surveillance is closely related to the degree of technological and economic development and the democratic institutionality of a country and represents one of the most relevant areas of State regulation in the social field. Additionally, the author states that one of the main functions of the modern democratic State is to protect and promote the health and welfare of its citizens. It is, therefore, up to the State to take care of collective interests, intervening in the activities of individuals and disciplining these activities when they threaten public health[12].

Costa and Bonfim[16] deepen this debate and argue that:

> The current pattern of organization of production, distribution, and consumption of technologies, goods, and services in the globalized economy has challenged the functions, State apparatus, and surveillance system hitherto focused on domestic production. It has also presented new challenges to the healthcare systems of many countries. The reorganization of markets, the increasing exchange between the various regions of the planet and the speed of risk propagation clearly point to new demands regarding the redefinition of concepts, the incorporation of new points of attention and control concepts into health surveillance actions, requiring technical, managerial and operating competence.

Costa[17] further notes that:

> Only recently there is a movement for reflection on the area of health surveillance and its interconnections gained momentum [...]. One of the most relevant aspects of this movement is related to the disruption of the traditional conception of health surveillance, with the emergence of a new paradigm. In this new paradigm, health surveillance begins to be perceived as actions to protect and promote health, with a clear intervening role in the processes of building access to essential goods of health interest [...]. However, the concept of health surveillance, its functions, knowledge, practices and instruments of action are not yet well understood in the health field itself, and the function of health surveillance is often confused with the institutional model that has predominated over time in Brazil, [...] almost always restricted to enforcement actions that most health professionals and managers are unaware of in their technical-scientific, legal-political and sanitary grounds.

Based on this assumption, and expanding the understanding of health surveillance as a practical field, an important management milestone within the National Health Surveillance System (SNVS) was the publication of the Health Surveillance Master Plan – PDVISA. In 2007, this Master Plan outlined a very bold view of the role played by the regulatory process in the mediation between social, technological, health and economic demands. The document states that:

> Health Surveillance can be seen as a space of State intervention whose goal is to adapt the productive system of goods and services of health interest, as well as the environments, to social demands and the needs of the health system. Its main role is to act to prevent, eliminate or minimize the health risks involved in its areas of activity, promoting and protecting the health of the population. Therefore, its actions have the purpose of implementing ethical conceptions and attitudes regarding the quality of relationships, production processes, environments and services. Because of their regulatory role, these actions are an important possibility of articulating governmental [...] authorities and improving social relations[5].

Thus, as communities expand their production capacity and create market imbalances and new technological risks, there is the need to interfere directly in the various areas of collective and individual interests and in the health-disease-quality of life relationship. To strike a balance, planning is necessary as a strategy for prioritizing actions. It is, therefore, essential for the proper management of health risk in a given territory[18].

In this sense, Freitas and Silva[8] advocate that health regulation is legitimately enforced for the benefit of society through the regulation, control and inspection of relationships of production, consumption and access to goods, products and services of health interest. In addition, Flexa et al.[19] argue that health surveillance becomes more powerful when it incorporates the concepts of planning, development, control and assessment, abandoning a merely fiscal and punitive perspective toward more integrated work, with more feasible results for the society.

Strategic Planning and Balanced Scorecard in the Public Sector

In the 1970s, Strategic Planning was defined as a continuous and systematic process of strategy formulation that enables

rational decision-making through formal execution programs so that there is comparability between projected results and actual results[20].

According to the literature[21], there are several authors who defend this classic approach to strategy — as a formal plan[22,23]. However, it is also argued that there are those who understand strategy from a pragmatic perspective[24,25], where strategy is seen as a practice and ongoing process of formulating and implementing action adjustments and resource allocation.

Therefore, several authors are in favor of the idea that the formalization of a strategic plan is a fundamental tool for successful management, since it enables the allocation of efforts to reach common goals pursued by organizations. In the particular case of public administration, the absence of competition in State monopolies and the lack of other ways of measuring performance have postponed the adoption of Strategic Planning in the public sector, where it is focused on the pursuit of excellence in service provision to the citizens[26].

Thus, for a vision focused on providing services to the society, both the design and implementation of a strategic plan in public sector institutions have incorporated result-based management tools, with the ultimate purpose of effectively and efficiently increasing the citizens' welfare[26].

Another driver for public organizations to implement Strategic Planning is to reduce the impact of administrative discontinuity generated by changes in technical and political staff. However, the difficulty in its effective implementation is due to attachment to the past, slow decision-making processes and the immobility that are typical of the bureaucratic distortions found in the public sector[27].

From this perspective, studies show that the introduction of management tools in public organizations, in a context of pursuit of better results and greater effectiveness in actions promoted by the government, has been taking place in Brazil since the 1990s, with the objective of meeting the demands for quality services from increasingly aware and demanding citizens[28].

Among the planning and monitoring models used in the public sector, the Balanced Scorecard (BSC) stands out. This is a strategic management methodology developed by Kaplan and Norton in the 1990s, which provides a balance between the results of the organization and also aims to strengthen the monitoring tasks of the performance of formulated strategies. Classically, in this methodology, it is proposed that the organization's strategic objectives be grouped into four overarching perspectives: financial, clients, internal processes, and learning/growth. The financial perspective comprises the company's financial growth objectives, productivity, costs and other related questions. From a customer perspective, there is concern about the value proposition that the organization will provide to stand out from the competition. From the perspective of internal processes, the objectives related to the company's activities that need to be implemented or improved are addressed. Finally, the learning and growth perspective includes aspects such as the skills and expertise that are necessary to support the other perspectives[29].

According to Richers[30], strategic objectives refer to positions the organization wants to achieve over many years that seek to forecast changes in the environment and the company's adaptation to these changes. These are far-reaching objectives.

In a more contemporary view, the strategic objective is the signal of the action points where success is fundamental for the fulfillment of the mission and the achievement of the future vision of an organization. With this conception in mind, objectives are set by the organization's strategic managers and determine where to focus its efforts. Therefore, organizations should choose a limited number of objectives, whose satisfactory results will ensure proper performance and enable the vision of the future to come about[31].

According to Zimmerman[32], in the BSC, the strategic map is the tool that visually translates the strategic objectives that will be considered by senior management, as it materializes the perspectives and strategy that the organization will adopt to transform its future vision into reality, guided by its mission and values. For the author, its greatest strength is to enable alignment between the various strategic objectives, translating the adopted strategy in a visual and direct fashion. Furthermore, he highlights the leading role of the strategic map in three aspects: i) in defining and communicating, in a clear and transparent manner, at all levels, the focus and strategy of action chosen, and how the actions impact the desired results; ii) as a subsidy for effort allocation; and iii) to avoid scattering actions and resources.

The implementation of this planning methodology, with goal setting and monitoring, triggers major changes in organizational culture, especially in the public sector, where the stability of employees and compensation plans often fail to drive outstanding performance[28].

In the specific case of the National Health Surveillance Agency (Anvisa), the organization has already defined strategic planning cycles ever since 2010. For the 2010-2020 period, the composition of the Agency's strategic map was based on four perspectives, distinct from those traditionally seen in BSC, namely: i) Anvisa's mission; ii) governance and operations; iii) learning and growth; and iv) resources and budget. The perspectives generated Anvisa's strategic map for the period, grouping 18 strategic objectives around them[19].

Since strategic alignment involves many players, in practice one can see plans being changed, unexpected events and opportunistic adjustments made by some stakeholders, according to the moment[33]. Authors also point out that the strategic planning process has been reduced in its planning timeframe in recent decades, gaining flexibility to formulate

and implement the strategy, with emphasis on collaborative innovation and effective involvement of the stakeholders to execute and monitor it[34].

Because of the dynamism that is required when it comes to planning, the Agency's 2010-2020 strategic plan already forecast some revision and realignment, taking into account the emerging health protection needs of the population within the framework of health surveillance — rite led in 2015[19].

In 2015, therefore, the planning began to be reviewed, with execution in four stages: environmental analysis and strategic guidance; strategy formulation; strategy deployment and strategic management monitoring. The BSC methodology adapted to the logic of a public organization was once again used, generating the objectives listed in the synthetic strategic map — only two perspectives — described in Chart 1[19].

This paper briefly presents a comparative overview between the current strategic maps of three of the world's largest regulatory agencies — Anvisa in Brazil, the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) of the European Union. The intention was to analyze their future objectives as well as to understand the alignments between the challenges ahead — since their strategy-setting processes are based on the assessment of scenarios that can be internal or external to organizations — and the particularities of each organization.

METHOD

This is a qualitative research project characterized by the interpretation of phenomena and assignment of meanings[35]. We used the method of content analysis and the technique of condensation of meanings. In this case, the main forms of data collection and analysis derive from formal documents about the strategic management of the organizations studied and participant observation, in the case of Anvisa. These characteristics of the research are detailed below in the text.

Research data can be based on many sources of evidence, such as documentation, archival records, interviews, direct observation, participant observation, and physical artifacts.[36]. In this research, the main source of information were public documents from the agencies involved, with the presentation of their priority institutional objectives, especially the formal strategic planning documents — from the current cycle to the time the study was conducted (second half of 2017) — available on the websites of the three institutions — Anvisa, FDA and EMA: Anvisa, FDA 2016-2019 Strategic Map Strategic Priorities 2014-2018 and EMA Multiannual Work Programme to 2020.

One of the strengths of this data source is its stability, since documents can be checked multiple times without changing content. Another strength is their accuracy, since these documents are usually accurate as to names, references, and details. On the other hand, the weaknesses of document analysis may be in its recovery capacity or deliberate denied access, biased selectivity if the collection was not complete, and in the report of biases, reflecting preconceived ideas unknown to the researchers[36].

In the specific case of Anvisa, as stated above, in addition to the documents referring to the current strategic planning, the form of collection also included participant observation, since the researchers participated directly in the design of the Agency's strategic map. No interviews were used to collect primary data in this study.

A common method for qualitative data analysis is content analysis, understood as a set of research techniques whose aim is to search the meaning or the senses of a document. It consists of the detailed reading of all the collected material, the identification of words and word groups that are meaningful for the research, as well as the classification into categories or topics that have similarities in syntactic or semantic terms. This method has three phases for its execution, namely: i) pre-exploration of the material or reading of the contents; ii) selection of units of analysis (or units of meaning); and iii) categorization and subcategorization process[37,38].

To this end, condensation and interpretation of meanings were adopted as the classification technique. In this technique, the content of the descriptions of the strategic objectives of each agency was organized in a matrix, by grouping excerpts of contents as units of record with significance for the analytical objective in question[39].

The condensation of meanings aimed to organize and summarize the contents of the analyzed documents for the presentation of synthesis ideas about the research problem: how are the strategic maps of some of the world's largest health regulatory agencies currently designed and what relationships can be inferred from their strategic goals? The technique enabled the abbreviation of the meanings found in the content of the records in a condensed format without losing their essence, which made it possible to turn long sections into shorter notes. In turn, the interpretation of meanings sought the broadest sense of the ideas and topics raised, due to their connection with previously acquired knowledge. It also enabled the construction of a relationship between the contents read and the data surveyed[39,40].

RESULTS AND DISCUSSION

To start presenting the results of this research, it is necessary to explain the work done by the regulatory agencies under study and their strategic objectives, so that we can proceed to the comparative discussion between the strategic guidelines of each one of them.

Anvisa — the Brazilian regulatory agency in the field of health — was created in 1999 as an autarchy linked to the Ministry of Health and its mission is: "To protect and promote the health of the population by intervening in the risks arising from the

production and use of products and services subject to health surveillance, in a coordinated and integrated action within the scope of the Unified Health System". The agency works in pre and post-market activities of products and services subject to health regulation and, as such, has a broad scope of action, which includes:

- medicines for human use and their supplies;
- food;
- cosmetics;
- sanitizers;
- medical and hospital equipment and supplies, including kits, reagents and supplies for laboratory and imaging diagnosis;
- immunobiologicals, blood and blood products, human organs and tissues;
- cigarettes and other smoking products, whether or not derived from tobacco;
- pesticides; and
- any products involving the possibility of health hazards, genetically engineered or subjected to radiation sources[19,41].

Anvisa revised its Strategic Planning for the 2016-2019 cycle based on the BSC methodology and its strategic map currently has nine objectives. Objectives are divided into two perspectives: outcome objectives and enabling objectives. Outcome objectives are those linked to Anvisa's direct deliveries to society and target audiences: citizens, health professionals and the regulated sector. Enabling objectives, on the other hand, are those that generate the means for achieving the outcome objectives. That is, there is a "hierarchy" between perspectives, in which enabling objectives are necessary and fundamental in order to achieve outcomes objectives. The objectives and their descriptions are shown in Chart 1.

The US FDA, under the US Department of Health and Human Services of the American government, originated as a consumer protection agency in 1906. Its mission is to protect public health by ensuring the safety and efficacy of medicines for human and veterinary use, biologicals, health products, food, cosmetics, radiation-emitting products and tobacco products[42].

FDA's current strategic planning cycle covers the period 2014-2018 and the construction of objectives was guided by five cross-cutting strategic priorities, namely: regulatory science, globalization, safety and quality, smart regulation and organization and management[43]. Based on these priorities, four strategic objectives were defined. These objectives, in turn, are divided into 13 sub-objectives. The summary of objectives and sub-objectives can be seen in Table 2.

The EMA was founded in 1995 and since then it has been a coordinating agent among the health authorities of the countries that form the European Union in the pursuit of public and animal health protection through the evaluation of medicines according to strict scientific standards and independent scientific information on these medicines. The EMA, together with the national competent authorities, has designed a strategic plan for the period 2016-2020, with the aim of drawing up the Agency's Multiannual Work Programme — MAWP. The MAWP is divided into four topics and each has four long-term strategic objectives. Every strategic objective is further divided into medium-term objectives, initiatives, execution time, and performance indicators for monitoring[44,45]. For the purpose of this research, only the topics and strategic objectives will be presented, to maintain consistency with the analysis levels applied to the two agencies previously presented (Table 3).

After compiling the strategic objectives of the three agencies and treating these data based on content analysis and meaning condensation, as described in the aforesaid methodology, it was possible to identify seven major groups of common topics:

1. premarket activities;
2. post-use activities;
3. regulation and standardization;

Chart 1. Anvisa's Strategic Objectives (Brazil) - Strategic Map 2016-2019.

Type	Objective
Outcome objectives	Expand population access to safe products and services subject to health surveillance
	Improve the regulatory framework on health surveillance
Enabling objectives	Optimize premarket actions based on health risk assessment
	Improve post-use surveillance actions, focusing on control and monitoring of products and services
	Strengthen the coordination actions of the National Health Surveillance System
	Increase the efficiency of Port, Airport and Border operations
	Improve international cooperation and regulatory convergence actions
	Implement a governance model that favors integration, innovation and institutional development
	Strengthen health surveillance education and communication actions and the institutional relationship model

Source: http://portal.anvisa.gov.br/mapa-estrategico.

Chart 2. FDA Strategic Objectives (USA) - 2014-2018.

Strategic objective	Sub-objective
Strengthen surveillance of FDA regulated products	Increase the use of regulatory science to improve the development of analytical standards and decision making
	Reduce risks in the production and distribution of regulated products
	Strengthen problem monitoring on regulated products
	Improve responsiveness to identified or emerging issues in regulated products
Improve and ensure access to FDA regulated products for health benefit	Increase the use of regulatory science for product assessment
	Improve the effectiveness of the product development process
	Improve the predictability, consistency, transparency and efficiency of evaluation processes
Promote improved decision making regarding the use of FDA-regulated products	Strengthen social and behavioral sciences to help patients, consumers and healthcare professionals make better informed decisions about the use of regulated products
	Improve access to information on benefits and risks related to regulated products
	Improve public information on product and service safety
Strengthening organizational excellence and accountability	Recruit, develop, retain and strategically manage top technical staff
	Improve FDA operation and organizational effectiveness
	Invest in infrastructure for productivity improvement

FDA: Food and Drug Administration
Source: adapted from FDA[43].

Chart 3. EMA Strategic Objectives (European Union) - 2016-2020.

Topic	Strategic objective
Contribution to human health	Focus on key public health priorities, including drug availability and antimicrobial resistance
	Ensure patients timely access to new medicines, with quality and safety
	Support patient-focused innovations and contribute to the life sciences industry in Europe
	Strengthen regulatory competence and transparency
Contribution to animal health and human health related to veterinary medicinal products	Increase availability of veterinary medicines and promote the development of innovative medicines and new technologies
	Promote better regulation
	Improve the functioning of the single market for veterinary medicines in the European Union
	Focus on key animal and public health priorities, including antimicrobial resistance
Network operation optimization	Strengthen the regulatory and scientific capacity and competence of the network
	Pursue operational excellence
	Ensure effective internal and external communication
	Strengthen connections with other authorities and stakeholders
Contribution to the global regulatory environment	Ensure product, supply chain and data integrity
	Seek convergence with global standards and contribute to international forums
	Ensure the good use of resources by promoting mutual trust and work sharing
	Support training, competence building and promote the European Union regulatory model

Source: adapted from EMA[45].

4. network coordination;
5. regulatory convergence;
6. organization and management;
7. institutional communication.

Premarket activities can be understood as part of the process of access and expansion of the offer of products and services, through processes of regularization of products and services subject to health regulation. After-market activities include inspection, monitoring of products and services, market monitoring and the effectiveness of health risk management actions. The regulation and standardization group addresses issues concerning the methods and criteria for producing health regulations. Network coordination refers to the objectives related to the interaction between agents that are within the scope of the agencies' direct action. Regulatory convergence comprises the relationships of agencies with other international agencies, seeking to harmonize practices between them. The organization and management category observes the strategic objectives related to people management, infrastructure, information systems, internal communication and internal governance dynamics. Institutional communication is about the relationships of agencies with their various stakeholders.

In the category of pre-market activities, we can notice some convergence among the three agencies regarding strategic guidelines to increase the speed and efficiency of the release

of regulated products in the market, ensuring safety, efficacy and quality. However, both the FDA and EMA state more explicitly the importance of supporting these agencies in the innovation process, as enablers working together with the regulated sector to reduce new product development time, thus playing an important role in the innovation process within their regulatory environments.

In the category of post-use activities, there is an explicit strategic orientation of Anvisa and the FDA to strengthen control and monitoring activities of products and services. While the EMA also has this concern, expressed through the guarantee of product integrity and throughout the supply chain, this agency brings up a new issue, which has translated into the strengthening of the single market for veterinary medicines in the European Union. This is a particularity of the EMA, once it is an agency that integrates and guides the regulatory practice of several countries, unlike Anvisa and the FDA, which focus only on their own countries, even though these are countries with federative structures.

Regarding the group of objectives related to regulation and standardization, it is clear that the three agencies have strong convergence regarding the implementation of smart regulation, better regulation or quality regulation. All have concerns about establishing strong science-based standards and criteria, grounded on substantial regulatory impact analyses.

In the network coordination category, both Anvisa and the EMA outline strategic objectives that focus on the broader view of the entities that make up the health regulatory system, although these agencies are in different contexts. In the case of Anvisa, the coordination of the SNVS is required. The SNVS is composed of federal, state and municipal entities, with their independence guaranteed by the federative pact. In the case of the EMA, this coordination takes place between independent countries, but with rules agreed within the European Union. Both cases require major efforts to agree and coordinate actions, which comprise various activities, ranging from network capacity building to improved communication between the parties. The FDA is in a federative context that is similar to that of Brazil, but it has no strategic objective that guides the action toward strengthening the coordination of a national network.

The analysis of the objectives identified in the regulatory convergence group shows a behavior similar to that described in the network coordination. Both Anvisa and the EMA include in their strategic objectives the need for harmonization of practices with other regulatory agencies. The EMA also includes initiatives to share information and work processes in a global manner. Although the FDA considers globalization and the importance of regulation in transnational trading environments as one of its cross-cutting priorities, there is no definition of a specific strategic objective that deals exclusively with this issue. This guideline, however, appears in the description of other US agency strategic objectives.

The management and organization category has great convergence among the three agencies, and the pursuit of operational excellence as a key theme in all cases stands out. Anvisa and the FDA give strong emphasis to people management, with highlights to the recruitment, development and retention of excellent technical staff, as well as the importance of maintaining infrastructure that ensures the productivity of the agencies. Anvisa and the EMA have strategic objectives that focus on internal communication and their role as enablers of good organization management.

Institutional communication as a category that addresses the relationship between agencies and society as a whole shows that this concern stands out more in the case of the FDA. Although all agencies set out strategic objectives for this topic, the FDA deepens the discussion, reinforcing its role in shaping the decision-making of patients and healthcare professionals on the use of regulated products and services, underscoring the importance of providing information on the risks and benefits of these technologies.

Few strategic objectives could not be grouped into any of the seven categories described above. The first one, from Anvisa, deals with the increased efficiency of operations in ports, airports and borders (PAF), an object that does not explicitly appear in the FDA and EMA strategic plans — since it is not part of their scope. The second objective that did not fit any group was the focus on key public and animal health priorities, including antimicrobial resistance, present in the EMA planning. This objective was potentially cross-sectional to several of the seven outlined groups and therefore did not fit exclusively into any of them.

CONCLUSIONS

The design of a strategic plan is an opportunity to rethink mission and long-term strategic objectives, analyze the points of attention of the external environment, observe the characteristics of the internal environment, and adjust the strategy, that is, think strategically[46].

In public organizations, because of their size, complexity and bureaucratic rigor, the formalization of the planning process (schedules, manuals, definition of responsibilities) and plans is very important and requires special attention so as to not hinder the planning process itself. Communication needs to be clear, objective and appropriate to the different levels and individuals that make up the organization[27].

In this study, we observed that three world-class regulatory agencies, which have been acting both locally in their jurisdictions — whether national or continental — and in the main contemporary international forums of regulatory convergence, have a clear definition of planning, with the design of strategic objectives on synthetic and problem-focused maps, with emphasis on the use of clear, concise and objective language — thus ensuring what is of paramount importance for any strategy: focus.

If in the public context planning is necessary — albeit complex — in the regulatory arena, this government role is even more important, since it is a normative field that tries to balance social demands and economic pressures, in addition to drive innovation and promote development. Because we are addressing health organizations, the precept of strategic planning takes on finer contours — in which health risk management requires well-coordinated, transparent and science-based action.

From the analyses we made of the Anvisa, FDA and EMA strategic objective maps, we can highlight the following considerations as relevant:

- How subjects are addressed and the reasonable degree of homogeneity of the topics, as well as the style of purpose writing — consistent with the state of the art of the regulatory field — favors greater alignment between these agencies, which, in turn, enables greater possibilities of international regulatory convergence.
- Having well-written strategic maps aligned with current good management practices is not enough. Consistent strategy communication actions, both internally and externally, should be undertaken on an ongoing basis to provide clarity of purpose to all stakeholders. After all, in general, strategies are designed to favor change and changes are precisely the biggest obstacle to the implementation of any planning process. Communicating effectively, using a good monitoring rite and all available resources, can be the key to the success of intended intentions in stated strategic objectives.
- The conciseness and objectivity found in the strategic objectives we analyzed refer to a pragmatic perspective in the formulation of such management elements within the studied organizations. This pragmatism, understood as the ability to provide organizational management with systemic analysis, focus, direction, and intentionality, can and should appear in the strategy implementation, provided that it follows the basic principles of execution that were accurately described by Bossidy and Charan[47], when they discussed execution as a discipline aimed at achieving results:

  > [...] being able to finish what was planned, having specific milestones for measurement, promoting an intense monitoring process and fast information flows enable not only the evolution of the strategy but also the communication of results — this is a key factor for institutional alignment around the pacts entered into under a strategic plan.

REFERENCES

1. Lafley A, Martin R. Playing to win: how strategy really works. Boston: Harvard Business School; 2013.
2. Mintzberg H. View from the top: Henry Mintzberg on strategy and management. Acad Man Exec. 2000;14(13):31-42.
3. Silva ACP, Pepe VLE. Vigilância sanitária: campo da proteção e promoção da saúde. In: Giovanella L, Escorel S, Lobato LVC, Noronha JC, Carvalho AI, editores. Políticas e sistema de saúde no Brasil. Rio de Janeiro: Fundação Oswaldo Cruz; 2008. p. 819-49.
4. Albuquerque K. A visão da secretaria de gestão do ministério do planejamento, orçamento e gestão. In: Proença JD, Costa PV, Montagner P, organizadores. Desafios da regulação no Brasil. Brasília: Escola Nacional de Administração Pública; 2006. p. 83-104.
5. Agência Nacional de Vigilância Sanitária - Anvisa. Plano diretor de vigilância sanitária. Brasília: Agência Nacional de Vigilância Sanitária; 2007.
6. Silva GHT. Performance regulatória: uma análise do programa de melhoria do processo de regulamentação da Anvisa no contexto da atual agenda de reforma regulatória no Brasil [dissertação]. Rio de Janeiro: Escola Nacional de Saúde Pública Sergio Arouca; 2013.
7. Silva GHT. Regulação sanitária no Brasil: singularidades, avanços e desafios. In: Proença JD, Costa PV, Montagner P, organizadores. Desafios da regulação no Brasil. Brasília: Fundação Oswaldo Cruz; 2006. p. 215-62.
8. Freitas DRC, Silva GHT. Visa e regulação no mundo contemporâneo: regulação do risco em perspectiva, o papel e os desafios da Visa para a proteção da saúde. Ciclo de debates em vigilância sanitária: desafios e tendências: textos de referência; 2015, Brasília, Brasil. Brasília: Agência Nacional de Vigilância Sanitária; 2015. p. 9-16.
9. Jordana J, Levi-Faur D. The politics of regulation in the age of governance. In: Jordana J, Levi-Faur D, editores. The politics of regulations: institutions and regulatory reforms for the age of governance. Massachusetts: Edward Elgar; 2004. p. 1-28.
10. Baldwin R, Scott C, Hood C. Introduction. In: Baldwin R, Scott C, Hood C, editores. A reader on regulation. Oxford: Oxford University; 1998. p. 1-55.
11. Lodge M, Wegrich K. O enraizamento da regulação de qualidade: fazer as perguntas difíceis é a resposta. In: Proença JD, Costa PV, Montagner P, organizadores. Desafios da regulação no Brasil. Brasília: Escola Nacional de Administração Pública; 2006. p. 17-36.
12. Lucchese G. Globalização e regulação sanitária: os rumos da vigilância sanitária no Brasil [tese]. Rio de Janeiro: Fundação Oswaldo Cruz; 2001.

13. Lazzarini M. A voz dos consumidores nas agências reguladoras. In: Proença JD, Costa PV, Montagner P, organizadores. Desafios da regulação no Brasil. Brasília: Escola Nacional de Administração Pública; 2006. p. 59-80.

14. Lucchese G. Globalização e regulação sanitária: os rumos da vigilância sanitária no Brasil. Brasília: Agencia Nacional de Vigilância Sanitária; 2008.

15. Maia CS. Inserção da vigilância sanitária na política de saúde brasileira [tese]. Brasília: Universidade de Brasília; 2012.

16. Costa EA, Bonfim JRA. O movimento de construção do sistema de vigilância sanitária no país. Divulg Saude Debate. 2001;25:5.

17. Costa EA. Vigilância sanitária: proteção e defesa da saúde. 2a ed. São Paulo: Sociedade Brasileira de Vigilância de Medicamentos; 2004.

18. Alves SMC. Processo de participação da sociedade civil nas consultas públicas realizadas pela Agência Nacional de Vigilância Sanitária - Anvisa (2000-2006) [dissertação]. Brasília: Universidade de Brasília; 2008.

19. Flexa, RGC, Silva Júnior JB, Brito RL, Sousa AIA, Araújo FF, Martins MAF. Planejamento estratégico em vigilância sanitária: aplicação do *balanced scorecard* (BSC). Vigil Sanit Debate. 2017;5(2):13-23. https://doi.org/10.22239/2317-269x.00937

20. Ansoff HI. Estratégia empresarial. São Paulo: McGraw-Hill; 1977.

21. Silva FA, Gonçalves CA. O processo de formulação e implementação do planejamento estratégico em instituições públicas. Rev Adm UFSM. 2011;4(3):458-76.

22. Ansoff I, McDonnell E. Implantando a administração estratégica. São Paulo: Atlas;1993.

23. Porter ME. Vantagem competitiva: criando e sustentando um desempenho superior. 13a ed. Rio de Janeiro: Campus; 1989.

24. Whittington R. Strategy as practice. Long R Plan. 1996;29(5):731-5. https://doi.org/10.1016/0024-6301(96)00068-4

25. Mariotto FL. Mobilizando estratégias emergentes. Rev Adm Empres. 2003;43(2):73-98. https://doi.org/10.1590/S0034-75902003000200006

26. Álvarez SO. Implementación de un plan estratégico: alineamiento de la gestión institucional para el logro de objetivos: experiencia de la dirección nacional del servicio civil para el período 2014-2018. 21o Congreso Internacional del CLAD sobre la Reforma del Estado y de la Administración Pública; 2016; Santiago, Chile. Caracas: Centro Latinoamericano de Administración para el Desarrollo; 2016. p. 1-11.

27. Giacobbo M. O desafio da implementação do planejamento estratégico nas organizações públicas. Rev TCU. 1997;28(74):73-107.

28. Silva F, Mário C. O processo de formulação e monitoramento do planejamento estratégico de tribunais de contas. Rev Adm Publica. 2015;49(6):1401-27.

29. Kaplan RS, Norton DP. Organização orientada para a estratégia: como as empresas que adotam o *balanced scorecard* prosperam no novo ambiente de negócios. Rio de Janeiro: Elsevier; 2001.

30. Richers R. Objetivos como razão de ser da empresa. Rev Adm Empres. 1980;20(3):7-18. https://doi.org/10.1590/S0034-75901980000300001

31. Brasil. Lei Nº 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. Diário Oficial União. 20 set 1990.

32. Zimmerman F. Gestão da estratégia com o uso do BSC. Brasília: Escola Nacional de Administração Pública; 2015.

33. Abib G, Hoppen N. O papel do consultor no processo de alinhamento estratégico. Rev Adm Contemp. 2015;19(5):584-605. https://doi.org/10.1590/1982-7849rac20151384

34. Yoshikuni AC, Albertin AL. Sistemas de informação estratégicos habilitando estratégia como prática na incerteza ambiental. Rev Adm Contemp. 2018;22(4):552-76. https://doi.org/10.1590/1982-7849rac2018170253

35. Lacerda D. O Planejamento Estratégico em instituições de ensino superior: compreendendo se e como as intenções transformam-se em ações estratégicas [tese]. Rio de Janeiro: Universidade Federal do Rio de Janeiro; 2010.

36. Yin RK. Estudo de caso: planejamento e métodos. Porto Alegre: Bookman; 2005.

37. Campos CJG. O método de análise de conteúdo: ferramenta para a análise de dados qualitativos no campo da saúde. Rev Bras Enferm. 2004;57(5):611-4. https://doi.org/10.1590/S0034-71672004000500019

38. Belei RA, Gimeniz-Paschoal SR, Nascimento EN, Matsumono PHVR. O uso de entrevista, observação e videogravação em pesquisa qualitativa. Cad Educ. 2008;(30):187-99. https://doi.org/10.15210/caduc.v0l30.1770

39. Kvale S. Interviews: an introduction to qualitative research interviewing. London: Sage; 1996.

40. Araújo Jr JLAC. Health sector reform in Brazil 1995-1998: a health policy analysis of a developing health system [tese]. Leeds: University of Leeds; 2000.

41. Agência Nacional de Vigilância Sanitária - Anvisa. Relatório de atividades 2016. Brasília: Anvisa; 2017.

42. Food & Drug Administration – FDA. About FDA. Washington: FDA; 2017[acesso 12 abr 2017]. Disponível em: https://www.fda.gov/aboutfda

43. Food & Drug Administration – FDA. FDA Strategic priorities 2014-2018. Washington: FDA; 2014.

44. European Medicines Agency – EMA. History of EMA. Amsterdam: EMA; 2017[acesso em 12 abr 2017]. Disponível em: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000628.jsp

45. European Medicines Agency – EMA. Multiannual work programme to 2020. Amsterdam: EMA; 2016.

46. Poister TH, Streib GD. Strategic management in the public sector: concepts, models and processes. Publ Prod Manag Rev. 1999;22(3):308-25. https://doi.org/10.2307/3380706

47. Bossidy L, Charan R. Execução: a disciplina para atingir resultados. Rio de Janeiro: Elsevier; 2005.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.