


“Rolling a stone uphill?": the work of professionals in health inspection of medicines on the internet


“Enxugando Gelo?": o trabalho dos profissionais na fiscalização sanitária de medicamentos na internet

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Abstract

Contemporary society is plagued with uncertainties and vulnerabilities, demanding from regulatory systems the surveillance of unregistered and/or falsified medicines sold online. This study investigates the work of federal health surveillance professionals in the inspection of medicines sold online and the elements that guide their technical decision. A qualitative, single case study based on the ergological approach was conducted between December 2020 and September 2021, with data collected by interviews and participant observation. Ergodialogical maps, developed using Atlas.ti, underlined the analysis of discursive practices classified according to the tri-polar knowledge-action-value schema, resulting in three categories. Professionals are always called upon to decide on and manage unpredictable situations, questioning the institutional capacity to understand and act on the problem. The work thus takes on the sense of “rolling a stone uphill” due to the volume of demands and the limited effects of surveillance on the e-commerce of medicines. Norms, technical knowledge, experience, and social responsibility, among other elements, inform the decision-making process of professionals, who are aware that, by acting, they protect public health. Different forms of knowledge, scientific or experiential, can better qualify decision-making in surveillance, making it more effective, assertive, and transparent. **Keywords:** Health Inspection; Drug Regulation; Postmarketing Surveillance; Decision Making.

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Resumo

A sociedade contemporânea convive com incertezas e vulnerabilidades que exigem a atuação dos sistemas regulatórios na fiscalização do comércio eletrônico de medicamentos não registrados e/ou falsificados. Investiga-se o trabalho dos profissionais da vigilância sanitária federal na fiscalização de medicamentos na internet e os elementos que orientam sua decisão técnica. A metodologia utilizada foi a pesquisa qualitativa, do tipo estudo de caso único, ancorada na abordagem ergológica, entre dezembro de 2020 e setembro de 2021, por meio de entrevistas e observação participante. Os mapas ergodiológicos, elaborados no Atlas.ti, subsidiaram a análise das práticas discursivas classificadas conforme esquema tripolar saber-agir-valor, resultando em três categorias. O profissional é sempre convocado a fazer escolhas e gerir situações imprevisíveis, havendo inquietações sobre a capacidade institucional para compreender e agir sobre o problema. O trabalho adquire, assim, o sentido de “enxugar gelo”, em função do volume de demandas e dos poucos efeitos da fiscalização no mercado eletrônico de medicamentos. As normas, o conhecimento técnico, a experiência e a responsabilidade social, dentre outros elementos, estão presentes na tomada de decisão dos profissionais, conscientes de que, ao agir, protegem a saúde da população. Constatou-se que diferentes saberes, científicos ou empíricos, podem qualificar melhor o sistema decisório na fiscalização, tornando-o mais efetivo, assertivo e transparente.

Palavras-Chave: Fiscalização Sanitária; Medicamentos; Vigilância de Produtos Comercializados; Tomada de Decisão.

Introduction

We live in a society of hyper-consumption of products that promise happiness in the form of pills or the modification of bodies with “magic drops” (Lipovetsky, 2007). The “hypermodern times” have characteristics based on the here and now; on the rapid expansion of consumption and popularization of the internet; on the weakening of norms and institutions; and, mainly, on the growing appreciation of the body or image (Lipovetsky, 2007). Lipovetsky’s hyperconsumption society (2007) or the risk society defined by Beck (2011) coexist with uncertainties, vulnerabilities, and ambiguities, which require governments to take protective measures and respond quickly to risks, and the function of national regulatory systems is to act in the control and inspection of medical products potentially harmful to human health (Costa, 2013; Lucchese, 2018).

In the inspection scenario, medicines are therapeutic products with a high potential for health risk and with “a strong weight in the structure of public and private health spending” (Costa, 2013, p. 29), which makes them a frequent target of counterfeiters and criminals. The advertising and marketing of substandard, falsified, and unregistered (SF/NR) medicines on the internet has increased significantly, according to the World Health Organization (WHO). (WHO, 2017)

In this sense, several countries and international organizations have been debating the control of medicines sold and advertised on the internet and on e-commerce platforms, in which the number and registration of reports of falsified or unregistered pharmaceutical products or of those being sold without retention of prescription—in cases where it should be mandatory—is increasing. This phenomenon requires national regulatory systems to develop strategies to control risks on product quality and origin; the legal accountability of the companies involved; and proof of the veracity of the information passed on to the population (WHO, 2017).

Sanitary inspection is one of the instruments of intervention of sanitary surveillance to protect public health (Costa, 2009). With the globalization of production, the movement of

people, of consumer relations, and “globalized” technological innovations, the process of sanitary inspection becomes increasingly complex, since it represents the state public power within the scope of the Brazilian Health Regulatory Agency (ANVISA) and the Brazilian Health Regulatory System (SNVS), with decisions that directly affect individual and collective, social and economic interests (Lucchese, 2018; Silva; Costa; Lucchese, 2018).

To inspect means to examine, to verify compliance with the standard and to issue a judgment. It is a human activity, immersed in legal norms, with knowledge and values that are its own, and is multiprofessional—with the work of lawyers, pharmacists, veterinarians, nurses, physiotherapists, among others who are, at all times, called upon to make choices to seize or prohibit suspicious products that may harm public health (Costa, 2009; Schwartz; Durrive, 2010).

The uniqueness of the action of each professional goes beyond the work prescribed in constant debates of standardization and renormalization, since the need arises to intervene in the unpredictability of production processes and social relations of consumption, which can result in consequences such as the limitation of rights and freedom of choice in the risk society (Beck, 2011; Costa, 2009; Schwartz; Durrive, 2010).

Restrictions and social isolation during the COVID-19 pandemic, between 2020 and 2021, accelerated changes in consumer relations and work processes. Thus, how do health surveillance professionals at the federal level understand the current context of drug inspection on the internet? What choices are made by them to cope with the risks arising from the consumption of these products?

To deepen how such issues are intertwined with the work of inspection of irregular medicines, to know what knowledge and experiences are mobilized for the debate of norms and values, as well as to identify the aspects that influence the decisions of professionals, the ergological approach was chosen, considering that guiding the work as an object of study of science can boost the “action that modifies the state of things” (Durrive; Schwartz, 2008, p. 25).

Work is a human activity of life in society—an encounter that mixes technical and normative aspects with professional action, crossed by the world of values. To work is to live immersed in the debate of norms, and is related to the way each person feels, thinks, invents, and carries out the activity, mobilizing knowledge and experiences to manage unpredictability and produce new norms during its realization (Schwartz; Durrive, 2010). In the dialectic between the “micro” of work and the “macro” of social life it can be understood that the questions of society relating to values, to social aspects, and to economic structures are intertwined with the activity of work (Schwartz; Durrive, 2010, p. 128).

Some studies (Delgado, 2013; Hurtado; Lasmar, 2014) have proven the need for improvements in the inspection process and in ANVISA’s technical and operational capacity, which will only be achieved with the actual involvement of the professional who performs the activity.

In this sense, this study aims to analyze the work of professionals in the sanitary inspection of medicines sold on the internet, identifying the elements that guide the operational decision-making by inspectors at the federal level.

Materials and methods

This is a qualitative research, of the single case study type, whose unit of analysis is the sanitary inspection process of medicines on the internet carried out by ANVISA (Yin, 2015). The study is anchored in the ergological approach, which consists of studying the work activity, understood as “an intersection between preceding norms and renormalization attempts in the relationship with the environment can be noticed, where constant debate about values occurs, resulting in choices made by individuals and groups” (Scherer; Pires; Schwartz, 2009, p. 772).

Any work situation is governed by the preceding norms, understood as everything that can guide, conduct, and regulate the activity, seeking to anticipate the work that must be performed (Schwartz; Durrive, 2010). In this sense, in the inspection activity, these standards comprise laws;

decrees; scientific, technical, organizational, and legal norms; national and international regulations; reports; inspection scripts; manuals; guides; standard operating procedures (SOP); spreadsheets; written and unwritten, formal and informal rules; among others (Schwartz; Durrive, 2010).

Renormalizations take place in the confrontation between the preceding norms and what the work situation requires, in the arbitrations and in the choices of the individual or the work team (Durrive, 2011; Schwartz; Durrive, 2010). Thus, the management of the “dramas of the use of the self” is entangled in the renormalization processes in work situations and in the permanent rework of the antecedent norms, as a source of new knowledge of the activity itself (Schwartz; Durrive, 2010, p. 79).

Data were produced with semi-structured interviews and participant observation, from December 2020 to September 2021.

A total of eighteen interviews were conducted with professionals in the inspection or surveillance area of ANVISA, according to the following inclusion criteria: career employees of the agency who worked (or had worked) in inspecting medicines and pharmaceutical inputs, with at least two years of experience. The exclusion criteria were professionals who were on vacation, on maternity/paternity leave, or on medical leave. A semi-structured script was used with questions that allowed the professionals to reflect and express their point of view about their work in the inspection of medicines, their experiences, and the situations they encountered.

All participants have graduate degrees; belong to the career of Specialist in Health Regulation and Surveillance or are pharmacists of the Specific Cadre; have an average of 14 years of professional practice in the Agency and five years in the inspection and surveillance sector. The interviews lasted between 50 and 90 minutes, and were carried out on ANVISA’s official virtual platform, safeguarding the confidentiality of the tool, with audio recording and transcription in full, after signing the consent form sent by e-mail. They were also coded by the letters “IP” (Interview of the Participant), followed by sequential numbering.

The participant observation was carried out during three meetings of the working group

(WG) made official in an ANVISA ordinance and composed of professionals with different academic backgrounds, representing the organizational units that deal with the inspection of most products regulated by the Agency. With a semi-structured script, capturing real work situations, dialoguing, and recording the collective construction of the process, the conditions, and the changes caused by the pandemic was possible. With an average duration of four hours in each online meeting, the observations were recorded in the field notes, generating three documents for analysis, one for each day.

The data produced with the interviews and participant observation were entered into the Atlas.ti v.9[®] software, used in qualitative studies to document the “analytical decisions in a transparent, reflective, rigorous, and systematic way” (Paulus; Lester, 2016, p. 405).

In operational terms, the coding process was applied, assigning “codes” to segments of information whose meanings were of interest to the research (Paulus; Lester, 2016). An immersion reading was carried out in the empirical material (interviews and observations), with the selection of the basic units of analysis and their subsequent transformation into *in vivo* codes in the Atlas.ti.v.9[®], resulting in the conception and construction of ergodialogical maps, a re-signification of the maps of association of ideas or the dialogical maps, widely used in qualitative studies that address discursive practices (Spink et al., 2014).

Considering the comprehension of discursive practices as language in action (Spink et al., 2014), it can be deduced that “no work situation can be described ‘outside’ language” (Schwartz, 2009, p. 102). In this sense, discursive practices manifest and circulate the language of the dynamic device of three poles of ergology and are applied as a strategy of methodological analysis to dialogue between the different types of knowledge, invested, constituted, and reported by professionals. Discursive practices also serve to understand the elements that guide their choices, as well as the perspectives of transformation of the work process in question (Schwartz; Durrive, 2010).

Professionals are called upon to “do their activity differently,” a moment in which the knowing-acting-value triangle unfolds in imprecise and unpredictable work situations (Durrive, 2011). Thus, the tripolar device is a dynamic, dialectical, and dialogical instrument: in pole I are the discourses related to knowledge, concepts, prescriptions, norms; in pole II are the discourses that deal with the action, the action carried out by the professionals; and pole III are the values and ethical principles that permeate the choices of the participants in the inspection work (Schwartz; Durrive, 2010; Holz, 2013).

In the next step, the codes were mapped and related to the pole of the triangle with the closest approximation (networks) and to the categories that emerged from the data analysis (groups of codes). To codify the discursive practices, according to the tripolar scheme composed by Schwartz (Durrive, 2011), the following definitions were adopted

- Subject: situation or category and subcategories; formed by the groups of codes and defined by the researchers.
- Pole I (knowledge): excerpts from the testimonies or fragments of the texts of the participant observation that demonstrate knowledge, an explanation (why), or knowledge about the work situation.
- Pole II (action): excerpts of speeches or records that express an action of the professional (I) or the team (us).
- Pole III (values): fragments of testimonies or records that denote a principle, a value, or a value judgment, or even an ethical point of view.

The ergodialogical maps subsidized the deepening of the analysis and facilitated the visibility of the results, with the graphic representation of the discursive practices classified according to the poles of the knowledge-action-value triangle, assuming the corpus of the research as the collective character of the discursive practices (Spink et al., 2014).

Note that the antecedent norms, the renormalizations, the dramas of the use of the self and other conceptual dimensions of ergology constituted the core of the analysis, due to the

current model of inspection of medicines marketed in the virtual environment.

The analytical process allowed the organization of the results into three categories, analyzed in the light of the ergology framework: (1) “Controlling the internet is impossible”: changes in the work environment during the pandemic; (2) “Feeling like you are rolling a stone uphill”: what choices are possible?; (3) “Another approach, active search”: discursive practices for the transformation of the sanitary inspection of medicines.

This study followed the guidelines of research with human beings and was approved by the Human Research Ethics Committee of the Faculty of Health Sciences of the University of Brasilia, under opinion nº 4.058.595, of May 2020. All participants signed the informed consent form (ICF), and the data collection was duly authorized by ANVISA’s managers.

Results and discussion

The results are organized to construct a narrative in which the three categories fit to meet the objective of the study. The first analyzes the changes in the context of work, the increase in its volume, and how the professionals experienced such changes. The second shows the discursive practices that reveal issues of the work process and the elements that make up the operational decision. The last category shows discursive practices that propose improvements to the activity of sanitary inspection of medicines in the virtual environment..

“Controlling the internet is impossible”: changes in the work environment during the pandemic

With the advent of the COVID-19 pandemic in 2020, the interviewees reported that social media and the press gave important prominence to the role of health surveillance in society. In view of the restrictive measures and social isolation that affected the home-work world, ANVISA’s inspection teams started to work remotely. Moments like this require from the professional quick learning, adaptation, and rework efforts, seeking to correspond to the desires of the organization, which leads to the “reconstruction

of their experience acquired in the course of their work and social life” (Lima; Bianco, 2009, p. 648).

Reflecting from the ergological perspective, the discursive practices in Figure 1 exemplify the “dramas of the use of the self” in the face of new work situations, to which knowledge, experiences, values, and other elements associated with competence, fundamental to understand and seek new ways of acting in the pandemic context, were moved (Schwartz; Durrive, 2010)

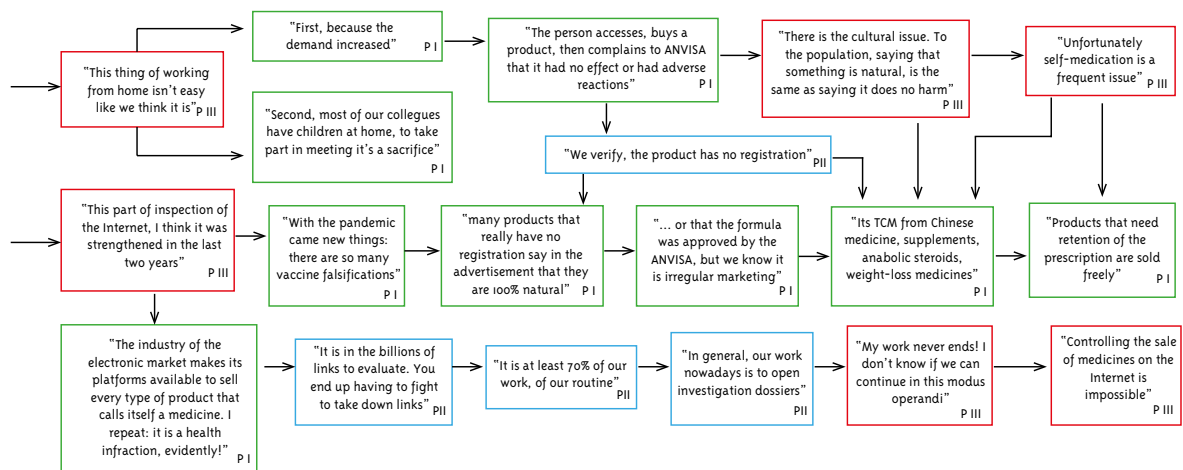
The “dramatic” dimension of the activity means that nothing in this action can be “mechanical” or a mere application of pre-established protocols.” The “work” activity refers to choices, therefore to a world of values that allow us to make a decision. These choices generate new situations, they make “history” that no

rationality could predetermine. (Schwartz, 2011, p. 132)

The discourses of the PII pole show that the professionals resort to their “reserves of alternatives,” characterized by the competence and individual effort to reorganize their work activities (access to ANVISA’s internal network; completion of spreadsheets and systems; management of the home-work routine in the same environment). It reveals the human capacity to “understand-transform what is at stake at work, (re)inventing, creating new conditions and a new environment pertinent - to oneself and to the situation” (Schwartz; Durrive, 2010, p. 10).

The discursive practices of the professionals showed great concern with the issue of the commercialization of irregular medicines on the internet, as shown in Figure 1.

Figure 1 – Ergodialogical map on the context of the pandemic and the commercialization of irregular medicines on the internet



PI: Pole I (knowledge); PII: Pole II (action); PIII: Pole III (values)

Source: Prepared by the authors, 2022.

The narratives that cross the tripolar scheme in Figure 1 reveal that the new routine in the personal life and the increase in the volume of work have raised concerns about the institutional capacity to deal with the magnitude of the problem and to adapt the work process. The fact comes to light that controlling, supervising, or regulating the virtual trade of SF/NR medicines is impossible. The WHO report (WHO,

2017) corroborates the impossibility of this control by national regulatory systems and points out that, despite the partnership and collaboration between countries, many factors make the problem complex, such as dishonest and illegal practices that hide in the anonymity of e-commerce platforms.

The speeches of the PI pole confirmed the diversity of suspicious products that should be

investigated, listing the volume of demands, the modus operandi and the scope of the virtual environment to inspect:

Our scope has thus increased immensely. You can't even enumerate it. Because before everything was physical inspection establishments and now, it's everything, it's basically the virtual environment that we inspect. Because if you're going to compare the physical environment to the virtual environment, the virtual environment is much bigger. (IPo5)

At all times in the work activity, professionals are required to make choices and decisions based on norms and values. However, such choices carry risks and consequences, considering that “choosing this or that option, this or that hypothesis is a way of choosing yourself - and then having to assume the consequences of your choices” (Schwartz; Durrive, 2010, p. 198).

The transformations in the social relations of consumption and work, the care of body image and health demands, as well as the spending on new technologies of the “pleasure of experience for the sake of experience” (Lipovetsky, 2007, p. 63) have caused a type of irresponsible consumption, which entails health risks. The professionals mentioned SF/NR products related to weight-loss medicines, anabolic steroids, supplements, herbal medicines, and controlled products:

There are products for growing hair; products for impotence; products to get stronger. Every day there is something new. Weight loss is the main thing. (IPo5)

It's a sad thing to talk about, but there's even advertising for suicide medicines. And this affects our emotions, because you are dealing with something that you want to stop, but you know that our capacity is limited, no matter how much we regulate and supervise everything, it is very difficult to stop it. (IPo8)

The way of doing things of each professional is always unique; since they make “uses of themselves,”

employing their capacities, their resources, and permanently summoning their values to make the best possible decision (Schwartz; Durrive, 2010):

Because I have to think about who uses it, who depends on the work, because in fact the person says: “look, it was approved by ANVISA,” they trust and want to trust us. (IP17)

The relationship of trust between society and health surveillance is implied when an advertisement is seen that such a product is approved or recommended by ANVISA. By raising issues related to the culture and practice of self-medication (Figure 1) in Brazil, professionals try to understand the reasons why the population consumes so many pharmaceutical products virtually.

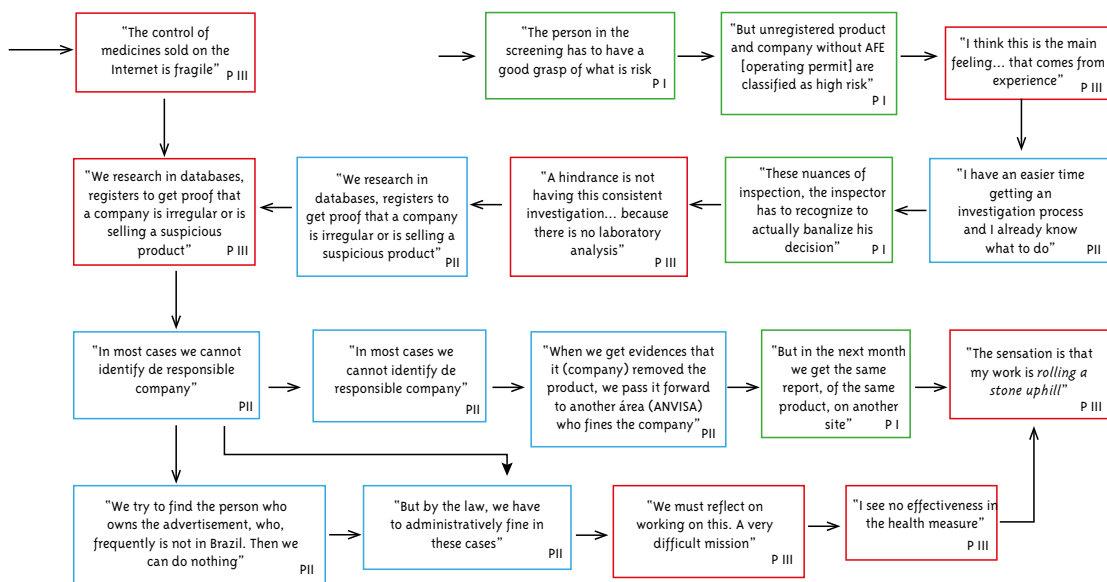
Scholars have proven that the pandemic has brought changes in the demand for and access to medicines and facilitated self-care, self-diagnosis, and self-medication behaviors among the world's population (Fittler et al., 2021). However, such behaviors, added to misinformation and the desire for quick results, can have serious consequences both for individuals—for example, adverse effects, ineffective treatment, use of SF/NR products—and for health systems—hospital admissions, increased expenses, and even death (Fittler et al., 2021; WHO, 2017).

“Feeling like you are rolling a stone uphill:” what choices are possible?

According to health standards (Brasil, 1977; 2009), the decision-making process at the operational level occurs when sanitary measures are adopted after screening, investigation, and verification of the sanitary infraction, imposing the need for a rapid response to mitigate and control risks to public health. This decision is materialized in measures of prohibition, seizure, and disablement of medicines considered irregular or illegal, as well as unregistered or falsified products, marketed and disseminated by companies without ANVISA's operating authorization (Brasil, 1977; 2009).

However, sanitary measures are not always effective, since the control of irregular medicines sold

Figure 2 – Ergodiological map on the process of inspection of irregular medicines on the internet



PI: Pole I (knowledge); PII: Pole II (action); PIII: Pole III (values)

Source: Prepared by the authors, 2022.

in the virtual environment is fragile (Figure 2). For professionals, this situation acquires the meaning of “rolling a stone uphill,” causing feelings of frustration and restlessness.

The discursive practices in Figure 2 show that professionals use effort, time, and dedication to intervene in risks and protect public health, but that, in actuality, few products have been effectively removed from the internet. The difficulty of identifying the responsible company or the hosting of websites outside the country; the realization that this is a worldwide problem, among others, reinforces the sense of doing something that has little effect on reality. Such situations can also be understood by the following statements:

We go crazy, because we feel like we're rolling a stone uphill, because they take down the site and create it on another domain. This is a worldwide thing, it's not just here. The world is having this problem of overseeing the internet. (IP07)

There's no penalty of offenders per se. I think that's why it becomes so recurrent. We order them to shut down websites, remove advertisements, and they

open other websites, they continue the same products. The "Product x", for example, is often sold as an abortifacient. (IP09)

I don't see that the measures I write change the dynamics of irregular advertising. (IP01)

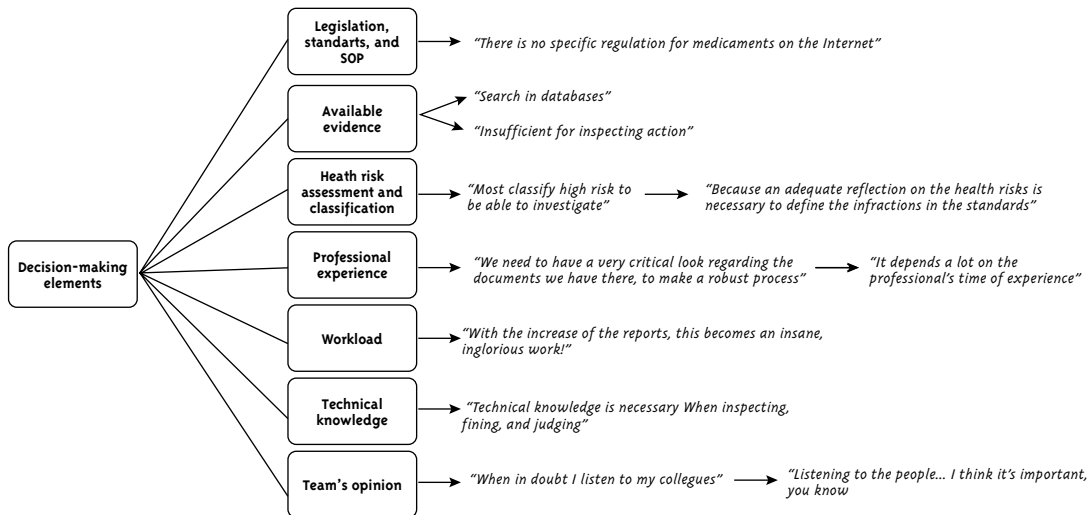
In the action of the police power, that is, in the investigation, decision, and justification for the determination of sanitary measures, professionals experience multiple situations that require reassessment—new judgments about procedures, choices, and interests—which materialize in renormalizations with the purpose of continuously seeking better results in the work performed (Holz; Bianco, 2014; Schwartz; Durrive, 2010).

In the analysis of the inspection work, the elements that support the professional's decision-making (Figures 2 and 3), according to discursive practices, are strongly based on the current legislation, standards, and standard operating procedures (SOP), also involving the available evidence and the assessment of the health risk, as

well as the technical knowledge, the workload, the professional experience, and the opinion of other members of the team.

Figure 3 – Dialogic map of the elements of decision-making by the professional in the inspection of irregular medicines on the internet

The WG debates showed that some difficult decisions must be made, with many rules and prescriptions, and they must be well grounded in legal norms, with the peculiar language of health law predominating. In the



Source: Prepared by the authors, 2022.

interviews, the perception stands out that some laws and resolutions are so outdated that they prevent advances in the inspection of medicines since they are essentially pragmatic, procedural, and restrict the possible alternatives for the professional's decision-making. Most of them date back to the 1970s, prescribing the obligation to investigate all suspected health violations, regardless of the risk assessment. Such laws and norms have not been updated to the point of keeping up with the changes in social relations and practices brought about by the technological revolution and the worldwide spread of the internet.

It is law 6437 of 1977 that has this requirement of opening a process for everything. That, for me, is a hindrance! I am aware of the propaganda inspection part, we have to open a dossier for everything that arrives from denunciations. (IP15)

Professionals are calling for changes in the regulatory framework and in the inspection model, arguing that just prohibiting the advertising and

e-commerce of medicines may not be enough and will not achieve the expected results. In addition, the current sanitary regulations do not meet the expectations of the market, and are quite restrictive to the professional performance of the sector, since only pharmacies and drugstores open to the public, authorized, and licensed, with a responsible pharmacist and site with the “.com.br” extension, can have the electronic commerce of regularized medicines (Brasil, 2009; Fagundes et al., 2012).

In the interviews, the importance of the educational nature of the inspection was addressed, however, the context of the internet has limits. Many sites are shut down at a given time and then reopened at other URLs, while others deliberately disregard the measures prohibiting the sale of the product:

There is the fine, in addition to companies being able to appeal several times, they end up not being fined, or perhaps it is an insignificant amount, given the company has already profited by making the infraction. I think that's why it becomes so recurrent. We shut down websites, we receive a

report of a product, we order the company to remove it immediately from the site. (IPo7)

A study on the illegal trade of medicines over the internet showed that many websites are not intimidated by regulations, laws, and their respective penalties, remaining in the market for a long time (Fagundes et al., 2012, p. 36).

With the pandemic, the workload progressively intensified, which seems to be due to the high number of complaints, added to the pressure to meet productivity targets, translated as “insane, inglorious work” by some interviewees. On this issue, Bianco and Lima (2009, p. 644) state that the act of working brings with it many contradictions and ambiguous feelings that can generate both personal satisfaction, when achieving pre-established goals and objectives, and dissatisfaction, caused by difficulties in meeting organizational requirements.

Regarding the evidence available for decision-making, the professionals reported that they do not always have sufficient information, or the procedural instruction is incomplete, with little data on the product or the irregular company. There have been reports that, in situations where the evidence is insufficient to assess the risks, the choice of the professional is to apply the precautionary principle to protect public health (Figure 3). These professionals apply their principles, values, and subjectivity at work, both individually and collectively, to manage the distance between what is prescribed to them and the demands of work situations (Trinquet, 2010).

The discursive practices reveal that most SF/NR medicines are classified as high risk, an alternative for an investigation dossier to be immediately opened, without archiving the process, so that, when identified, the company is immediately held responsible for the sanitary infraction committed, with ample defense guaranteed.

In the inspection environment, even remotely during the pandemic, the professionals emphasized the cooperation and trust in the work carried out. They mentioned meetings, case discussions, and exchange of knowledge and experiences in the application of legal norms, in addition to mutual help in the face of the difficulties faced during the period.

Frequently, “relatively pertinent collective entities” (RPCE) have been formed, characterized as temporary and invisible spaces, whose objective is to promote articulation and cooperation in the work environment, varying according to the pace and content of the activity. With the RPCE we can understand how the teams’ way of working is collectively processed, which goes beyond the individual and is materialized in networks of cooperation and collaboration for decision-making (Scherer et al., 2022; Schwartz; Durrive, 2010).

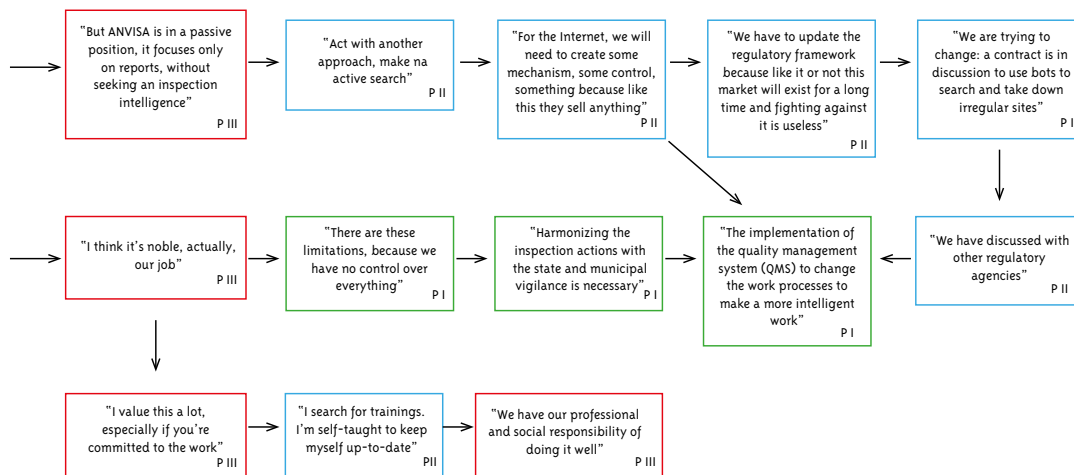
Professional experience and technical knowledge are elements that stand out in discursive practices for decision-making, revealing that professionals with more experience assume the management of the sector or the role of internal consultant for the discussion of more complex cases when deciding on an investigation. Inspection scripts and technical procedures are present in the work routine and are generally prepared and updated by more experienced professionals and validated by ANVISA’s quality management team.

“Acting with another approach, active search”: discursive practices for transforming the sanitary inspection of medicines

The professionals can propose changes in the work process, based on their reflections and experiences, in the discussion of legal norms, in the ability to perceive the dynamics of the organization and in the dialogue with other professionals (Figure 4), considering that they are transforming agents of the institution, but are also transformed by it throughout their trajectory (Schwartz; Durrive, 2010).

Although the work feels ineffective, some participants revealed commitment and pride in carrying out sanitary inspection, assuming values such as nobility and social responsibility when performing the activity, assuming the desire to “do the right thing” (Figure 4).

Figure 4 – Ergodiological map of discursive practices for the transformation of inspection of medicines on the internet



PI: Pole I (knowledge); PII: Pole II (action); PIII: Pole III (values)

Source: Prepared by the authors, 2022.

The current model of drug inspection is of the passive-reactive type and is criticized by professionals due to the lack of greater rationality or control mechanisms that bring more agility to the inspection activity. They argue that ANVISA needs to evolve the model of action in post-marketing and that professionals should “act with another approach” to work, proposing a proactive model, with strategies for active search for irregular medicines; and the development of technological tools (artificial intelligence with machine learning) that automatically take down links without the need to open an investigative process.

They also highlighted the importance of the quality management system (QMS) already in place, with harmonization of inspection actions within the scope of the SNVS and systematic evaluation of procedures, both internally and externally, considering the point of view of professionals. That is, to understand “the knowledge of experience and those codified in a cooperative way”; the interests of the market; and the concepts (norms and standards) of the SNVS, “so that new knowledge can be produced,

a solution to the conflict situation inherent to the regulatory arena” (Gamarra, 2014, p. 490).

In this way, they believe that they will be able to make decisions based on the best evidence, applying aspects of “intelligence” in inspection and prioritizing actions with criteria, to intervene in cases that have greater added value or the potential to harm a greater number of people, for example (Figure 4).

According to the participants’ reports, the transformation of the inspection process involves updating health legislation, establishing institutional partnerships, and fostering international cooperation. In this regard, WHO proposes strategies focused on prevention, detection, and response, with investment in the technical capacities of national regulatory authorities (NRAs), in the formation of networks of focal points and in the cooperation and exchange of information in a timely manner for the recall of harmful products in the global market (Aung; Liang; Mackey, 2015; WHO, 2017).

In this regard, the professionals revealed that training and constant updating, at least every six

months, are as important as professional experience, considering the variability and unpredictability of situations during the inspection activity.

Final considerations

This study showed specificities of the drug inspection process on the internet, identifying, with discursive practices, the elements that guide operational decision-making by professionals working in this sector, to protect public health.

The professional is always called upon to make choices and analyses to manage unpredictable situations in current contexts, as was the case with the COVID-19 pandemic. The discourses in the tripolar scheme revealed that the new routine in the life of the inspection professional and the increase in the volume of work caused concerns about the institutional capacity to understand the magnitude of the problem and transform the work process. We point out the need to review the laws and regulations that limit the discretionary power of ANVISA and of the inspection agent itself.

The discursive practices distributed in the triangle of the three poles reinforce the sense that the work process itself, as it is being carried out, has little impact on social reality, since few products are removed from the internet. The work overload is justified by the significant increase in complaints and notifications of unregistered and falsified medicines marketed electronically, posing serious risks to public health.

The proposals for transforming the process are based on strategies for prevention, detection and the ability to provide an effective response in the control of medicines sold on the internet. Different knowledge, both scientific and from professionals' experience, can better qualify the decision-making system in the sanitary inspection of medicines, making it more effective, assertive, and transparent, in addition to accelerating the control of risks to public health.

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Acknowledgments

To ANVISA for the authorization of leave for the development of the first author's doctoral research. This text represents solely and exclusively the opinion of the authors and does not represent ANVISA's institutional position.

Authors' contributions

Martins worked on the conception, data collection and analysis, and the final drafting of the article; Scherer participated in the conception and collaborated in the data analysis, writing and final revision of the article. Both authors approved the final version of the text.

Received: 03/01/2023

Approved: 22/03/2023