Strategic planning in health regulation: application of the Balanced Scorecard framework

Planejamento estratégico em vigilância sanitária: aplicação do *Balanced Scorecard* (BSC)

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ABSTRACT

This article main objective is to present the method, framework and guidelines applied by the Brazilian Health Regulatory Agency (Anvisa) Strategic Planning, for the period 2016-2019. In order to provide information about the concepts that are used in the project, there is a section that shows Strategic Planning and Balanced Scorecard theoretical frameworks, with an emphasis on how these concepts are applied to Public Management. Then, the authors show how these frameworks were implemented by Anvisa. This article focuses on the Strategy Map review and, in this regard, it compares the previous Strategy Map and the current one. In this comparison, there is a discussion about its elaboration and validation methods, as well as about the guidelines for its preparation.

KEYWORDS: Strategic planning; Balanced Scorecard; Strategy map; Brazilian Health Regulatory Agency; Sanitary Surveillance

RESUMO

Este artigo objetiva apresentar o método e a estrutura do ciclo de Planejamento Estratégico (PE) para o período de 2016 a 2019 na Agência Nacional de Vigilância Sanitária (Anvisa). Para isso, utilizou-se o referencial teórico sobre PE, apresentando, especificamente, a metodologia *Balanced Scorecard* (BSC), com destaque para o emprego desses conceitos na Gestão Pública. A partir disso, é apresentado como a metodologia BSC foi aplicada na Anvisa, na forma de um estudo de caso, com ênfase no método utilizado para a construção do PE, bem como nas diretrizes para sua elaboração. Discute-se ainda a revisão do Mapa Estratégico da Agência, com análise comparativa entre os mapas anteriormente vigente e o atual, descrevendo-se as etapas de construção e validação dos diferentes elementos do Mapa. Conclui-se que o método de Planejamento apontado é aplicável à Gestão Pública, de tal forma que é possível desenhar a estratégia e priorizar os objetivos, com vistas a alcançar resultados e melhorar o desempenho da instituição pública.

PALAVRAS-CHAVE: Planejamento estratégico; *Balanced Scorecard*; Mapa estratégico; Agência Nacional de Vigilância Sanitária; Vigilância Sanitária

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INTRODUCTION

Achieving improvement in organizational performance is one of the main goals of any organization, whether in public sphere or in private sector, given the importance of making the best use of the available resources and running the intended activities as well as possible[1].

In order to reach this aim, companies need to define a minimal path to be followed, considering their performance in an economic and dynamic social environment, intricate and highly uncertain[2]. The success of a company depends on its ability to define a simple strategy, clear and concise, thus, everyone can internalize it and use it as a compass when making decisions[3].

Therefore, strategy can be defined as a large set of choices (main strategy) and a portfolio of potential wide-ranging experiments that guide the management of the present and build the future on a long-term horizon under conditions of uncertainty[2]. These points of view highlight the importance of the application of SP concepts, techniques and tools as a way to advance the performance of organizations, either public or private.

However, SP gains some specific nuances when applied to Public Management due to each agency's role, the nature of the service provided, and the uniqueness of their target audience. The key role assigned to public organizations in the modern world is to expand - in a systematic and integrated way – the opportunities to the citizens[4]. The reason of the existence of a public administration is to fulfill the collective interests, or better stated, the demands of the population[5]. In this regard, the interests of the citizen, as target audience, will work as guidance for definition of the mission of the public organization, in addition to configuring the design of their challenges and strategic objectives.

In this context, Brazil has the Brazilian Health Regulatory Agency (Anvisa), whose mission is to "Protect and promote the health of the population through the intervention on the risks arising from the production and use of products and services subject to health regulation, in action coordinated and integrated in the framework of the Brazilian Public Health System". This article aims to discuss the SP cycle for the 2016 to 2019 period in Anvisa, with focus on the elaboration of the Strategic Map (SM). For this, we used the theoretical reference about SP, specifically the *Balanced Scorecard* (BSC) methodology, which was chosen by the organization. Finally, we focused on applying these concepts to Public Management. From the exhibition of these points, we show how the BSC methodology has been applied in the institution. Despite its wide range of tools and products, the focus of this paper is on the debate about the Agency's SM review, through a comparative analysis between the maps of the previous SP cycle (2010-2020) and the current cycle (2016-2019). Issues like the method of construction and validation are also discussed, in addition to the guidelines for design and implementation.

METHOD

To define a problem, we must first identify the reasons that lead the researcher to choose this topic of research[6]. Therefore, the starting point for the research is the definition of the problem or question that is going to be answered or in which there is interest in increasing the knowledge. The chosen topic in this study was "how to apply the BSC in a public organization, particularly in the construction of Strategic Maps?".

The characterization of the research aims to place the study under various and distinct aspects. This characterization is necessary because it indicates the work method, as well as the units of collection and the data analysis plan[7]. Concerning its nature that is: (i) an applied research, an issue regarding the implementation of the methodology BSC in Anvisa that will be discussed; (ii) descriptive-exploratory, since describe and analyze the reality to understand the scope of the planning methodology; (iii) qualitative approach, namely as a case study (Anvisa).

It was also used procedures of the bibliographic research to inform the theoretical framework and acquiring of e documents in the studied institution. As mentioned previously, the chosen institution was Anvisa, by reviewing its SP using the BSC methodology, and the data that was collected during the development of the new SM construction, to be enforced during the 2016-2019 period.

As for the ethical aspects of the project, all records were kept in strict confidentiality.

Conceptual reference

Health Regulation as a field of practices of the SUS (Brazilian Public Health System)

Health regulation is in the Constitution as one of the competencies of the Brazilian Public Health System (SUS) which is necessary to achieve health as a right[8]. Law 8.080 of 1990, which regulates the SUS, defines health regulation in its Article 6, as:

> a set of actions able to eliminate, reduce or prevent risks to health and to intervene in the health problems arising from the environment, the production and circulation of goods and services of interest to health: covering: I – the control of consumer goods that directly or indirectly relate to health, comprising steps and processes, from production to consumption; and II – the control of services that relate directly or indirectly to health[9].

There is currently a huge amount of products and services that make life easier and extend human survival, in a way that could not have been imagined a few decades ago. However, such products and services have a great potential to cause harm, bringing to modern society concern over issues such as quality, effectiveness, safety, health and rationality in the use and consumption of these products[10].

In this context, we can say that the increase in the use of health-related services and technologies, and the growth of

the populations purchasing power in recent decades means that health regulation acquires a new *status*. It now requires the managers of SUS to better understand its contribution to the social right to health[11].

This is reflected in social, economic and contemporary environmental demands, which, allied to the growth of health awareness and greater social expression on the issues surrounding our environment, cause, without doubt, impact on health regulation. People demand answers in a timely manner and greater governmental cohesion [12].

Thus, as communities expand their production capacity, they create market imbalances and bring in new technological risks. This interferes directly with the various areas of collective and individual interests and with the health-disease-quality of life equation. To strike a balance, planning is necessary to create a strategy with measures that are essential for the proper management of health risks in the territory[13].

Health regulation initiatives become even more powerful as they incorporate the concepts of planning, development, control, and evaluation. This includes not only supervision and penalties, but more integrated actions with greater return to the society. Knowing the framework of healthcare, the environments in which it operates, the demographic structure of a given territory and, thus, detecting problems that need to be acted on, allows for better planning, resource optimization, appropriate setup of teams and, as a consequence, greater efficiency and effectiveness in the intervention.

Strategic planning and BSC in the public sector

Strategic planning: general definitions and the perspective of the public sector

In the 1970s, SP was defined as a process of continuous and systematic formulation of strategies that enable rational decision-making through formal execution programs, so that there is comparability between the projected results and the actually achieved results[14].

According to the literature[15], there are several authors in favor of the classical approach to strategy – as a formal plan[16,17]. However, it is also stated that there are those who defend strategy on a pragmatic basis[18,19]. For them, strategy is seen as practice and as a continuous process of formulation and implementation of adjustments and resource allocation actions.

Several authors are favorable to the idea that the formalization of a strategic plan is a key instrument for successful management, since it allow us to target our efforts to achieve common goals. In the specific case of the public sphere, the lack of competitiveness in the state monopolies and other ways of measuring performance have made it so that the use of SP in the sector is more recent than in the private sphere and focused on seeking excellence in the provision of services to citizens[15].

Therefore, for a vision centered on providing services to the society, both the design and the implementation of a strategic plan in an institution of the public sector have incorporated tools of management based on results, with the final purpose of increase, effectively and efficiently, the well-being of the citizens[20].

Another motivation of public organizations for the implementation of SP is the reduction of discontinued administrative impact generated by the turnover of technical staff and politicians. Nonetheless, the difficulty of its effective implementation is due to attachment to the past, slowness in the decision-making process and the immobility typical of the bureaucratic distortions of the Brazilian public sector[21].

Studies have shown that, in this perspective, the introduction of management tools in public organizations, in a context of search for results and greater effectiveness in the actions promoted by the government has been occurring in Brazil since the 1990s. Its goal is to better fulfill the demands of citizens who are more aware and now demand better services [22].

The BSC methodology

Between the models of planning and monitoring used in the public sector, BSC stands out. It is a methodology of strategic management developed by Kaplan and Norton in the 1990s, which provides a balance between the results of the organization. Additionally, one of its goals is to strengthen the monitoring of the performance of formulated strategies. Especially, in this methodology, it is proposed that the strategic objectives of the organization are regrouped into four major perspectives: financial, customers, internal processes and learning/growth. In the financial perspective, the company's financial growth goals, productivity, costs and other related issues are included. In the costumer perspective, there is a concern with the value proposition that the organization will provide to differentiate itself in the competitive environment. In the internal processes perspective, there are goals related to the activities of the company that need to be implemented or improved. Finally, the prospect of growing and learning includes aspects such as the skills and knowledge that are necessary for supporting the other perspectives[23].

The SM formed by the four perspectives helps communicate the strategy throughout the organization. This helps employees understand how the objectives are intertwined and how they can contribute to the implementation of the strategy[23].

The original architecture of BSC has been adjusted to government entities, since the financial perspective, that was originally at the top of the hierarchy, is not a priority here and may be replaced with the citizen's perspective[15].

The implementation of this planning methodology, with the definition and monitoring of goals, triggers major changes in the organizational culture, especially in the public sector, where job stability and career plans do not usually encourage extraordinary performance[22].

So as an alternative to the BSC, Moore has created the *Public Value Scorecard* (PVS) as a model of performance evaluation for public and non-profit organizations. This model is centered on three elements: public value, legitimacy and operational capacity. The public value deals with what the entity intends to produce, without the initial financial concern, but with focus on the social goals and in the delivery of services to citizens and other users. Legitimacy deals with the support and authority for the management of the listed services in the perspective of public value, including, for example, the relationship with the agents as the sponsors of the service. The operational capacity deals with the ability of the organization to achieve the desired objectives, including the financial integrity of the organization, organizational learning, as well as the ability of partners, employees and other stakeholders[24,25].

Although PVS is consolidating its position in the public sphere, the case that is object of this article was based on the methodology of BSC, with some adjustments. The method adapted for Anvisa is detailed in the following item.

RESULTS AND DISCUSSION

Case study

Anvisa is an independent agency under a special regime, which operates in activities of pre and post-market products and services subject to Health Regulation. For this reason, it has a wide scope, which covers foodstuffs and beverages, cosmetics, sanitizing products, medical equipment and hospital supplies, immunization, blood-based products, human organs and tissues, tobacco and agrochemicals.

This article investigates the application of the BSC in two cycles of Anvisa SP: the 2010-2020 cycle and the review, in 2015, for the cycle of 2016-2019, with new elements. This study focuses on the development and evaluation of the SM of each one of the cycles in order to debate and discusses the advantages and limitations of the BSC methodology in a public organization.

Strategic planning 2010-2020

Strategic formulation

The Health Regulation Master Project is the political and administrative milestone of the National Health Regulation System (SNVS). It was published in 2007 and provided, in its guidelines, the development of the processes of shared and continuous planning, monitoring and evaluating, in the three spheres of government. The objective was to support them in dealing with their assumption of responsibilities, including the definition of targets and performance indicators, and the incorporation of the results of evaluation in to inform the decision-making process[26].

With that in mind, Anvisa's SP, enforced in force in 2015, which was developed in 2009 for the 2010-2020 period, as an instrument for better management of the organization, guiding its objectives, initiatives and results.

Due to the dynamism required when it comes to planning, the 2010-2020 SP already foresaw a review and a re-alignment, considering the emerging needs of population's health protection in the scope of Health Regulation – it was done in 2015 and it is described in the next subsection.

For the 2010-2020 period, the composition of the Agency's SM 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 SM for the period, comprising 18 strategic objectives, as shown in Figure 1.

For its construction, a diagnosis was developed with the objective of assessing the situation of management processes under development in the Agency, the main variables and indicators, players involved and their relationship with the actions performed. A Corporate Atmosphere Survey (CAS) was also conducted internally. A Satisfaction and Image Survey (SIS) was carried out with some of the Agency's external audiences.

Regarding the dynamics of the strategy formulation, five meetings with the Board of directors were held to determine the mission, vision, values, guidelines and strategic themes of the Agency. After these deliberations, two other meetings were held with the Agency's management team for developing the SM, which was later validated by the Board of directors.

Strategy deployment and monitoring

After the SM's definition, there was the SP deployment in 12 initiatives, detailed in 57 action plans, 261 macro-actions and 39 strategic indicators.

These 12 strategic initiatives started to have a monitoring cycle, coordinated by the Agency's Planning Consultancy. For this, the responsibilities concerning the actions were assigned as follows:

a) Sponsor: a superintendent who is responsible for promoting the effective execution of a strategic initiative (or a set of them), ensuring and facilitating coordination between the operational responsibilities of the areas and their commitment to the deployment implementation of SP actions.

b) Initiative coordinator: a manager – usually the general manager – responsible for driving conduct action plans and indicators included in the strategic initiative, exercising leadership across the Agency, since the strategic action encompasses a variety of areas.

c) Action plan coordinator: A person responsible for the execution of the actions included in each action plan.

The monitoring methodology was designed based on four main monitoring pillars: operational analysis, strategic analysis, realignment and planning revision.

The operational analysis was often done quarterly. The initiative coordinator was responsible for it, and for managing strategic initiatives and inserting activities and updates in the
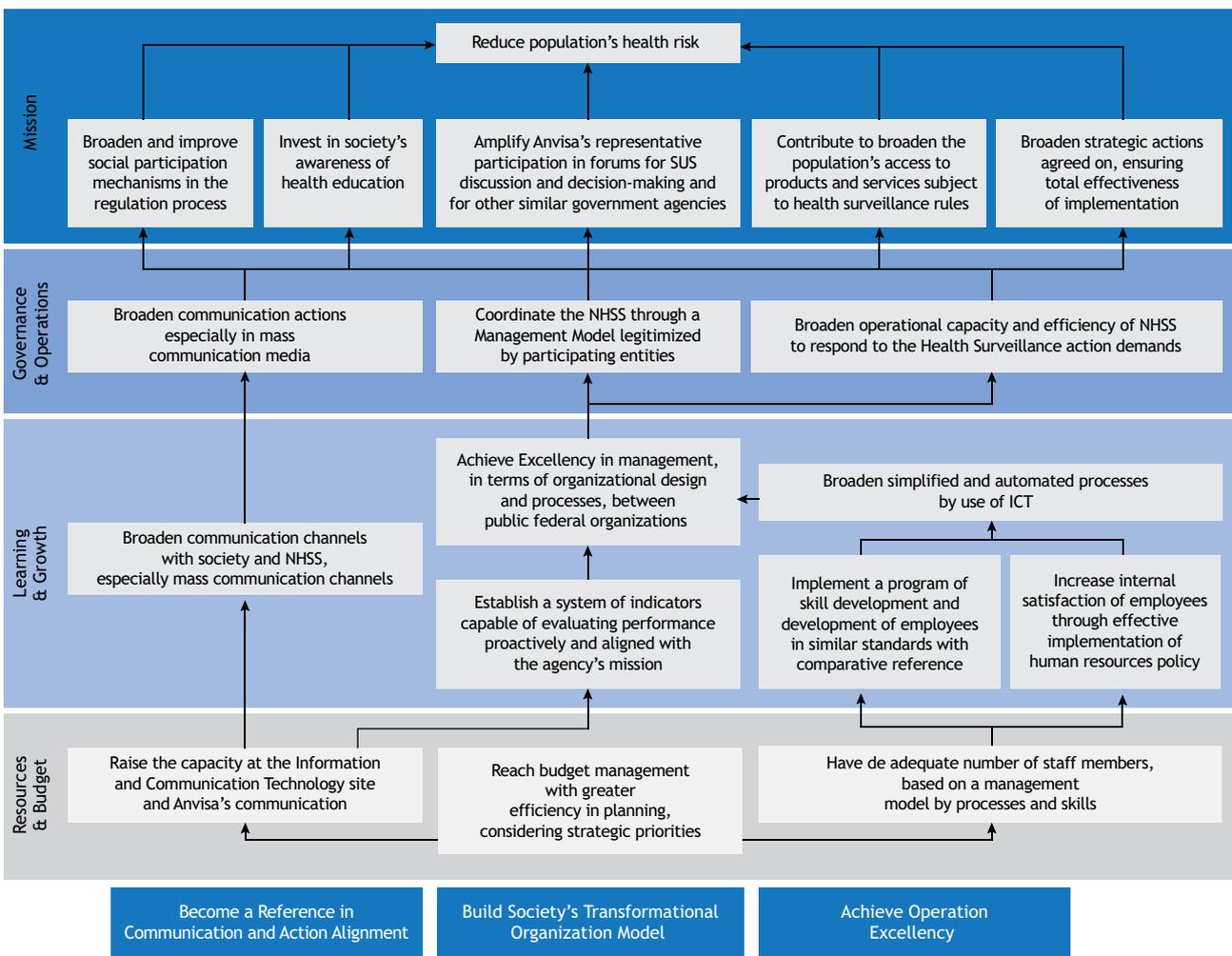
Figure 1. Anvisa's Strategic Map – 2010-2020 period (Anvisa Planning Office, 2015).

GPWEB project-monitoring tool. The operational analysis step also considered the analysis of monitoring indicators results, the improvement of processes and teams' the problem solving skills of the teams, with the definition of corrective actions.

However, the strategic analysis was done every six months by the initiative's sponsor. This analysis corresponded to the management of strategic initiatives and the evaluation of results from these initiatives and their products. In this step, the sponsor checked the level of compliance with the initiatives and the results from the indicators.

The realignment was run on a yearly basis and, performed carried out by the sponsors of strategic initiatives. In it, by means of result verification, it was assessed whether these were contributing to the achievement of the strategic objectives, prospecting for adjustments and additions of new strategic actions, indicators and initiatives.

The Planning review, however, was expected to occur every five years and it was to be conducted by the Agency's managers and the sponsors of strategic initiatives, evaluating external and internal atmosphere behavior, the achieved results and the

adequacy of strategic milestones, such as the SM and the Agency's value chain, proposing the necessary adjustments.

Review of the 2016-2019 cycle plan

In 2015, the plan was reviewed in four steps: environmental analysis and strategic guidance; strategy formulation; strategy deployment implementation and monitoring of strategic management.

Strategic formulation

To start this step, the external and internal environments were primarily analyzed primarily by the SWOT matrix, which highlights strengths and weaknesses (internal environment), and opportunities and threats (external environment) of the Agency.

Key strengths were identified as society's trust in Anvisa's regulation process and qualification of technical staff. As highlighted weaknesses, the vulnerability in NHSS coordination process, the incipient rationalization of the regulatory processes, based on health risks, and the issues of internal and external communication.

Concerning the analysis of external environment, it is worth to highlight the opportunity for expansion of regulatory convergence actions with other countries of interest to Brazil and, as threats, NHSS's underfunding, in addition to conflicts of powers between Anvisa and other government agencies.

For a more robust external environment analysis, the PEST matrix was also adopted, in which Political (P), Economic (E), Social (S) and Technological (T) factors that influences the environment where Anvisa is inserted are assessed. In the political context, the main highlighted points were: conflicts of competences between different agencies for assessing issues related to food, agrochemicals and household products; expansion of the number of legal proceedings for unregulated products not yet imported, and the absence of alignment between the NHSS coordination and various government spheres. Regarding social factors, the highlights were on the society's little lack of awareness of Anvisa's role; broadening of popular participation in the regulation of products subject to Health Regulation through public consultation; consolidation of Brazil's big mass events, resulting in the greatest health regulation concern in ports, airports and boundaries; and the trend for a healthier diet, generating the need for access to information on foodstuff labels.

The analysis of the economic factors indicated the need for simplification, transparency and predictability in regulatory processes, rise in the number of generic medicines sales in Brazil, and the growth of agricultural production, with a consequent potential increase of agrochemical consumption in Brazil. Among the technological factors, emphasis was given on to the introduction of new technologies, such as radio-pharmaceuticals radiopharmaceuticals, bio and nanotechnology, production of prosthetics using 3D printers and GM products.

A new SM was built based on the assessment of external and internal environment, as well as interviews with the Agency's senior management, in which the main challenges for the next four years were raised identified. The analysis of the management instruments used by the Agency, such as the Pluri-annual Plan (PAP) 2016-2019, the National Health Plan (NHP) 2016-2019, Anvisa's Management Contract with the Ministry of Health and the Assessment of Institutional Performance (AIP) were also addressed.

For its elaboration, we used the BSC methodology, adapted to the logic of a public organization. In the first adaptation, we changed the perspectives of the SM, meeting Anvisa's strategic objectives in only two perspectives: result objectives and enabling objectives. The result objectives are those related to direct deliveries to the society and Anvisa's targets: citizens, healthcare professionals and the regulated sector. Moreover, the enabling objectives are those that create the means for the achieving objectives to be achieved. In other words, that is, there is a "hierarchy" between the perspectives, in which the enabling objectives are necessary and essential so that the result objectives can be achieved.

In this sense, the Agency's SM was composed of nine strategic objectives, divided between the two cited perspectives mentioned before. SM's visual representation can be observed in Figure 2.

The strategic objectives are the drivers driving force of the organization's performance within the 2016-2019 timeframe. In this sense, they are directly related to the vision range and consistency with Anvisa's mission (as in Figure 2).

The result objectives are focused on:

- Expansion of the population's safe access to products and services subject to Health Regulation – reason why the Agency exists - allowing the identification of priorities that are linked to the analysis of regulatory impact, the effectiveness in health risk management and the expansion of products and services available, while respecting quality, effectiveness and health safety pillars.

- Improvement of the regulatory framework on Health Regulation to ensure the protection of health and the sustainable development of the sector, aligning Anvisa's strategic management at in the government level, in order to ensure regulatory quality through good governance, transparency and social participation.

The enabling objectives, in turn, are focused on the following aspects:

- Optimization of pre-market actions, based on health risk assessment, so as to provide the society with faster qualification and certification processes, as well as processes for regularization of products and services subject to health regulation, streamlining procedures and allowing these products and services to have their risks mitigated or reduced before their introduction in the market.

- Improvement of health regulation actions in the after-use, focusing on control and monitoring of products and services, such as the adoption of sanitary measures for mitigation of health risks upon verification of adverse events and technical complaints. Additionally, it aims to measure the effectiveness and efficiency of enforcement actions, monitor products, services, markets and the effectiveness of health risk management actions.

- Strengthening NHSS's coordination actions, with emphasis on harmonization of the actions and procedures between the entities that make up the system, in order to strengthen the tripartite relationship and coordination by Anvisa. This objective is cross-sectional, since it considers harmonization actions between the federated entities, and skill building and education actions geared to NHSS, like NHSS's most qualified participation in the regulatory process.

- Enhancing the efficiency in Ports, Airports and Borders (PAB), seeking to enable the restructuring of the existing model, including the improvement of processes and the revision of the regulatory framework, to reduce the risks related to goods and imported products, transportation, facilities and travelers, in the PAB Health Regulation context.

- Enhancing Anvisa's cooperation actions and regulatory convergence at the international level, in order to contribute to the Agency's international relevance, as well as aligning the

▶ 2016-2019 STRATEGIC MAP

MISSION

"To protect and promote the health of the population through intervention on the risks caused by the production and use of products and services subject to health surveillance, in coordinated and integrated action with the Brazilian Public Health System"

ANVISA
Agência Nacional de Vigilância Sanitária

VISION

"To be an institution that promotes health, citizenship and development, in an agile, efficient and transparent way, playing a leading role in the field of regulation and sanitary control, both nationally and internationally"

RESULT OBJECTIVES

1. Broaden population's safe access to products and services subject to health surveillance

2. Improve the regulatory framework in health surveillance

ENABLING OBJECTIVES

3. Optimize pre-market actions based on health risk evaluation

4. Improve after-use surveillance actions, focusing on control and monitoring

5. Strengthen the National Health Surveillance System's coordination actions

6. Improve operation efficiency in ports, airports and borders

7. Improve cooperation and regulatory convergence actions internationally

8. Implement a governance model that favors integration, innovation and institutional development*

9. Strengthen education and communication actions on health surveillance and the institutional relationship model**

* Considers management of people, infrastructure, information systems, internal communication, and management dynamics
** Citizens, health professional, regulated sector, other government agencies, legislative branch, judiciary branch, civil society, and others

Figure 2. Anvisa's Strategic Map of the 2016-2019 quadriennium (Anvisa Planning Office, 2015).

technical requirements of products subject to health regulation with partners of interest, improving Anvisa registered products' quality and the increasing Brazil's participation in the international market.

- Deploying a governance model that promotes integration, innovation and institutional development, focusing on the execution of actions related to people management, infrastructure, information systems, internal communication and the dynamics of governance, so that the performance of structural management initiatives reflects positively on the Agency's results.

- Strengthening education activities and communication in health regulation and in the institutional relationships model, emphasizing the improvement of Anvisa's communication with society, in addition to the expansion and improvement of citizens' participation in health regulation actions and improvement of the relationship with other institutional players, like agencies from executive and legislative branches and from regulated sector.

Strategy deployment and monitoring

To support the achievement of strategic objectives, we proposed 38 performance indicators, 13 strategic projects, and nine contribution panels. The monitoring of these instruments was designed in three cycles: Strategic Analysis Meetings (SAM), Monitoring of the Strategic Projects Portfolio and Monitoring of Contribution Panels.

SAM should be carried out, ideally, every quarter or semester and has as its guidelines the results of the strategic indicators, in addition to the summary of the strategic projects, requiring the mandatory attendance of directors, advisors, general managers, project managers and other invited managers. In these meetings, resolutions should be about the adjustments and referrals for strategic projects (solution of any problems and constraints), and alignment of goals -: their steps, schedule and anticipated results - for key performance indicators.

Projects portfolio monitoring meetings should be carried out on a monthly basis, due to their dynamic nature. Such projects could be followed up on a weekly or fortnightly basis by their management teams and other professionals involved, depending on their criticality. Nevertheless, classically, this should be conducted by the Planning Consultancy staff and by the project leaders, having as a guideline the identification of results (checking of intermediary marks defined in the schedule and Analytical Structure of the Project), as well as problems and solutions for the good progress of the strategic projects.

Contribution panels monitoring meetings, however, must be held on a quarterly basis in order to coincide with Anvisa's other

management tools. This enables better information management on the managers' part. In the nine contribution panels – one for each SM Goal – there is tactical-operational content defined by Anvisa's organizational units, for contribution to the Agency's objectives, goals and strategic projects. Managers, partners and their occasional guests are part of this dynamic. These meetings' agenda includes monitoring of the contribution objectives, contribution indicators, as well as tactic-operational initiatives for the areas in each panel.

Evaluation of methodology implementation in both cycles: highlights to the strategic map

The first difference found between the Strategic Maps was the number and specification of the perspectives that were used. In both cases, BSC traditional structure, which sets out the views for financial, customer, internal processes, and learning and growth, were adapted to best comply with the content of the public organizations.

In the 2010-2020 cycle – actually enforced from 2010 to 2015 -, the "top" perspective is Anvisa's very mission, the reason for its existence, which is to reduce health risks for the Brazilian population. We chose to describe SM's top as "result objectives", showing the main direct deliveries to Anvisa's target audience (citizens, healthcare professionals and the regulated sector).

In order to add value and boost the proposition, we chose to group all strategic objectives that aim at the Agency's internal improvement in a single perspective – fundamental – described as the enabling objectives perspective. In the previous cycle, these objectives were divided into three different perspectives: governance and operations (focused on external communication and NHSS coordination); learning/growth and resources/budget (both focused on a broad sense of management, IT and human resources).

Another point of comparison is the number of objectives in each of the Maps. The number was reduced from 18 to nine strategic objectives. On the Map from the 2010-2020 cycle, in the diagnosis stage of the review process, during reformatting for the 2016-2019 SM, the respondents and participants of focus groups – members of the Agency's managing team and technical staff – reported a perception of imbalance between the objectives related to the finishing functions and to the middle functions. Of the 18 goals, three refer explicitly to the NHSS, while none of them made reference to actual pre or post-market actions. In addition, out of the total goals, eight referred to middle functions, even though this can be analyzed by the maturity level presented by the organization's internal management, created in 1999. The 2016-2019 SM was designed with nine goals, including two result objectives and seven enabling objectives. The strategic objectives of the new map linked to the value chain (shown in Figure 3), aiming at society-oriented results.

Thus, there were objectives connected to actions of regulatory and pre-market nature, operations and control mechanisms and monitoring – setting up monitoring processes in the after-use, and some objectives that are linked to the roles of organizational support and management, namely: governance, institutional relations, communication, education, NHSS coordination and even focus on cooperation and international convergence.

The third important point in the construction of the Maps is the involvement of Anvisa's technical and management staff and the interfaces with promotion of an organizational culture that fosters results. In the 2010-2020 cycle, although there was strong participation of internal and external construction of the diagnosis, by means of the Organizational Environment Survey and Customer Satisfaction and Image Survey, the strategic formulation, with regards to the Map construction, was restricted to the management team and the Board of directors. In the 2016-2019 cycle, a hybrid strategy was chosen *top-down* and *bottom-up*, in which the first SM version was built and pre-validated with the Directors and subsequently presented to the management team, for collecting ideas and suggestions in an eight-hour workshop, and for the technical staff through wide consultation on the intranet. The suggestions from the workshop and the guided consultation were taken to the Directors, for the final validation of the SM, thereby ensuring broad involvement of Anvisa's professionals in this result.

Such involvement of the people and the set of values, beliefs, customs and norms itself that are shared by these people who make up the organization and bring these to adopt certain behaviors – that is, the organizational culture – are also key elements for the implementation of a strategic plan [20,27].

We often speak of the culture of an organization as if it were simply "the way things are". But no culture is static. Cultures are permanently reinforced by how we live with each other in our everyday lives. By connecting these elements as part of a cycle of deep learning, this format conveys the important assumption that all of these elements can change, and truly due so (albeit slowly) – and, when they change, they tend to evolve together[28].

Therefore, one should get in a consensus about which aspects of culture should be modified or developed and which should be maintained or even deepened, clearly identifying levels of results that must be attained for a new stage of development defined by the strategy[20].

In the 2016-2019 plan, a distinctive feature was the formulation and implementation of a parallel project to the SP, called More Value[29], aimed at developing process improvement and a result-oriented culture, with principles and guidelines that encourage the collective commitment as strategic moves to improve results, following the cultural transition methodology proposed by Zorzi[30].

CONCLUSIONS

Strategic Planning is a complex topic, because oftentimes people lack knowledge to inform their decision-making process. Sometimes, there is even sufficient knowledge, but decisions are postponed. Finally, there are those in which decisions are required even in the face of scarce evidence[31], especially in a field such as health regulation, which always works based on the precautionary principle.
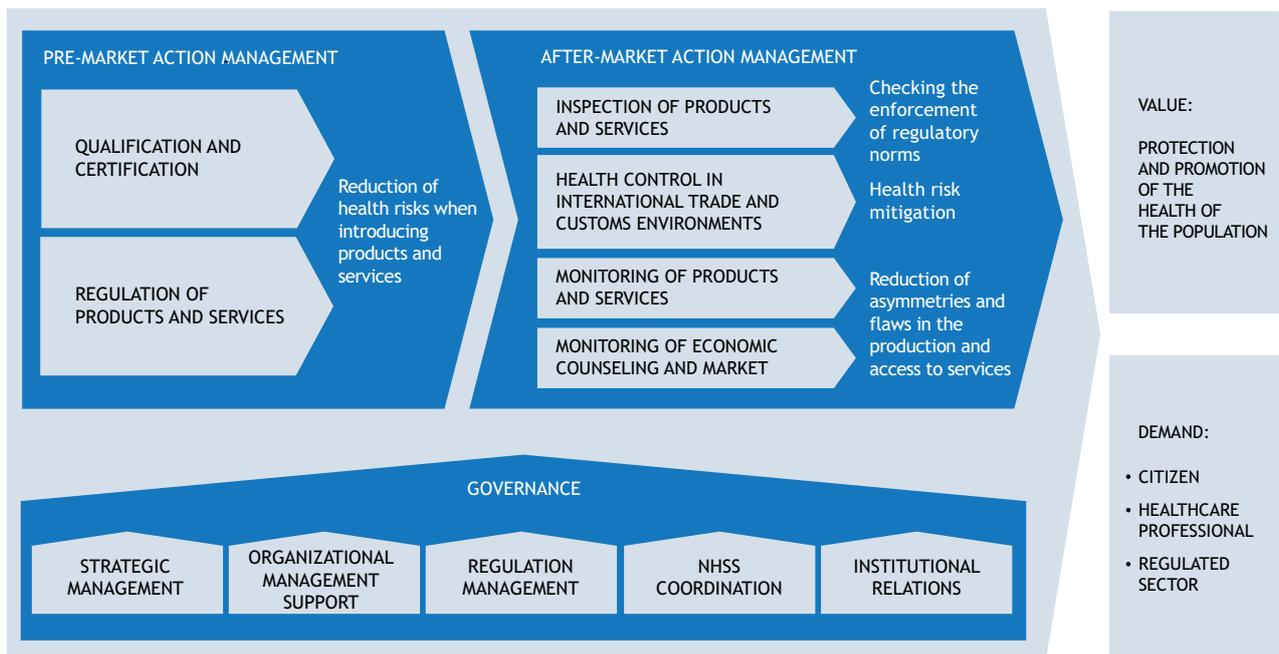
VALUE CHAIN

Figure 3. Anvisa's value chain (Anvisa Planning Office, 2015).

In regards to Anvisa's strategy, what can be observed is that, since 2010, the institution maintains dynamics and structured instruments of planning, with maps, strategic elements and procedures that are clear-cut and monitored.

In this path, an inflection point was observed in 2015, when, through revision of the enforced plan, more synthetic models were created. They were, therefore, more focused on facilitating enforceability and governance. They also had greater communication potential – organizational and social – for the major goals, projects, and objectives of the Agency.

About the feasibility and governance of the strategy, literature points out that the essence of management lies in the implementation of what you want to achieve and what the main bottlenecks in the organizations performance are, not so much in the specific tasks that are performed by each individual, but rather in the way one carries out coordination of the actions[20].

This article's recommendations go the same way:

- attach value to the execution, with focus on constant and real deliveries, and as an intrinsic, dynamic and powerful part of the strategic map – effective *momentum* of achievement;

there are permissible and desirable course adjustments, and adjustments of expectations too; and

- make significant efforts – dynamics and tools of strategic coordination to align initiatives and results and then achieve the principles and objectives set out in the mission, vision and Anvisa's strategic map – an integrative perspective, not fragmented, in which the institution can effectively raise its services levels and gradually improve its deliveries to the society.

Whatever the strategy map, the path is mutant, dynamic, alive, adjustable, in pursuit of results. At any rate, it will need good guidance, accurate execution, and seamless coordination. Goals and strategic projects must be clearly designed and communicated, and implemented and monitored continuously.

In this way, according to authors like Bossidy and Charan[32], when discussing execution as a discipline aimed at achieving results, being able to finish what was planned, having specific milestones for measurement, and promoting an intense and fast-flowing monitoring process of information are elements that facilitate not only the evolution of the strategy, but also the communication of results - a key factor for the institutional alignment around the pacts within the framework of a strategic plan.

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Conflict of Interest

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