

Analysis of work scenarios in the sanitary enforcement of medicines from the federal regulatory agency

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Abstract *This study analyzes the work situations experienced by professionals in the sanitary fiscalization of medicines at the Brazilian Health Regulatory Agency, during the COVID-19 pandemic. This is a single-case study, qualitative in nature, with an ergological approach. The data were collected from 2020 to 2021. During this period, 18 interviews and 3 online work meetings were conducted. The discursive practices were systematized in ergodialogical maps, resulting in three categories: the works experienced in the sanitary enforcement of medicines; the variabilities of the organizational context and the renormalizations facing the pandemic. The fragilities of the information systems, the outdated regulatory framework, the performance model, the fragmentation of the work, among others, have caused barriers to the professional's activity. The conformation of a new way of performing the sanitary fiscalization of medicines involves the combination of interventions aimed at prevention, detection, and response to the consumption of medicines that are harmful to health. The necessary transformation goes beyond the restricted function of control and punishment and consolidates itself as a new proactive and dynamic action model, based on health risk management and the implementation of Good Fiscalization Practices.*

Key words *Health Supervision, Drug control, COVID 19 Pandemic, Work*

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Introduction

Globalization, technological progress, the increasing use of the Internet and the effects of the COVID-19 pandemic are phenomena which have repercussions in every dimension of life in society^{1,2}, including the labor universe^{3,4}. The work of health surveillance is a human activity interferes in the work of other people and is affected by the current context, provoking changes in society and in the production and consumption relationships, with the purpose of protecting health⁵.

With ample presence in the media and visibility in society, health surveillance professionals from State, Municipal and Federal levels, experienced situations of uncertainty at work during the global public health emergency in 2020 and 2021. On one hand, there was considerable dissemination of the role of health surveillance and recognition for the services provided to society, however, on the other hand, many of those professionals were heavily criticized or even received threats against their physical integrity^{6,7}.

In Brazil, sanitary fiscalization might be the most visible work performed by health surveillance, and it is a historical and social practice which is defined by a set of actions supported by legal norms, regulations, procedures, and controls. These actions are conducted by teams which consist of professionals from various backgrounds, such as lawyers, pharmacists, chemists, and veterinarians, with the purpose of identifying sanitary infractions, impose penalties and remove from the market those products which are irregular, ineffective, or harmful to human health^{5,8}.

The sanitary fiscalization is defined by an interventionist, legalist and punitive participation of the State, which defines different organizational structures depending on the political, social, and economic context at the three levels of administration of the Unified Health System (*Sistema Único de Saúde - SUS*)^{5,9,10}. Studies¹¹⁻¹⁴ have questioned those characteristics and identified problems related to the sanitary legislation, to working conditions, as well as the mechanisms of responsabilization and application of fines for transgressors, which affect the efficiency of health surveillance at the federal level.

The work of the sanitary enforcement of medicines seeks to promote sanitary safety and protect the health of the population, reducing

damages and grievances resulting from the consumption/use of medicine which are substandard, falsified (SF), or unregistered medicine (NR)¹⁵. However, the fiscalization takes place in a context riddled with disputes and interests, so there is a need for acting as a State function, regulating and disciplining social relationships in the production-consumption cycle⁵. This cycle is characterized by two interacting logics: that of the globalized market, which seeks profits and promotes intense consumption of products and technologies; and the logic of contemporary society, which demands access to those products, with quality, safety, and effect, in order to address its needs in terms of health and welfare^{5,9,16}.

In this scenario, we contemplate how the Anvisa professionals interact with each other, how they deal with situations at work when performing activities of the enforcement of medicine, and how they handle the difficulties and unpredictability during the pandemic.

We sought to answer those questions by means of an ergologic approach, highlighting the determining role of the Anvisa professionals in order to understand the situations at work, since those professionals are the responsible agents for the singularization of those situations and for transforming them¹⁷. In every situation at work, the professional becomes involved, makes use of his intellect, of language, subjectivity, of his body, of his life history and his relationships with other people, reinventing, making choices and decisions, managing the boundaries between prescribed and actual work^{18,19}.

That management happens through norms and restructuring of norms, in other words, everything that guides and anticipates the work, the antecedent norms, the demands of each situation which provokes the expertise of the professional, requiring adjustments, renormalization, in order to perform efficiently²⁰.

Considering that in the essence of work “lies a complex human being who is involved in doing the work”²¹(p.283), the production of understanding on how professionals work and build their social relationships contributes to improving the conditions and the way in which work is performed^{20,21}.

Therefore, this study aimed to analyze the work situations dealt with by the professionals of the sanitary fiscalization of medicine from the federal regulatory agency, during the COVID-19 pandemic.

Methodology

This is a unique case study, of a qualitative nature and ergologic approach, and its unity of analysis is the process of sanitary fiscalization of medicine performed by the Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária* - Anvisa)²². Anvisa is the national regulatory authority (NRA), and it is an autarchy linked to the Ministry of Health and instituted with the purpose of regulating, controlling, and inspecting products, goods, and services that pose a potential risk to public health, thus promoting the protection of the population's health²³. The agency is responsible for most of the process of sanitary fiscalization of medicines, producing regulation, routes, flows, procedures, and sanitary measures for the removal, recall, prohibition, and apprehension of medicine in the national territory; it also promotes the training of professionals who work in the realm of the National Health Vigilance System (*Sistema Nacional de Vigilância Sanitária* - SNVS).

Data was generated by triangulation, by means of participant observation and semi-structured interviews, between December 2020 and September 2021.

Interviews were conducted with 18 Anvisa professionals who met the inclusion criteria: to work or have worked in the sanitary enforcement of medicine; and have at least two years of experience on the job. The participants have a college level education, most have post-graduate degrees, and 14 years of average professional experience in the agency, in the area of inspection and enforcement.

A semi-structured script was used, with questions related to the way in which work is performed; the conditions and regulation involved. The participants were also asked to provide examples of real situations that they went through. The interviews lasted on average of 70 minutes, given that that 17 interviews were conducted in the agency's exclusive virtual work platform, and one by telephone, at the participant's requests.

Interviews were recorded, transcribed, and archived in an external device (HD), and for the sake of anonymity, were codified with the letters "E" and "P" (Participant's Interview) followed by sequential numbers.

The participant observation was conducted in three meetings of the Anvisa's Working Group (WG), comprising professionals with different academic backgrounds, indicated by the inspection and enforcement sector, to elaborate the

normative instrument proposal for the process of sanitary fiscalization²⁴. The WG was conducted in the format of online workshops which lasted on average 4 hours, and employed problem root-cause analysis, as well as discussions about work situations, reaching a collective construction of proposals for the problems presented.

Observation was guided by a script with work situations identified in the interviews, and it was applied by the researchers with the purpose of encouraging discussion in the WG about "what they do" and "how they do" in face of each situation presented. Information was registered in a field diary, resulting in three data banks.

For the analysis, the concepts from the ergologic three-pole dynamic device (DD3P) were used, together with the discursive practices by Spink²⁵ with the purpose of "dimensioning what is told and what is done in the unfoldings of the work as a universal human activity"²⁶(p.94715). Discursive practices, such as language in action, are used because they guide the view into work relationships and convert into senses the points of view of the professionals, translating the telling and the doing of work situations²⁶. The DD3P is a resource which transforms into dialectics the formal, technical, and scientific *knowledge* (pole I) combined with the experiences and knowledge generated by *acting* (pole II), permeated by the universe of epistemological and ethical *values* (pole III), which indefinitely move, recreate, and renovate the work activity^{20,27,28}.

For data manipulation, the Atlas.ti, v.9.1²⁹ app was used, which is a methodological tool to support the analysis of data collected in qualitative research and is able to work with large volumes of data and information, as well as can combine different analytical techniques according to the objectives of the study^{29,30}.

The transcriptions of the interviews and the information recorded in the field diary were organized in the app, and after attentive reading, the process of codification was started²⁹. The sections of the material which were more significant (which carried sense) were selected and *in vivo codes* (discursive practices) were attributed, resulting in categories and subcategories for analysis.

The codification of the discursive practices followed the tripolar scheme of experience - knowledge - ethical values by Schwartz^{20,27}: (1) generating theme related to the situation or to categories/subcategories, defined by code groups; (2) pole I (knowledge) - sections of the testimonies or fragments of participant observation

notes which indicate some kind of knowledge (a “because”), or knowledge regarding the work situation; (3) pole II (experience) - quotes of records which reveal actions by the professionals (“I”) or the team (“we”); (4) pole III (values) - fragments of testimonies of records which denote principles, values or judgment values, or ethical points of view.

As a result of the articulation of the DD3P and the idea of association maps (or dialogical maps according to Mary Jane Spink²⁵), the concept of ergo-dialogical maps was developed, which are analytical tools that can deal with the relationships established by professionals, schematized in the dynamics of the discursive practices attributed to the different poles. Those maps, therefore, allow one to view the positioning of the participants; the interactions, the debates regarding norms and re-normalizations in the work activity; the dialogics of the analyzed situations and the values present in the “telling” and the “doing” of sanitary enforcement^{20,31}. The maps show one of more possibilities of interpretation, following one single direction or several, in order to provide sense for the reader.

The results were systematized in three categories which complement each other creating a triad: (1) the work situations in the sanitary fiscalization of medicines; (2) the variability of the organizational context, and (3) the renormalization in the context of the pandemic. These categories create a visualization map which facilitates the understanding of what was observed and told about the work, as well as the difficulties and the perspectives which emerged from the professional discourse by those who work in the sanitary enforcement of medicine.

This study was conducted according to the recommendations in Resolution No. 466/2012 by the National Health Council (*Conselho Nacional de Saúde - CNS*)³², and was approved by the Ethics Committee on Human Research from the Faculdade de Ciências da Saúde da Universidade de Brasília (UnB), Decision No. 4,058,595 from May 29th, 2020.

Results and discussion

The work situations lived during the sanitary fiscalization of medicines

In the work situations described by the professionals, there is the typification of different “*situations lived*”, which are dynamic, intertwined

and in movement, and represented in the discourse practices related to the poles of the tripolar device, according to the ergo-dialogical map shown in Figure 1.

In the discursive practices, the “*bureaucratic work*” is present, originated by the excessive level of control and procedures, sometimes necessary, sometimes redundant and unnecessary, requiring numerous documents for each phase of the process. Some aspects hamper the activity, such as having control instruments in the form of Excel spreadsheets, having an outdated database, and the presence of Sanitary Administrative Process (PASs), which are still fully digitized for internal procedures of the agency. The fragilities in the information system and other technological resources are at the core of the discussions regarding working conditions, and impact in the agency’s ability to prevent, detect, and respond to sanitary infractions, such as fraud, illicit practices, or due to problems related to quality and safety of products, according to reports by the WG.

The bureaucratic work is a sort of “*police work*” in terms of health surveillance. On Figure 1, the different poles related to this kind of work indicate the desire to move away from the “policing” stigma which has been historically associated with sanitary enforcement yet maintaining the control of sanitary risks³³. The professionals realize that policing brings poor results, as it does not bring changes in the behavior of the infractors; therefore, they propose a more educative approach.

Some experts^{12,14} argue that there is a need to improve the debate regarding the punitive-pedagogical nature of the sanctions imposed in cases of sanitary infractions, in order to reach more effective results, in more conformity with the Brazilian reality.

One study¹³ which investigated the inspecting work done by Anvisa between 2011 and 2015 found out that the work of sanitary fiscalization, including that which is performed through PAS (Sanitary Administrative Process) is costly for the administration and “produces little effect in terms of reeducating and compensating for the damages caused by infractors”¹³(p.258). The lack of rigor in enforcing sanitary infractions; the delay in the application of fines and the difficulties in administrative responsabilization of the companies, were all problems identified in the study by Delgado¹³, which corroborated some of the discourse practices seen in Figure 1.

The “*limited work*”, because of the sanitary legislation, which defines sanitary infractions,

sanctions, and the flow of the PAS³⁴, or because of the working conditions, reveals the sense that the service is stuck in place and time, and the professionals resent that, by the force of the Law, they have the obligation of investigating every report of irregular medicine.

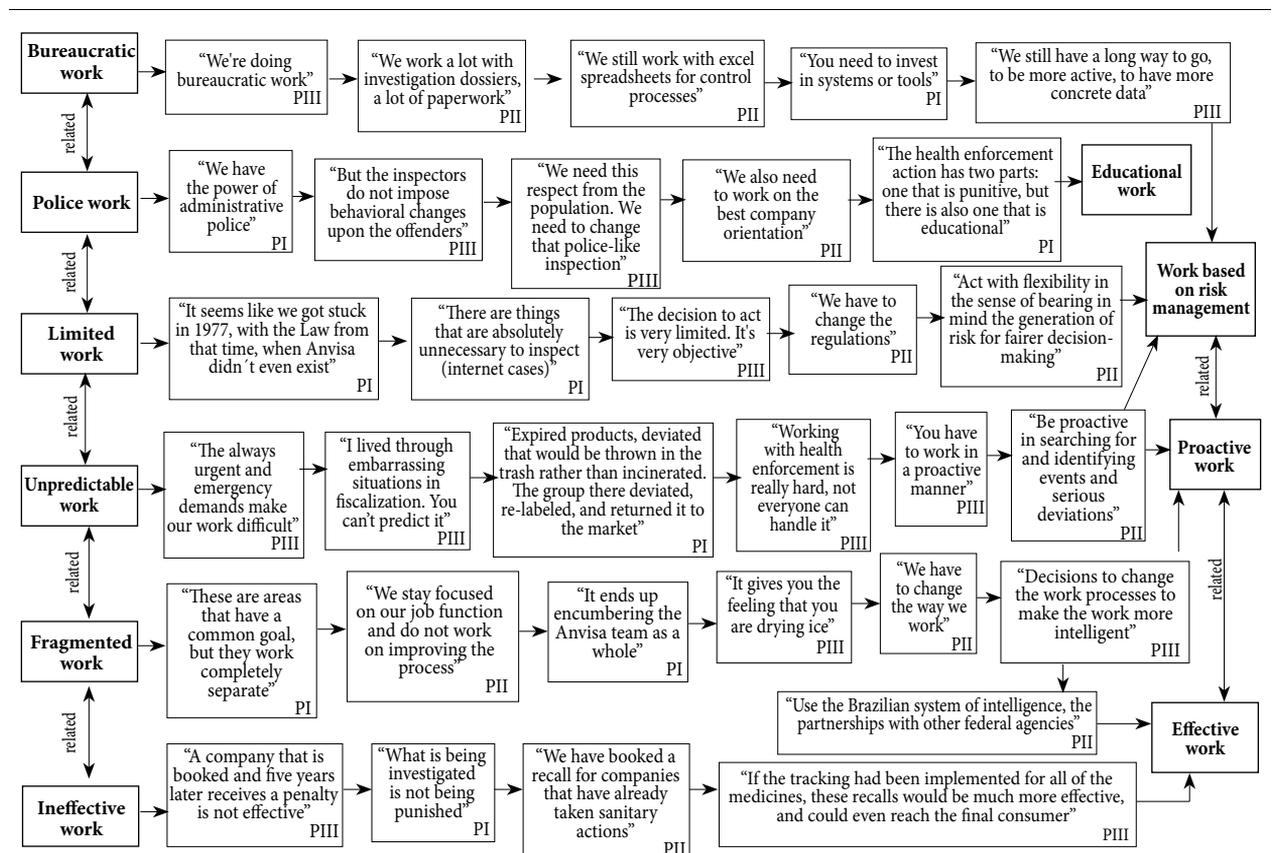
By the tripolar device, situations are revealed which are considered as unnecessary and other forms of enforcement are suggested, based on rationality and in risk management for decision making.

In the WG debates, it was established that the legislation does not correspond to the regulatory demands of current society, and it may become, at times, a hindrance to Anvisa's decision-making capability. For example, it is mandatory to charge companies which proceed into voluntary recall of medicine, which is outside of the general standards; or the requirement for opening dossiers

for the investigation of all of the unregistered pharmaceutical products promoted on the Internet, which are deemed to be of high risk.

The antecedent norms of the sanitary fiscalization of medicines have to the legislative and legal basis of the 1970s, leave the professionals in situations of conflict and contradiction, which require permanent negotiation when faced with the risks and the need to protect the population's health. Even considering their professional autonomy and the profusion of norms and prescriptions that guide decision-making at the operational level, they feel limited in their choices, in the application of the discretionality principle which is intrinsic to sanitary enforcement¹.

Uncertainty resulting from demand unpredictability is a characteristic of the work in the public sector⁵. In the sanitary enforcement of medicine, the professionals often face the "unpre-



Captions: Author | PI = Pole I (knowledge) | PII = Pole II (act) | PIII = Pole III (values)

Figure 1. Ergodological map of the work experienced regarding the sanitary fiscalization of medications.

dictable work” (Figure 1) when situations that are urgent, unexpected, or even embarrassing happen because of the sale of irregular products or because of illegal or unlawful practices which put people’s lives at risk. Such situations can interfere directly in the manner in which the professionals plan and perform their activities.

The companies sometimes say that they do not have a certain document, and in a few moments, that document appears. When we looked into quality control, that was it, the mystery was solved, and we were able to find the infractions. It is a kind of investigative work. Sometimes, in the middle of an investigation, strategies are created, by talking to a colleague or commenting with another; one has an idea, someone else gives another, and we put some understanding together. One thing is certain, you program things and think that everything will work, sometimes, however, none of it happens and you must completely change the strategy during the investigation (EP09).

The real work situations of sanitary fiscalization will require the professionals to resort to, besides the knowledge of the norms, the knowledge which was acquired through experience in managing the discretionary power that the agents have, since not every situation that they face will be predicted by law¹.

As one participant mentioned in the working group, the professionals plan before they go out in the field to investigate, and prepare themselves to prove irregularities indicated in accusations. It is common, though, that in the course of an investigative inspection, they find themselves in unexpected situations, which they did not plan for. In those cases, collective work groups are formed in order to discuss possible alternatives and make the more adequate choices in each situation, for example, shutting down the company or prohibiting the manufacturing of the product, depending on the norms and experiences they share.

The collective groups, defined by Schwartz as relatively relevant collective entities (RRCE)²⁰, are transitory associations of people which are formed between individuals who share trust and working methods, in search of common objectives, going beyond the prescriptions by organizations, and representing “working life itself”²⁰.

The discursive practice attributes present in the poles (Figure 1) indicate that many different Anvisa sectors are responsible for some part of the sanitary enforcement process, in what is called “*fragmented work*”. Departmentalization is noticeable, as well as overlapping of activities, the lack of communication between sectors, and

delay in application of penalties, and one might wonder about the feasibility of reaching effects in terms of expected results.

Fragmentation of the work process is directly related to “*ineffective work*”, causing the professional to feel that he is trying to “*dry ice*”, considering that the results are nowhere close to what is expected by the professional or by the organization (Figure 1).

To rethink the organization of the work would require overcoming the fragmentalization inherent to the model based on meeting the spontaneous/denouncement-related demands, and not articulated with other regulatory actions; the inspector would be the agent of the transformation process in sanitary enforcement⁵.

Reflections about the work produce alternatives for change. The work protagonists expressed their expectations regarding changes in the working model, in the sanitary legislation, in terms of establishing inter-institutional partnerships, in terms of investments in information technology, in tracking medicine, among others. Expectations regarding the values which guide professional performance were mentioned, as well as the ability to work in a team, to be proactive, fair and intelligent and to make decisions having the risks into consideration, in the micro dimension of work.

Changes on the process of the sanitary enforcement of medicines achieve a sense of agility, proactivity, justice, integration, rationality, as well as the effectiveness of the work activity, being expressed as “*educative work*”; as “*work based on risk management*”; as “*proactive work*” and as “*effective work*”.

Variability in the organizational context

Ergo-dialogical Figure 2 shows that acting simultaneously in inspection for certification for regular companies and enforcement of irregular companies, which are suspected of illegal practices or crimes, is something that requires attitudes, expertise, values, and different abilities for the execution of each action.

The discourse reinforces the idea that some personal characteristics, such as being interested in the activity or having investigative abilities are essential for conducting inspections in an efficient manner. In this sense, there is predominance in discursive practices associated with the PIII pole, that about values.

Constant reorganization of the processes of medicine inspection and enforcement, has re-

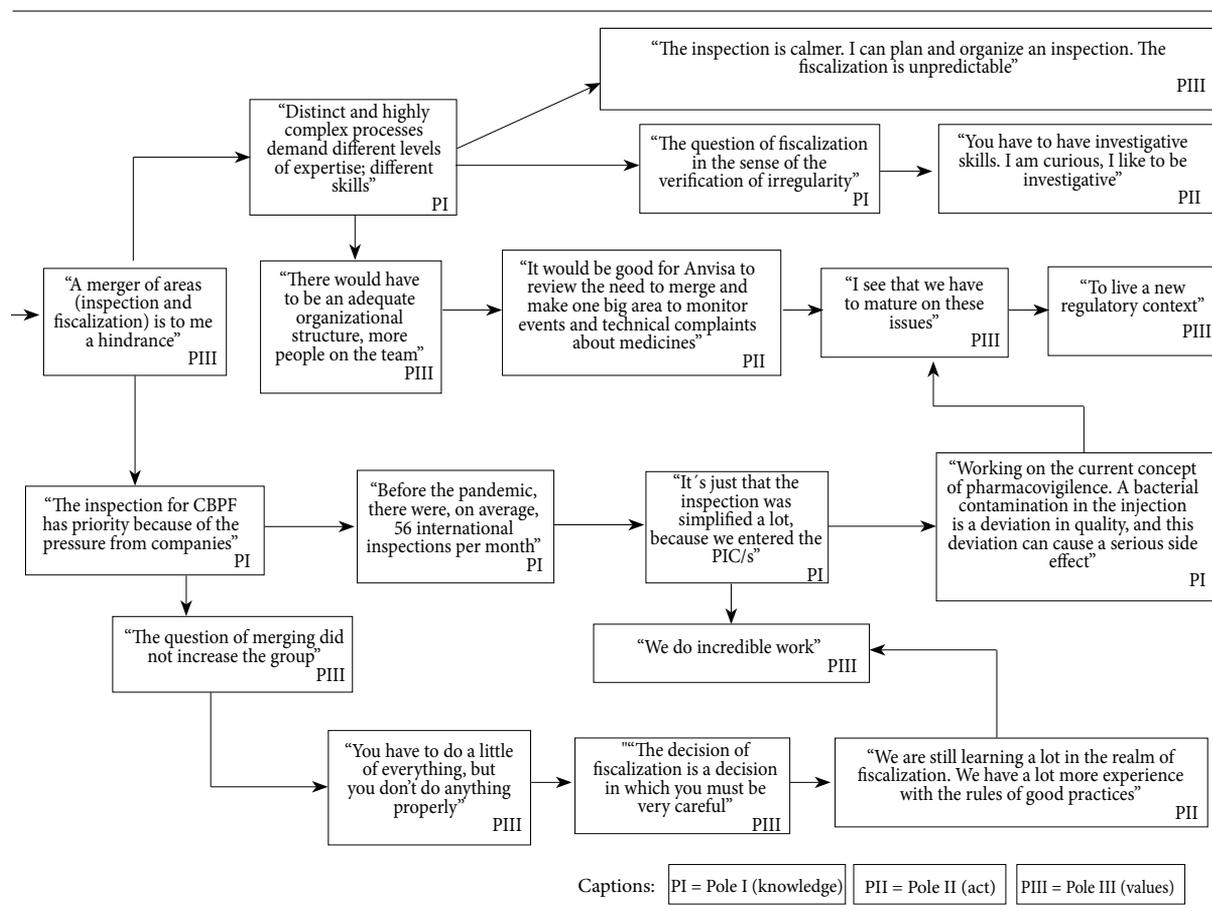


Figure 2. Ergodological map of the organizational variability of the sanitary fiscalization of medicines.

Source: Authors, 2022.

quired the professionals to develop new abilities, in a long process of adaptation, which was, again, affected by the COVID-19 pandemic:

We know that there are different people here: some people do things easily, do things in less time than what is determined. In my case, I do not have that ability for some situations. I like to write things down, detailing all of the processes, the dossiers (EP13).

During the pandemic, Anvisa implemented new procedures in an extraordinary, temporary character for the certification of companies, and prioritized the activities related to the inspection of medicine and pharmaceutical inputs. Some reports indicate that demands for international inspection have been declining since Anvisa was approved in the Pharmaceutical Inspection Cooperation Scheme (PIC/S), and this might generate new reconfiguration in the institution's structure.

The regulatory systems require legal instruments that are up to date, as well as robust mechanisms and adequate resources, in order to conduct efficient inspection and take immediate measures in the pharmaceutical market when they identify potentially harmful products^{35,36}. However, the progress in the fiscalization is limited when there are not enough professionals with the proper training and in sufficient numbers to perform the work³⁶.

Changes in the structure and in the working conditions acquire different meanings, individually and collectively, and there is no simple model which prescribes how the professional should (re)act²⁰.

The areas of inspection and enforcement were put together and split up at least a couple times since 2005. And this last change put together inspection with enforcement of medicine, and I think that the structure was demolished, to begin with,

because we had a management that was only for enforcement (EP05).

We lost many people and now we have to do both things: inspection and enforcement. Those are distinctive processes, very complex and that require different expertise (EP08).

Difficult situations involving the overlapping of tasks, the lack of human resources, the diversity of actors and little control over one's own work result in an intensification of labor, leading the worker to debate norms and values and make choices about what actions should be taken²⁰.

The difficulties by the professionals in face of institutional changes happen because no one is capable of conforming to impositions of the environment, as if workers were machines that could be adjusted whenever the organization deems necessary. It is in subjectivity, indeed, that the professionals seek to re-center their own norms and adapt to the variability of the environment when performing their work activities^{20,27}.

In pole PIII, there was a predominance of defending the organizational structure, to make it more adequate to the enforcement activity, as well as in terms of changes in the conception, in the model of work and in the work processes related to postmarketing surveillance of medicines, which expresses the sense of "living in a new regulatory context" at Anvisa.

In pole II, there was a suggestion for configuring a technical unit for monitoring, control, and enforcement, in the sense of expanding pharmacovigilance into the follow-up of adverse reactions and of technical complaints, all under responsibility of the same management.

The WHO¹⁵ proposes that regulatory authorities implement the approach "prevent, detect, respond" to prevent SF and NR medicine, implying in the use of multiple strategies, evolving integration with the systems of pharmacovigilance.

In the international scenario, some regulatory systems went through changes in the sanitary fiscalization of medicine based on principles which subsidize the work of the professionals, implementing the so-called "Good Fiscalization Practices" (*Boas Práticas Fiscalizatórias*), with elements which include the rights and the obligations of the inspectors; powers; enforcement procedures; among others^{37,38}. In the study by the OECD³⁷ recommendations are presented for the improvement of the relationships with the normalized productive sectors, and for the adoption of a multidisciplinary approach with a new perspective, and guaranteeing the adequate training of the professionals. A solidarity attitude by the

professionals is sought, and they should focus on risk analysis in order to reach real, tangible results, removing from the market any falsified products, or that are substandard or unregistered. These recommendations address issues related to legislation, methods, procedures, as well as work mechanisms and organizational culture.

Re-normalization due to the pandemic context

As shown in Figure 3, the pandemic context provoked changes in the sanitary fiscalization work process, requiring from the professional new ways of acting, adapting, and learning in terms of relationships and of using technologies, as well as an intense normalization process in order to find a balance between work and home⁶.

People have to change their "way of doing" according to new situations at work²⁰. By having a humble attitude, the professional is aware of his/her knowledge, of the antecedent norms that were incorporated, and understands that they may be updated, re-normalized in the "here and now" of the work activity.

The discursive practices shown in Ergo-dialogical Figure 3 demonstrated feelings of pride and satisfaction by the professionals because of their work being valued and recognized by society, and because of the role performed by Anvisa in the context of the pandemic, which brought the agency a lot of visibility.

In March 2020, the agency's professionals switched to remote work in an urgent manner, and then there was great adhesion to the Management Program Aimed at Results (*Programa de Gestão Orientada à Resultados - PGOR*), which established productivity goals for individuals and work teams³⁹.

The participants reported difficulties in adaptation and organization of work at home during the pandemic period. There was an increase in domestic expenses, difficulties with time management, in the choice of adequate places to work at home, at times compromising their personal and professional wellbeing (Figure 3). Such difficulties may have been sources of discomfort at work, and therefore, may potentialize the risk of workers becoming sick⁴.

The increase in number of tasks throughout the pandemic, with weekly shifts often going beyond 40 hours a week, and the "excessive demand to meet the productivity goals" were considered as a "discouraging factor", and led to "work overload".

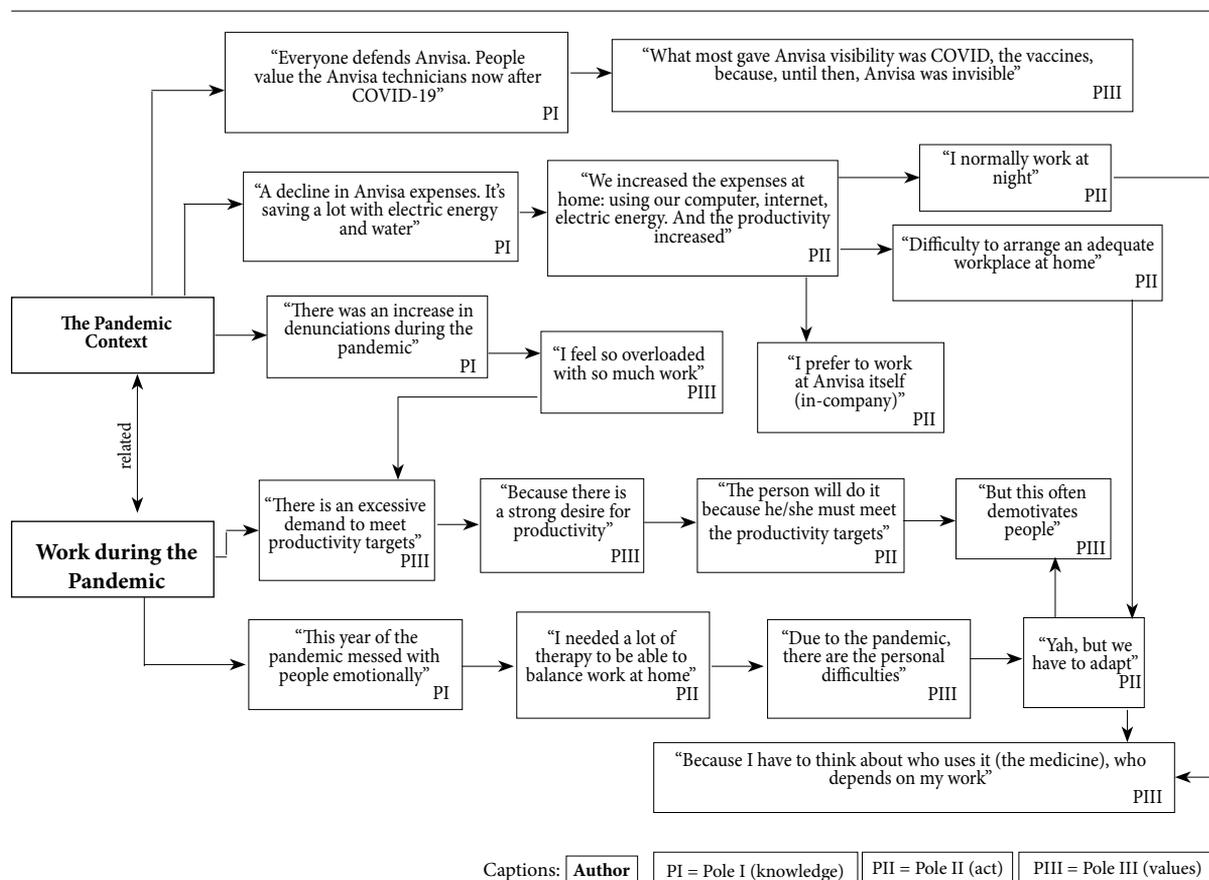


Figure 3. Relationship between the context and the work of the sanitary fiscalization of medicines during the COVID-19 pandemic.

Source: Authors, 2022.

When analyzing the discursive practices in the tripolar scheme on map 3, we can notice that the agency established goals for evaluation and control of the professionals as they worked remotely, and there was pressure for meeting the productivity goals amidst the uncertain context created by the public health emergency. By following that strategy, the agency failed in "valuing the involvement, the dedication, and the well-being" of the professionals, "forcing them to deal with a confrontational situation with their environment, to look for solutions," when they were in situations which they considered unmanageable⁴⁰(p.775).

In the discursive practices in pole PIII, the productivity goals acquire the sense of professional control of remote work, for the management, the teams and the organization:

Every activity gets a score. For example: certificates analysis has a score; report analysis has a

score, revision of reports as well. Responding to the Public Ministry or policing, everything has a score. We have to work hard in order to cope with the work. And imagine in the case of remote work, that adds at least 20% more difficulty (EP09).

Some professionals are resentful of the processes of quality control for achieving goals, whose focus is restricted to the quantity of processes analyzed or the number or investigation dossiers opened, without considering the quality of the work or the operational capability of the teams.

The reality of virtual work during the pandemic period, reiterates the need to further the debate on the risks associated with the increase in volume of work and in the number of hours required for the tasks, the fast pace, the family-work conflicts, the physical and mental burnout syndrome, and the psychosocial hazards, which were all intensified in the COVID-19 years^{3,4}.

One limitation in this study is the fact that it was conducted in the virtual environment, much of the information might have been missed, which would have been perceived if the work had been done in person, with more interaction between the researchers and the participants.

Final considerations

The present study shows what professionals did in terms of the management of work in response to changes in sanitary enforcement methods, accentuated by the COVID-19 pandemic. The fragility and limitations of the information systems, the out-of-date legislation, the model of work, the fragmentation of work processes, the overlapping of activities, the lack of personnel, among other problems, are present in the situations which compromise the activities performed by Anvisa professionals.

The analysis proves that inspection and enforcement require the management of variables

and dealing with unpredictable situations at work and in the organizational level, by means of re-normalization and adaptation. It is a matter of finding a way through the bureaucratic work, the policing work, the educative and proactive work, thus achieving effective work.

The results of this study shed light on the work of sanitary fiscalization, and at the same time they bring subsidies for the debate regarding the construction of a new model of work that needs to be adopted by the agency, which goes beyond simple control and punishment. Maybe there is no such a thing as a single model, the best solution would be to adopt several models adapted to different work situations and conditions in terms of inspection and enforcement, considering the normative nature of the work and its unpredictability. We suggest as a strategy, the implementation of the Good Fiscalization Practices (*Boas Práticas de Fiscalização* - BPF) by Anvisa, as a viable alternative to the international movements of reform in the work processes.

Collaborations

MAF Martins worked in the conception, data collection, and analysis, as well as in the final write-up the manuscript. MDA Scherer participated in the conception and collaborated in the data analysis, in the writing of the manuscript, and in the final revision of the article. Both authors approved the final version of the study.

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