Drug health surveillance in the risk society

Mary Anne Fontenele Martins, Magda Duarte dos Anjos Scherer

Essay

Drug health surveillance in the risk society

A fiscalização sanitária de medicamentos na sociedade de risco

Mary Anne Fontenele Martins[a,b]
https://orcid.org/0000-0002-8391-7695
E-mail: maryannefmab@gmail.com

Magda Duarte dos Anjos Scherer[c,d]
http://orcid.org/0000-0002-1465-7949
E-mail: magscherer@hotmail.com

[a]Universidade de Brasília. Faculdade de Ciências da Saúde. Programa de Pós-Graduação em Saúde Coletiva. Brasília, DF, Brazil.

[b]Agência Nacional de Vigilância Sanitária. Brasília, DF, Brazil.

[c]Universidade de Brasília. Faculdade de Ciências da Saúde. Departamento de Saúde Coletiva. Brasília, DF, Brazil.

[d]Centre de Recherche sur le Travail et le Developpement (CRDT), Conservatoire des Arts et Metiers (CNAM), Paris, France.

Abstract

Drug health surveillance protects the health of the population by preventing substandard, falsified, or unregistered drugs from being consumed and causing harm. This essay discusses drug health surveillance in a context of continuous exposure of individuals to risks that directly interfere with the health-disease process. Based on reflections about health risk and risk society, associated with Canguilhem's philosophy of life and Schwartz's ergology, it argues for the need to understand human activity and work to act on risk. Possible challenges for health inspection action include: (1) conceptual review; (2) regulatory updating; (3) development of regulatory mechanisms and tools; and (4) expansion of technical and training capacity. To face them, the involvement and participation of the various actors in cooperation and collaboration spaces, as well as the construction of a permanent forum of discussion or technical/sectorial meetings, is considered promising. Studies that highlight the concrete work of supervision teams and that analyze human activity in the relationship between the prescribed and the real can help to understand the experience of dealing with risk, the adequacy of standards, training needs, among others.

Keywords: Postmarketing Drug Surveillance; Drug Control; Health Risk; Work.

Correspondence
Mary Anne Fontenele Martins
QE 12, Conj F, casa 44, Guará I, Brasília, DF, Brazil. CEP 71010-360.

DOI 10.1590/S0104-1290202200853en

Resumo

A fiscalização sanitária busca proteger a saúde da população impedindo que medicamentos fora do padrão, falsificados ou não registrados sejam consumidos e causem danos à saúde. Este ensaio objetiva contribuir para o debate acerca da fiscalização sanitária de medicamentos, num contexto de exposição contínua dos indivíduos a riscos que interferem no processo saúde-doença. Baseado nas reflexões sobre o risco sanitário e a sociedade de risco, associado à filosofia da vida de Canguilhem e à ergologia de Schwartz, discorre sobre a necessidade de se compreender a atividade humana e o trabalho para agir sobre o risco. Foram identificados possíveis desafios para a ação da fiscalização sanitária: (1) revisão conceitual; (2) atualização normativa; (3) desenvolvimento de mecanismos e ferramentas regulatórias; e (4) ampliação da capacidade técnica - formativa. Para enfrentá-los, considera-se um caminho promissor o envolvimento e a participação dos diversos atores nos espaços de cooperação e colaboração, bem como a construção de fórum permanente de debates ou de câmeras técnicas/setoriais. Estudos que dão visibilidade ao trabalho concreto das equipes de fiscalização sanitária e que analisam a atividade humana na relação entre o prescrito e o real podem ajudar a compreender a experiência de lidar com o risco, a adequação das normas, as necessidades de formação, entre outros.
Palavras-chave: Fiscalização Sanitária; Risco Sanitário; Medicamentos; Trabalho.

Introduction

Health surveillance is one of the State's functions, directed mainly at promoting and protecting health by acting on the risks that involve the production-consumption cycle of goods and services related to health, in addition to the technological innovations that are made available on the market daily. It is part of the Public Health area, historically representing a field of knowledge and practices carried out by a set of processes that seek the balance of forces between the demands of the State, market, and society. These processes are developed in the activities of regulation, standardization, control, monitoring, and inspection of drugs, food, health products, sanitizers, cosmetics, among other objects, in a context full of political and economic interests, tensions, conflicts, and social pressures (Costa, 2009; Silva; Costa; Lucchese, 2018).

As a State's function, the work of health surveillance is closely related to objects under sanitary control, comprising the division of labor into two dimensions. The first dimension, of technical-scientific nature, controls the risks of the product production-consumption chain, using available intervention technologies. The second dimension is in the political-administrative work organization, related to the State's modes of systemic organization, where the means of work are distributed and organized, that is, "the material instruments or technologies of intervention, the technical and legal norms and the knowledge mobilized to carry out the work of sanitary control" (Souza; Costa, 2009, p. 99).

According to Ulrich Beck (2011), the risk is the founding element of modernity, and lack of safety is a mark of contemporary society. For the author, industrial, scientific and technological development is inseparable from the production of risks in society, which are invisible most of the time; they escape mathematical calculations and standards of science and can extrapolate territorial and temporal boundaries (Beck, 2011)."We live in the so-called risk society, which is also the consumer society" (Costa, 2013, p. 23), characterized by permanent tactics of inducing the product consumption, including drugs and technological innovations, which add many benefits but health risks as

well. Controlling these risks poses challenges to regulatory systems and, given their complexity and globalization, countries are obliged to reformulate their processes, strategies, and practices to protect the health (Costa, 2013; Lucchese, 2008).

With the progressive increased use of the most varied health services by society; large-scale drug production; population aging; globalization; purchasing power and the offer of various therapies (such as weight loss treatments), people began to have greater freedom of choice, increasing the risks to which they are exposed, and therefore there must be a necessary and organized State intervention in these production-consumption social relationships for the population's benefit (Elias, 1994).

In the field of health surveillance, the risk is polysemic, complex and leads to intervention and control actions in each of the objects and/or processes under its responsibility (Costa, 2009, 2013). Drugs, for example, are therapeutic products with a high health risk, because, although they play a fundamental role in the treatment or diagnosis of diseases and conditions, they present risks inherent to the pharmacological action that can cause adverse reactions, and also risks arising from production processes, such as inferior quality of inputs, deviations from standards, manufacturing and handling failures or contamination – justification for drugs to be submitted to rigorous regulatory controls worldwide (Costa, 2013; Caon; Feiden; Santos, 2012).

Brazil, like other developing countries, still imports a large volume of drugs and pharmaceutical ingredients from different regions of the world, which makes the health risk greater and requires the strengthening of the national regulatory system to ensure safety, quality, and effectiveness of the product imported (Delphim; Kornis, 2018). The consumption of substandard, falsified (SF), and non-registered (NR) drugs is a worldwide health problem, causing the following effects: 1) serious health risk, as these products prolong illness and can even lead to death; 2) increased antimicrobial resistance and drug-resistant infections; 3) discredit upon health professionals and health systems; 4) greater distrust in the effectiveness of vaccines and medicines; 5) waste of families' and health systems' resources; 6) increase in the income of offenders and criminals, if "urgent measures are not taken to prevent, detect and respond" to the proliferation of these products around the world (WHO, 2017a, 2017b, p. 7).

In this scenario, the work of health surveillance aims to protect the population's health, preventing SF/NR products from reaching consumption and causing damage to health.The health surveillance inspection team acts in the context of disputes and interests, and they have to mediate, evaluate and intervene in the production-consumption cycle, which interact dialectically in two logics: that of the globalized market, directed towards profit and the accentuated consumption of products, and technologies; and that of contemporary society, which demands access to these products and services with quality, safety, and effectiveness, in order to satisfy their demands for health and well-being (Souza; Costa, 2010; Gamarra, 2014).

The performance of health surveillance in Brazil and the world is moving towards strengthening the postmarketing drug regulatory system, which makes inspection one of the main activities to be rebuilt, restructured with a new approach and different mechanisms, strategies and instruments of action for the proper management of current and potential risks, in order to "prevent or minimize damage to the community's health and the proper functioning of production-consumption relationships" (Costa 2009; Barbosa; Costa, 2010, p. 3364). Therefore, how to understand this wide-ranging activity, of great responsibility, in the complexity of contemporary society, called risk society?

This theoretical essay, based on authors who discuss health risk and the risk society, along with contributions from George Canguilhem's philosophy of life and Yves Schwartz's ergology, aims to contribute to the debate about the drug health surveillance, in a context of continuous exposure of individuals to risks that directly interfere in the health-disease process.

The risk society and the health risk

Contemporary society lives under constant and permanent risk. The term "risk" is quite comprehensive and polysemic. Used by several areas

of knowledge, it acquires different meanings, and can be analyzed in two major dimensions: one that describes the identity between the possible and the probable, which implies some form (or formula) of apprehending the regularity of phenomena; and the other that relates to the sphere of values, that is, risk presupposes putting into play something that is valued, risk as an "adventure" (Spink et al., 2008).

Risks have characteristics of dependence on scientific knowledge, which, however, is insufficient to define them precisely, since it is considered that dangers are never reducible to the simple statement and description of facts; besides, risk situations are often invisible, as effects of radioactivity on humans, for example. Thus, the risk is based on the dimension of uncertainties, provoking a distrust in relation to scientific knowledge, since the complexification of phenomena in postmodern society refutes every minute "**scientific truths**" that were previously believed, consummated, and bought by the media and, consequently, by the common citizen as "**absolute truths**" (Beck, 2011).

In a globalized society, risks go beyond individual realities and even territorial and temporal boundaries, in such a way that social development opens the possibility for the phenomena of unpredictability and risk imponderability and volatility. The progress of science brings advances, but also undesirable consequences, increasing vulnerabilities and immeasurable, depersonalized, and even desired risks in the positive dimension of life, which is considered an adventure. However, regardless of their dimension, category or conception, to the extent that risks affect "the collectivity, they are obligatorily objects of public management, both in the micro contexts of each city, state, nation, and in the macro context of the globalized society" (Spink et al., 2008, p. 2).

The more people's lives are threatened, the less those people are able to deal adequately with risks, tensions, and conflicts, being "dominated by the resulting fears, hopes and desires" (Elias, 1994, p. 60). The more the people in a given society are vulnerable to the feelings and fantasy of the miracle, such as the consumption of weight-loss drugs or immediate healing, the less they are able to deal with the dangers, uncertainties, and threats to which are exposed.

The right to freedom of choice is given to the individual; however, this freedom is only fully exercised if the choice is made consciously and responsibly. The right to freedom is denied when the person is induced to choose a certain suspected drug, when all the alternatives available on the market are not offered, or when all the information necessary for a free and conscious decision is not available.

The scientific and technological advancement of products and services makes the population aware of several products that promise true "**technological miracles**" or life-saving and well-being drugs, generating new human needs, never imagined before. Citizens are constantly driven to increased consumption of questionable products, in addition to being bombarded by advertisements that do not always present the necessary information for a conscious choice. Nevertheless, such products have great potential to cause harm, bringing to the debate issues related to quality, efficacy, health safety, biosafety, in addition to their rational use and consumption (Costa, 2009; Lucchese, 2008; WHO, 2017b).

In this context, as society does not have all the information necessary to choose whether or not to consume such a product, it places its "trust" in the State and transfers to it the responsibility to control the health risks to which they are exposed in the drug production-consumption chain. In turn, the State acts through health control and regulation institutions seeking to comply with its norms, in a permanent confrontation with the norms established by the various groups and individuals present in society, which are materialized in the relationship between the macro and the micro of human action.

Understanding human activity to act on the risk

Living in society requires rationality in all spheres of life, which is expressed in the normalization of technical means that will define how groups relate to social structures and to what comes to be considered a greater good, even if individuals are not aware of it (Canguilhem, 2014, p. 188).

Human beings' lives are a kind of anthropological dialectic between historical determinations and the history of their normative actions, their

acts of valuation and devaluation, always partly unpredictable (Schwartz, 2000). Norms come to frame what does not correspond to the requirement contained in it, "a norm, in anthropological experience, cannot be original. The norm only becomes a norm by making a norm, and this correction function arises from the very infraction" that will give rise to regulation (Canguilhem, 2014, p. 190).

The norm is not natural; it is value-laden, it is instituted in a human world inhabited by the ambivalences of the historical and cultural context. The norms crystallize as something "authorized," but also as the acquisition of collective experience, heritage, more as something of everyone than by constraints received in a heterogeneous way, and this situation creates fundamental ambiguity: norms are a kind of commensurability for all protagonists; however, individuals and groups make normative choices of fertility and very unequal degrees of universalization (Schwartz, 2000).

From the most micro-level of the social aspect to the most macro one, there are specific forms of previous norms, that is, norms that anticipate the action and compete with each other; the individual inserted in the groups, hierarchizes, makes choices, in a dispute of values. In this dynamic, norms will be apprehended by the human being as more or less imposed, external to themselves, or on the contrary, re-appropriated or transformed in the movement of re-singularization arising from the confrontation of the norm with what is demanded by the real (Schwartz, 2000).

The processes of re-singularization result from the fact that the way of life is unfaithful, and every human being, consciously or unconsciously, in order to live with health, seeks to be not only an actor but the author of their own history (Durrive, 2011).

The normative decision regarding a given standard can only be understood in the context of other standards (Canguilhem, 2014). Technical norms of sanitary control and regulation communicate with legal and economic norms; what is manufactured has to be consumed, and advertising can create needs by normalizing consumption. A virtual unit is created within a social organization full of bodies, information and decision systems, and so on (Canguilhem, 2014, p. 202), which seek to regulate life in society, including the control of health risks.

To act on risk, it is necessary to understand human activity and that living is a permanent debate about norms and values; understand that each being and each group has a heritage forged in their own experience, culture, etc., which will result in choices that can enter into conflict with hetero-determined norms. "Taking risks" can be a way of life to live with health, reiterating the idea of "desirable risks", of "risk as an adventure" (Spink et al., 2008, p. 3).

From this perspective, given the necessary State intervention in the production-consumption social relationships, ergology (Schwartz, 2000), a multidisciplinary approach to the analysis of work situations, helps understand the possibilities of health surveillance as part of human activity.

Understanding the work to act on the risk

Ergology is a multidisciplinary approach that seeks to produce knowledge and intervene in work situations from the experience and point of view of those who carry it out (Schwartz, 2000).

In its anthropological dimension, ergology conceives the human being as a being that interacts in its social environment and that treats norms in the sense of updating and personalizing them, since every living being carries in themselves a singularity in doing and in knowing how to do.

The work activity is understood as the management, carried out by a "body-self," of the distance between the previous norms and what is actually performed, in a permanent dispute of norms and values that result in choices. Activity has an abstract sense of inner activity, resulting from what happens in the mind and body of the person at work, in dialogue with themselves, with their environment, and with others (Schwartz, 2016).

The "body-self", the being of the activity, is an "enigmatic entity," body and soul, which carries a genetic, cultural, psychic, political heritage, encompassing all the dimensions of an individual who acts in the dramatic use of the self. The dramatic use of the self is the movement between the prescribed norm, the variations of the environment, and what it demands from the "body-self," which is faced with the unknown, the unforeseen, having to react and find

solutions in the singularity of situations, triggering re-normalizations (Schwartz, 2000).

According to Schwartz (2016), re-normalizations happen due to the insufficiency of what is prescribed to guide human action in the face of the unusual, but also because adhering strictly to the norm is to renounce the development of human capabilities, such as intelligence and creativity, that is, it becomes an attack on life.

Values are present in every moment of human activity. The workers in their actions are confronted by several requirements of the prescribed norms, and, sometimes, these norms can conflict with their personal values, leading to a constant conflict. In today's societies, individuals move between mercantile values, which are quantifiable or scalable; and non-scalable values, referring to the common good and health (Gamarra, 2014).

Several areas of knowledge, including health surveillance, think about and work on risk in a measurable and standardized way. However, the work of health surveillance is limited to what can be controlled at different levels of the production chain, making it impossible to control all risks or totally avoid damage to health (Castiel, 2005).

Acting in advance on health risk presupposes knowing the nature of the values present in contemporary society and intervening in real and potential risk factors, preventing or reducing damage, guided by current health safety standards for health protection (Barbosa; Costa, 2010).

The work of drug health surveillance

Health surveillance assesses compliance at the stages of the drug production chain; examines compliance with established standards, observing whether the company meets the demanded requirements and whether it has the authorization to manufacture or market drugs, or whether a product meets the identity and quality standards and presents the same specifications approved in the registration. It also investigates suspected fraud, illegal trade or technical failures in the production process, which can cause harm to the population and economic losses to countries (Chagas; Villela, 2014; WHO, 2017b).

Health surveillance aims to detect sanitary infractions, apply sanctions, and withdraw from the market irregular and ineffective drugs and those which are harmful to human health. Its scope of action includes drugs with some quality deviation (changes in appearance, color, odor, flavor, number of pills in the package, volume or presence of a foreign body), suspected of being unregistered, manufactured by companies without operation authorization, falsified or that are the result of other irregular practices (Costa, 2009; Caon; Feiden; Santos, 2012; WHO, 2017a, 2017b).

Nevertheless, it is observed that this action is reactive, as it starts only after receiving a complaint from consumers or notification from hospitals, clinics, health units, health professionals, and even drug manufacturers, as in the case of counterfeit drugs or voluntary recall of drugs with manufacturing issues.

The previous norms that guide the work of the drug health surveillance in Brazil comprise a set of laws, decrees, and federal norms with a positivist and pragmatic character, composing the legal framework of health surveillance, still in force. The main related legal norms are: Law No. 5,991/73 (Brasil, 1973) focused on the commercialization of pharmaceutical and similar products, and Law No. 6,437/77 (Brasil, 1977), which deals with sanitary violations and the rites of the administrative-sanitary process. It is noteworthy that the second law distinguishes the health surveillance worker and prevents them from being connected to the regulated sector due to the role of the State agent, giving them public faith to their acts and subjecting them to administrative, civil, and criminal sanctions in case of possible deviations in their actions and decision making (Costa; Fernandes; Pimenta, 2008).

The work of health surveillance has an ethical aspect "that goes beyond the individual scope and gains a collective dimension, compatible with the meaning of social responsibility of work in this area" (Souza; Costa, 2010, p. 3338). Health surveillance workers' ethical accountability is materialized in the supremacy of the public interest that overcomes the political and economic pressures of the productive sector (Souza; Costa, 2009).

There are also international regulations and agreements that support risk management and

organize the mechanisms and strategies to respond to counterfeiting and illicit practices; however, they do not cover all work situations currently encountered by the inspector when performing their activity (Costa; Fernandes; Pimenta, 2008; Nogueira; Vecina Neto, 2011).

Besides, the previous norms are also in the technical regulations, in the resolutions, and in the legal instruments that guide the work of the surveillance, in addition to the scripts that seek to standardize it and reinforce the notary, procedural and restrictive dimension, so that the worker is able to intervene directly in situations of non-compliance with the norms by companies and imminent risks to the population's health (Sales Neto et al., 2018; Souza; Costa, 2010).

The instruments or means of work for the sanitary control of products become social constructions, shaped by inspection actions, but which suffer variations according to political, economic, and social changes in the face of such a globalized world (Delphim; Kornis, 2018; Souza; Costa, 2009).

Health surveillance works similarly to an "expert system," defined by Giddens (1991) as a system of technical excellence or professional competence that organizes the large areas of material and social environments. In this sense, the notion of safety encompasses the situation in which one seeks to neutralize or minimize hazards, and it is linked to the idea of protecting health surveillance. "This is because it would incorporate the logic of acceptable risk established and monitored by a risk management system and the trust placed in an expert system," that is, health surveillance (Barbosa; Costa, 2010, p. 3363).

Thus, the enigmatic character of human activity is evident, always in the clash between norms and the action that the real requires, "relatively predictable work situations and at the same time new and unprecedented" (Scherer; Pires; Schwartz, 2009, p. 722), since all human activity has potential for social transformation. In any situation that requires the performance of the health surveillance inspector, there will be a need to use their knowledge for decision making, permeated by their values, experiences, singularities, and their life history, corroborating so that there are norm readjustments, as these are limited and unable to predict all real work situations (Gamarra, 2014; Schwartz, 2000).

Thinking about inspection from an ergology perspective implies understanding that scientific knowledge, transformed into codes and standards, and those constructed through practice and experience, from the worker's perspective, complement each other to explain the actual work of the activity and its effects on reality (Gamarra, 2014).

Thus, knowledge of the dimensions of risks and health safety that are articulated with notions and concepts inherent to the sphere of health protection, ethical commitment, and public responsibility is fundamental for the work of health surveillance. As scientific knowledge is insufficient to calculate or estimate all real or potential risks, it is possible to apply the precautionary principle, based on work experience, to deal with uncertainties in the manufacturing and marketing of drugs, aiming to increase the benefits and reduce or minimize the risks inherent to their production cycle (Barbosa; Costa, 2010; Chagas; Villela, 2014).

The activity of health surveillance, given its nature and peculiarity, can be analyzed as a dialectic between the "micro" and the "macro," the local and the global, "since it permeates the conscious and the unconscious, the verbal and the non-verbal, the biological and the cultural, the robotic and the values" (Gamarra, 2014, p. 484). It is an environment permeated by consumer relations and uncertainties (risks), a confrontation between previous norms and re-normalizations carried out at all times by inspectors. To act, they have the power of administrative police intrinsic to their activity, which "allows them to limit the exercise of individual rights in the public interest" (Costa, 2013, p. 26). In the name of protecting the population's health and space for State intervention, the work of health surveillance can take on a preventive or repressive character, such as the imposition of fines, infraction notices, interdiction of establishments, destruction of products, suspension of manufacture and marketing, product seizure, among others (Costa, 2013; Chagas; Villela, 2014; Silva; Costa; Lucchese, 2018).

Working is not simply to apply, to carry out what is prescribed; in the activity, workers partially

apply norms to themselves, self-legislate and recreate knowledge, values, and new norms (Schwartz, 2000; Scherer; Pires; Schwartz, 2009) as it has been demonstrated by several studies and that could be applied to the analysis of the health surveillance process.

A recent study on the work of health surveillance shows that for workers "the bright side is the feeling of accomplishment, of knowing that actions are for the population's good, that everything they suffer is worth it" when they realize that the population feels safe about the regulated services and products (Oliveira, 2016, p. 29). However, the difficulties lie in internal and external pressures, work overload, exposure to risks, lack of understanding, and devaluation of their work. The anguish, discouragement, stress, efforts, and suffering reported in the research acquire meaning when their work is recognized and provides a reason for the professional to continue their trajectory (Oliveira, 2016, p. 29).

According to Schwartz (2016, p. 93), "in a world saturated with antecedent norms in all actions, as the human world is, the ergology approach conceives the activity as a web of permanent renegotiations of these norms" in the different work situations. Competent action is permeated mainly by the values that circulate and is not restricted to an externally determined way but is also an experience of oneself, a relationship with one's own history.

To understand and transform a work process, the rationality of technical analysis of quality control or good manufacturing practices is not enough; it is also essential to consider the real activity of the worker, the knowledge and experiences arising from their choices in the management of their decision-making process, as well as collective and individual values (Holz; Bianco, 2014).

The nature of the activity in the drug health surveillance incorporates complex and specific functions to the professional's daily life, some of which are characterized as intersectoral and multidisciplinary. For the exercise of inspection activity, it´s essential the articulation and integration of knowledge and practices on health risks arising from the use or consumption of drugs. Other functions greatly contradict economic, corporate, and political interests by verifying compliance with health standards, determining the withdrawal of the product from the market, exercising the power of the State. There is also the function of acting in the diversity and dynamics of technological innovations for health promotion, as it understands that the organization of work encompasses the principles of (inter)complementarity and interdependence of processes, instruments, and means of work (Chagas; Villela, 2014; Souza; Costa, 2009; 2010).

Final considerations

In view of the above, possible challenges for the drug health surveillance in the risk society are identified in four dimensions: (1) conceptual review; (2) regulatory updating; (3) development of regulatory mechanisms and tools; and (4) expansion of technical and training capacity. In the ergology sense, these challenges are situated in the field of human activity, between the two poles of living: on the one hand, non-adherence, which, according to Durrive (2011, p. 52), "is the distance that the human spirit is able to take in relation to what happens" to conceptualize and, on the other hand, adherence, linked to social life, to work experience(Schwartz, 2000).

In the first dimension, one deals with the possibility of a new structuring concept of health risk suited to the uniqueness of the inspection activity and to changes in relationships and lifestyles in the risk society. According to Barbosa and Costa (2010, p. 3368), "the reflection on health risks is the starting point for understanding the new health crises," as well as the variability of the notion of health safety and the perception of risk for society. It would also consist of reviewing traditional control instruments; in the approach to managing global, current, and potential risks; in the assessment of risk factors and prioritization of the most critical ones, with interdisciplinary work and articulated with other areas that also deal with health risks (Souza; Costa, 2010; Chagas; Villela, 2014; Silva; Costa; Lucchese, 2018).

The second dimension is related to updating the regulatory framework that underpins health intervention in the market and the norms and

prescriptions that guide and subsidize the inspector's decisions. Throughout history, inspection work has become a legalistic, bureaucratic, and disciplining action in the drug production-consumption cycle, (Souza; Costa, 2010, p.3335) bringing, therefore, the challenge of transforming work through norms appropriate to the social reality, with flexibility and redirection of regulatory instruments and practices for new action in the face of unprecedented and timely situations in the risk society (Silva; Costa; Lucchese, 2018; Barbosa; Costa, 2010).

The third dimension involves the development of information management mechanisms and tools, synthesis of evidence, search for signs in social networks, encouraging notifications from health professionals, with a view to shaping a proactive regulatory action that seeks to understand the context and anticipates the movements of contemporary society, given globalization and frequent changes in the social relations between drug production and consumption (WHO, 2017b; Barbosa; Costa, 2010).

The World Health Organization (WHO) supports the strengthening of national regulatory systems and the integration of international networks to exchange information on SF/NR drugs on the market, cooperating with regulatory agencies to implement prevention, detection, and response strategies, in addition to develop technical capabilities and skills necessary for effective control of medical devices on the market (WHO, 2017a, 2017b).

One of the possibilities would be the development of a drug traceability mechanism, whose purpose would be to guarantee the authenticity and legal origin of the product, avoiding deviations in the production chain and allowing a faster action by the inspection team (for example, in the detection and seizure of SF/NR drugs on the market) (Nogueira; Vecina Neto, 2011; WHO, 2017b).

It is noteworthy to carry out their work, the inspectors are required to constantly update their technical-scientific knowledge, in order to accompany the technological development of the pharmaceutical sector. The expansion of technical-training capacity could go beyond the sphere of conventional disciplines that build the knowledge of health surveillance (Sales Neto et al., 2018; Costa, 2009, 2013). Seeking innovation in the training processes implies bringing the knowledge and experience of those who carry out the inspection, considering that different types of knowledge coexist and are distributed in a non-linear, non-disciplinary way, anchored in the stories and situations experienced by each professional (Scherer; Pires; Schwartz, 2009).

It is considered a promising way to face this set of challenges; besides, the involvement and participation of the different actors (health professionals, productive sector and civil society) in spaces of cooperation and collaboration could constitute a fifth challenge, as well as the construction of a permanent forum for debates or technical/sectoral chambers. Studies that give visibility to the concrete work of health surveillance teams and that analyze human activity in the relationship between prescribed and real work, between noncompliance and adherence can help understand the experience of dealing with risk, the adequacy of norms, and training needs, among others.

References

BARBOSA, A. O.; COSTA, E. A. Os sentidos de segurança sanitária no discurso da Agência Nacional de Vigilância Sanitária. *Ciência & Saúde Coletiva*, Rio de Janeiro, v. 15, n. suppl 3, p. 3361-3370, 2010. DOI: 10.1590/S1413-81232010000900011

BECK, U. *Sociedade de Risco*: rumo a uma outra Modernidade. 2. ed. São Paulo: Editora 34, 2011.

BRASIL. Lei nº 5.991, de 17 de dezembro de 1973. Dispõe sobre o controle sanitário do comércio de drogas, medicamentos, insumos farmacêuticos e correlatos, e dá outras providências. *Diário Oficial da União*, Brasília, DF, 17 dez. 1973. Disponível em: <http://www.planalto.gov.br/ccivil_03/leis/l5991.htm>. Acesso em: 5 abr. 2019.

BRASIL. Lei nº 6.437, de 20 de agosto de 1977. Configura infrações à legislação sanitária federal, estabelece as sanções respectivas, e dá outras providências. *Diário Oficial da União*, Brasília, DF, 20 ago. 1977. Disponível em: <http://www.

planalto.gov.br/ccivil_03/leis/l6437.htm>. Acesso em: 12 mai. 2018.

CANGUILHEM, G. *O Normal e o Patológico*. 7. ed. Rio de Janeiro: Forense Universitária, 2014.

CAON, S.; FEIDEN, I. R.; DOS SANTOS, M. A. Desvio de qualidade de medicamentos em ambiente hospitalar: Identificação e avaliação das ocorrências. *Revista Brasileira de Farmácia Hospitalar e Serviços de Saúde*, São Paulo, v. 3, n. 1, p. 23-26, 2012. Disponível em: <http://www.sbrafh.org.br/v1/public/artigos/201205030105BR.pdf>. Acesso em: 21 mar. 2022.

CASTIEL, L. D. O estresse na pesquisa epidemiológica: o desgaste dos modelos de explicação coletiva do processo saúde-doença. *Physis: Revista de Saúde Coletiva*, Rio de Janeiro, v. 15, n. suppl., p. 103-120, 2005. DOI: 10.1590/S0103-73312005000300006

CHAGAS, M. F.; VILLELA, W. V. Vigilância Sanitária e promoção de saúde: apontamentos para além da regulação e controle. *Vigilância Sanitária em Debate*, Rio de Janeiro, v. 2, n. 3, p. 30-36, 2014. DOI: 10.3395/vd.v2n3.178

COSTA, E. A. Regulação e vigilância sanitária para a proteção da saúde. In: VIEIRA, F. P.; REDIGUIERI, C. F. (org.) *A Regulação de Medicamentos no Brasil*. Porto Alegre: Artmed, 2013. p. 21-37.

COSTA, E. A. (org). *Vigilância Sanitária*: temas para debate. Salvador: EDUFBA, 2009.

COSTA, E. A.; FERNANDES, T. M.; PIMENTA, T. S. A vigilância sanitária nas políticas de saúde no Brasil e a construção da identidade de seus trabalhadores (1976-1999). *Ciência & Saúde Coletiva*, Rio de Janeiro, v. 13, n. 3, p. 995-1004, 2008. DOI: 10.1590/S1413-81232008000300021

DELPHIM, C. T. S.; KORNIS, G. E. M. Outro olhar sobre a vigilância sanitária de produtos no Brasil: a legislação de controle sanitário das importações em foco. *Physis: Revista de Saúde Coletiva*, Rio de Janeiro, v. 28, n. 4, p. 1-21, 2018. DOI: 10.1590/S0103-73312018280418

DURRIVE, L. A atividade humana, simultaneamente intelectual e vital: esclarecimentos complementares de Pierre Pastré e Yves Schwartz. *Trabalho, Educação e Saúde*, Rio de Janeiro, v. 9, n. suppl 1, p. 47-67, 2011. DOI: 10.1590/S1981-77462011000400003

ELIAS, N. *A Sociedade dos indivíduos*. Rio de Janeiro: Zahar, 1994.

GAMARRA, T. P. DAS N. Contribuições epistemológicas da ergologia para a regulação em saúde. *Trabalho, Educação e Saúde*, Rio de Janeiro, v. 12, n. 3, p. 483-498, dez. 2014. DOI: 10.1590/1981-7746-sip00001

GIDDENS, A. *As consequencias da modernidade*. 5. ed. São Paulo: Editora UNESP, 1991.

HOLZ, E. B.; BIANCO, M. F. Ergologia: uma abordagem possível para os estudos organizacionais sobre trabalho. *Cadernos EBAPE.BR*, Rio de Janeiro, v. 12, n. spe, p. 494-512, 2014. Disponível em: < https://www.scielo.br/j/cebape/a/vf6KV9HSD3y4bmQyY6hVSvN/?format=pdf&lang=pt>. Acesso em: 21 mar. 2020.

LUCCHESE, G. Globalização e Regulação Sanitária: os rumos da vigilância sanitária no Brasil. Brasília: editora Anvisa. 2008.

NOGUEIRA, E.; VECINA NETO, G. Falsificação de medicamentos e a lei n. 11.903/09: aspectos legais e principais implicações. *Revista de Direito Sanitário*, São Paulo, v. 12, n. 2, p. 112-139, 2011. DOI: 10.11606/issn.2316-9044.v12i2p112-139

OLIVEIRA, S. T. A. DE. *O mundo (in)visível dos trabalhadores da vigilância sanitária da região da 8ª Coordenadoria Regional de Saúde*. 2016. Trabalho de Conclusão (Especialização em Saúde do Trabalhador) – Universidade de Santa Cruz do Sul, Santa Cruz do Sul, 2016. Disponível em: http://hdl.handle.net/11624/1286. Acesso em: 21 mar. 2020.

SALES NETO, M. R. et al. Vigilância Sanitária: a necessidade de reorientar o trabalho e a qualificação em um município. *Vigilância Sanitária em Debate*, Rio de Janeiro, v. 6, n. 4, p. 56-64, 2018. DOI: 10.22239/2317-269X.01176

SCHERER, M. D. A.; PIRES, D.; SCHWARTZ, Y. Trabalho coletivo: um desafio para a gestão em saúde. *Revista de Saúde Pública*, São Paulo, v.

43, n. 4, p. 721-725, 2009. DOI: 10.1590/S0034-89102009000400020

SCHWARTZ, Y. Abordagem ergológica e necessidade de interfaces pluridisciplinares. *ReVEL*, São Leopoldo, edição especial n. 11, p. 93-104, 2016. Disponível em: <http://www.revel.inf.br/files/2e5e27e69e52df1113fd2b52d2d99f39.pdf>. Acesso em: 21 mar. 2020.

SCHWARTZ, Y. *Le paradigme ergologique ou un métier de philosophe*. Toulosse: Octares, 2000.

SILVA, J. A. A. ; COSTA, E. A.; LUCCHESE, G. SUS 30 anos: Vigilância Sanitária. *Ciência & Saúde Coletiva*, Rio de Janeiro, v. 23, n. 6, p. 1953-1961, 2018. DOI: 10.1590/1413-812320182360.04972018

SOUZA, G. S.; COSTA, E. A. Considerações teóricas e conceituais acerca do trabalho em vigilância sanitária, campo específico do trabalho em saúde. *Ciência & Saúde Coletiva*, Rio de Janeiro, v. 15, n. suppl 3, p. 3329-3340, 2010. DOI: 10.1590/S1413-81232010000900008

SOUZA, G. S.; COSTA, E. A. Trabalho em vigilância sanitária conceitos teóricos para a reflexão sobre as práticas. In: COSTA, E. (org.). *Vigilância Sanitária*: temas para debate. Salvador: EDUFBA, 2009. p. 83-106.

SPINK, M. J. P. et al. Usos do glossário do risco em revistas: contrastando "tempo" e "públicos". *Psicologia: Reflexão e Crítica*, v. 21, n. 1, p. 1-10, 2008. Disponível em: <https://www.scielo.br/j/prc/a/xKLbKHR7BRrM6JGdKxSyW6v/?lang=pt&format=pdf>. Acesso em: 21 mar. 2020.

WHO - WORLD HEALTH ORGANIZATION. *A study on the public health and socioeconomic impact of substandard and falsified medical products*. Geneva: World Health Organization, 2017a.

WHO - WORLD HEALTH ORGANIZATION. *Global Surveillance and Monitoring System for substandard and falsified medical products*. Geneva: World Health Organization, 2017b.

Authors' contributions

Martins and Scherer participated in all stages of elaboration and review of the essay, approving the final version.

Received: 08/09/2021
Resubmitted: 03/02/2021; 08/09/2021
Approved 12/17/2021