DOI: 10.1590/1413-81232018236.04972018

Unified health system 30th birthday: health surveillance

José Agenor Alvares da Silva [1]
Ediná Alves Costa [2]
Geraldo Lucchese [3]

Abstract *This article presents an overview of the nature, functions and history of health surveillance in the structure of the Brazilian Unified Health System (SUS). Bibliographical sources and official documents were used, with references from the careers of the authors, who have worked in health surveillance. Extremely serious adverse events in the mid-1990s gave political visibility to the fragility of Brazilian health surveillance, and were reflected in serious problems for the SUS. The creation of Anvisa and the SNVS surveillance system, and the support for bodies in individual states and municipalities, resulted in improvement in the structure and functioning of health surveillance, and improved recognition of the area as an emerging theme in research and education in public health. Several problems hamper the effective structuring of the SNVS. A change in the conception/design of health promotion is postulated, in which the large corporations, whose activities have strong connections with risk factors related to the current epidemic of chronic diseases, would be given a social responsibility. A set of challenges for better structuring of health surveillance in the SUS is also put forward.*

Key words *Health surveillance, Health risks, Health regulation, Health promotion and protection*

[1] Escola Fiocruz de Governo, Fiocruz. Av. L3 Norte s/n, Campus Universitário Darcy Ribeiro Gleba A. 70904-130 Brasília DF Brasil. jose.agenor@fiocruz.br
[2] Instituto de Saúde Coletiva, Universidade Federal da Bahia. Salvador BA Brasil.
[3] Pesquisador Voluntário, Departamento de Saúde Coletiva, Universidade de Brasília. Brasília DF Brasil.

Introduction

Brazil has its own specific expression for health surveillance – 'health vigilance' –but their actions are of a universal practice. According to Rosen[1], in all eras of history there have been interventions by the powers of authority in practices of cures, medication, food, water, and the environment.

Health Surveillance (HS) is an institutional space, and a historical reality, and is part of Public Health, inasmuch as it is a field of knowledge and a context of practices. Its duty is to take strategic action in relation to the health system, and create and effect regulation of the activities in the cycle of production and consumption of goods and services of interest to health, in both the private and public sphere. By its dynamics is linked to scientific and technological development, and political processes that involve the State, the market and companies on a both domestic and international level[2,3].

In Brazil, many things are under Health Surveillance: Food, medication, biological products – vaccines, hemoderivatives, organs and tissues for transplants; medical-hospital products, dental and laboratory products, orthoses and prostheses; sanitizing products, hygiene, perfume and cosmetic products, health and health-related services, and health control of ports, airports and borders. New powers have been included with the creation of Anvisa, such as consent to patents for drugs, and health control of tobacco products[4].

Any product, substance, process or service directly or indirectly related to health can be the subject of intervention[5], and this surveillance calls for knowledge from many different specialized disciplines of the area of health, and also others, such as Law, which are connected in an organized context of technical and political practices, of a multi-professional and inter-institutional nature, all dealing with protection of health.

The objective of HS is to eliminate, reduce and prevent risks to health that are inherent to the production and use of products and services of interest to the health or the conditions of its environments. To act, it has a police power, of an administrative nature, which enables it to limit the exercise of individual rights, to the benefit of the public interest[6].

With this apparatus of knowledge, functions and instruments, HS acts mainly through regulations on granting of health licenses for production and sale of goods and services; registry of products for manufacture and consumption; certification of good production practices; monitoring of quality of products and services; inspection of compliance with rules; communication and education on risks; and surveillance of adverse events related to the goods/assets.

Attention is drawn to the importance of this component of the health system, the actions of which are essentially preventive. As Lucchese emphasizes[7], health surveillance of the Brazilian Unified Health System (SUS) is a privileged space of intervention by the State, which can act to increase the quality of products and services and adapt the productive segments of interest to health and the environment to social demands in health and needs of the health system.

The purpose of this article is to set out an overview of the nature and functions of HS and its history in the shaping of SUS, taking into account both the creation of Anvisa – Brazil's National Health Surveillance Agency – and its National Health Surveillance System (SNVS) as important points of inflection. Bibliographical sources and official documents, were used with addition of the experience and career of the authors, who have worked in health surveillance bodies and also have had professional experience as researchers, teachers or operators of public policies in health.

Health surveillance: Prevention, protection and promotion of health

The health intervention strategy – prevention, protection and promotion – deals with the process of health and illness and the question of risks. In relation to the broadness of the discussion on these strategies, a short summary description of their dimensions within HS is given.

Preventive actions are defined as interventions designed to avoid specific illnesses happening, reducing their occurrence and prevalence. It is grounded on epidemiology, in which the concept of risk corresponds to the probability of an event of occurring, in a period of observation, in a population exposed to a given risk factor, and is always collective[8]. This concept of risk is fundamental, but insufficient for the area of HS. The greater part of the actions are directed to protection and defense of health, having risk as a possibility[3], due to the great difficulty of carrying out probability calculations.

Protection of health is grounded on a structural concept of risk as possibility[9] of occurrence of events that will be able to cause damage to health – without necessarily being possible to de-

fine what the event is, and/or whether one will occur. From this concept of risk as a possibility there is derived comes the notion of potential risk, which is an operative concept for HS, since the essentially preventive nature of its actions will activate many interventions in view of the possibility that something under surveillance might cause damage to health directly or indirectly[3,10].

Promotion of health is more widely defined: it is oriented to improvement of the state of well-being, quality of life of the group or community, and seeks to identify and confront the macro-determinants of the health-illness process and turn them towars health[11]. Health surveillance actions also promote health, by acting on goods, services and environment to improve their quality, and also on diffuse risks, present and potential, that could directly or indirectly cause damage to individual or collective health; and by regulating the advertising of products, practices and services that might be damaging to health and to the environment. These interventions include community actions in defense of health, which help to strengthen individual and public capacities to deal with the multiple and diverse factors that influence health.

The context in the creation of Anvisa

With the development of the forces of production, the scope of HS actions was widened, to regulate, for example: the risks related to work; the transport of cargo and people – due to the risks of dissemination of carriers and pathogenic agents; medical-pharmaceutical research; advertising of interest to health; activities in mass events; and increasingly, risks and surveillance of adverse events related to products and technologies used in health.

At the end of the 1990s, Brazil had already experienced many negative events related to the area of HS activity, and these received great attention in local and international media. Falsification of medications became worsend from 1996 to 1998; the Health Ministry documented 172 cases, including very widely consumed drugs such as Androcur® (cyprosterone acetate), Epivir® (lamivudine) and Invirase® (saquinavir)[12]. Thefts of cargoes of drugs, sale of illegal medications (without registry in Brazil, or smuggled) and drugs with low quality or beyond their expiration date, made up a picture that caused great concern and uncertainty with drugs in general in the country.

The radioactive tragedy in Goiânia, in the State of Goiás (GO), in 1987, due to a cesium ampoule previously used by a radiotherapy service being abandoned; the deaths of elderly people at the Santa Genoveva clinic in 1996 in Rio de Janeiro (RJ State); the deaths of 71 patients in two hemodialysis clinics in Caruaru (PE State) in 1996, due to contamination of the water by algae; deaths of 85% of newborn babies in the N. Senhora de Nazaré Children's Hospital in Boa Vista (RR State); 82 reports of problems with the use of Ringer's lactate solution, with 32 deaths; deaths of patients in private hospital networks in Recife (PE) in 1997, thromboembolisms caused by contamination of serum from the Endomed® laboratory, and the case of the 'flour pill' in 1998 related to the Microvlar® contraceptive pill of Schering do Brasil, mainly in São Paulo, among other states – all these had a deep effect on public health and expressed the fragility of health regulation at the time[13]. The situation was much the same in the states and municipalities, with very limited structure, insufficient to carry out the HS mission specified in the SUS legislation. The situation created many risks to health and was even a hindrance to the productive sector, due to the uncertainty and delay in institutional action by authorities.

In this context an overall proposal to reform the state apparatus and reconfigure the model of the State as provider of goods and services, in favor of the model of the state as regulator, was put into effect. In the government's logic, the expected outcome would be evolution from the current bureaucratic model to a management-led model, with focus on control of results and quality care for the citizen[14]. Thus regulatory agencies were created for activities in areas of operation of the State that were privatized, and two agencies created in the social area – *Anvisa* and the *National Health Agency* (ANS), to regulate supplementary care.

Initially, the creation of Anvisa caused concerns that a separate agency might threaten the unity of SUS[15], and that the agency model might would bring HS too close to the process of privatization and activities which the State was at that time developing. But Law 9782/1999 incorporated the Agency into the constitutional rules and structure of SUS.

SNVS: Anvisa and the other federal-structured entities

Law 9782/1999 formalized SNVS but effectively created a gap in relation to configuration, organization, principles and directives/guide-

lines. This absence, which persists today, indicates the reality of a system that is fragmented, without direction, and with a fragile structure in cooperation corrections and responsibility and of relative efficacy.

On the other hand, the creation of Anvisa is seen as a "watershed" in the structuring of HS in Brazil. It incorporated the functions of the previous ministerial department and new functions, that give it features more in line with the scope of the present needs of health regulation in the domestic and international context.

One change was in the financing of SNVS: The budget of the Health Surveillance Secretariat (of the Ministry of Health) in 1998 was ridiculously small, and simply hindered the execution of the main activities of health Surveillance[16]; with Anvisa, this no longer prevented compliance with its duties in its own direct activity or support to the other entities. The relationship of the federal entity with the sub-national entities now included a regulated transfer of funds to the state and municipal HS bodies for them also to structure themselves, in accordance with the realities and the decentralization policy of SUS[17]. However, the low scale of these transfers did allow an appropriate structure concerning the mission of SNVS[18].

In spite of the achieved progress, the relationship with the state and municipal managers suffers from the centralizing stance of Anvisa, which does little to help decentralization take effect. It does not recognize, in regulations, technical and legal attributions of these levels in certain work processes. To date, there has been no political decision to consolidate the SNVS in the environment of the SUS. If, on the one hand, this system has been laid out in terms of rules, on the other, it suffers what might be called incomplete restructuring, because only the federal component has been structurally reformed[19].

The systemic nature of SNVS, made up of parts that politically operate the SUS, confirms the prerequisite that protection of public health against health risks which have origin in social processes, although it has the vital support of technical and scientific knowledge. It is a task of a political nature and thus should be perceived as such and demanded from the managers of health[20].

The decentralization of the HS actions is, as well as a principle that provides guidance and direction, a strategy for its strengthening in the three spheres of government. To be effective, it needs to be accompanied by funds, technical support and instruments of management that are necessary for strengthening of the federal entities, in accordance with the guidelines and principles of SUS[16] – and decentralization with institutional responsibility, not only with extemporaneous support to the demands of the agency, in one-off activities, due to the political and geographical proximity of states and municipalities to the *loci* of the identified problems.

The financing of HS has the peculiarity of having its own source of collection. It would be expected that this collection source would be allocated to finance SNVS; but the funds raised in states and municipalities through collection of charges are incorporated into the cash positions of the respective treasuries and are not allocated to the budgets of the area. In the case of Anvisa, the collection of charges accounts for a considerable part of its annual budget, but when there is a surplus, the amounts go into the account of the national treasury, and are prevented from being used for another purpose, and do not directly return to the budget of the Agency, nor may they be allocated to the other partners of the system[17].

Thus, it can be said that since the creation of Anvisa the activity of the entities of the SNVS has been very much improved, with qualification of personnel, better physical structure and other resources of health control and inspection; and that the action of the SNVS has been the main determining factor in making sure that the calamitous cases of the 1990s, and the widespread fears at the end of that decade, have not taken place in the same proportion.

At the same time as progress, there are many remaining gaps of a theoretical-conceptual nature, and this is related, among other factors, to: the fact of this area presenting itself as fundamentally an applied activity; the hegemony of the medical-assistential model centered on the illness; and the isolation in which HS has been kept in Brazil, separated from the other health policies – restricted to inspection, even while this function is, as it still is, insufficiently exercised[2].

Cross-sectional nature of health surveillance in the SUS

The events of the 1990s showed that the SUS was the victim of its own fragility: public and private hospitals contracted or operating under agreements bought falsified or adulterated drugs from illegal or fraudulent producing companies or wholesalers; and providers of services to the SUS carried out insufficiently qualified care

Ciência & Saúde Coletiva, 23(6):1953-1962, 2018

which, in several cases, led to the death of many patients[16]. It is inferred that full structuring of HS is crucial to implementation of the SUS, above all because of its power to make rules and inspect services operating under agreement or contract, and diagnostic inputs and therapies used in the services. And although they are part of the duties of HS, actions in health control of the health services have not been sufficiently allocated to develop competencies in terms of the quality of healthcare.

Data recently published as part of a study by the Medical Faculty of the Federal University of Minas Gerais, commissioned by the Supplementary Health Studies Institute[21], show a worrying situation in the health service network. Every day, on average, 829 Brazilians die due to adverse events, in public or private hospitals: a total of 302,610 deaths in 2016. These events also have knock-on effects in harming skills for daily tasks, as well as psychological suffering and increased care cost.

The study was based on data from 133 hospitals, during the year, and included errors of diagnosis, dosage or administration of medication, incorrect use of equipment, hospital infections, etc. These adverse events are classified as fully avoidable. The number of deaths is impressive, and this factor is reportedly the second cause of death, second only to illnesses of the circulatory system, according to information systems of the health ministry[22].

These facts highlight the importance of the 'quality of health services' and the vital need to establish the culture of safety of the patient, a concept which involves the objective of reducing the risk of unnecessary damage associated with healthcare to an acceptable minimum. HS action is shown to be essential to the success of the National Patient Safety Program, instituted by Ministerial Order 529 of April 1, 2013, followed by Anvisa Regulation 36 of July 25th, 2013.

Authors point out that inappropriate, mistaken or abusive use of prescribed drugs is the third largest cause of death worldwide after heart problems and cancer[23]. The USA and Europe are living through two highly lethal epidemics, due to the use of tobacco and of drugs, which have caused concern and induced nations to formulate health protection policies[23]. In Brazil, these have involved important actions by HS. Corroborating the information of other authors, such as Angell[24], Gøtzche[23] points out the large, and delicate, problem of handling of data and of the lack of transparency in clinical trials, which are the grounds for the decisions of drug regulation agencies.

Although studies that give a clearer portrait of the situation of Brazil are not yet available, beyond the examples that have been the subject of a major repercussion in conditions of health and in determination of the profile of demands for health services, one can refer to the question of food and its relationship to epidemics of hypertension, obesity and diabetes, and the problem of weedkillers which, like medical drugs, have suffered abusive use – a subject that has become banal although of great concern – with considerable damage to health, such as endocrine deregulation, neurological problems, psychological and genetic effects, and cancer, among other effects[25].

As well as these more critical subjects, that are part of the new modernity of a highly technological society, HS has to operate actively in favor of health safety in the population's everyday life: from hygiene in restaurants for the rich, to cheap street cafés, snack parlors, kiosks and street food operators who feed a significant contingent of the population; from truth on labels of products related to health, to the price of drugs; from agrochemicals in vegetable foods, to residues of veterinary products in foods with animal origin.

In general, technological processes impose the need for increasingly greater surveillance, more qualified and experienced professionals, more equipped structures and more complex control systems[26] – and mechanisms to oppose and neutralize arguments from industry associations and politicians, who defend private economic interests of the agents involved[27].

Health regulation and surveillance today

The complexity of health regulation becomes apparent when one considers that it operates in functions that are very sensitive to economic interests, such as control of smoking, toxicological assessment of agrochenicals, food quality, prices of drugs, and their efficacy and safety. The disputes that arise from mediation between the interests of the regulated segments and the public policies for protection of health demonstrate the repercussion effect on the population's health, when dealing with health regulation only from the point of view, and parameters of the market economy.

A recent discussion points to the need for review of the concept of health promotion, as well as an appeal to hold individuals responsible, and the creation of healthy environments[28]. Current

lifestyles, which predispose to the epidemic of chronic conditions, arise mainly from the articulation between economic development and the advance of productive forces, globally planned by the major corporations.

Identification of the determinants of lifestyles opens a new route to regulatory and the strategic action of the state in confronting the risk factors that lead to the epidemic of chronic illnesses which afflicts society and the health systems. This action will include making the principal public and private economic agents carry the burden of social responsibility; and a state regulation on industrial production, in areas of strong connection with health issues, among them those responsible for products that disseminate risk factors for illnesses such as diabetes, heart diseases, cancer and other chronic conditions[28].

It can be seen that enhancement of regulatory policies requires both (i) engagement and adhesion on the part of other public bodies in the formulation of policies with a social-health reach; and (2) activities in international regulation, seeking new global policies that can assume a protagonist position in preservation of human health, and in ensuring that cross-sector interests – the outcome of organized pressure of lobbies – do not become superimposed on the interests of preservation of life on the planet.

The area of HS illustrates the complexity of the social determination of health; but only recently has it taken the form of an emerging issue in research and teaching in Brazil –when a process of perception of its social-cultural and economic importance also began. It has this importance both from the point of view of two requirements: (i) full integrality of healthcare, and the right to health; and (ii) pursuit of certain standards of ethics and qualification in provision of health services and production of goods, essential to the insertion of the country into the globalized market.

Relationships with legislature and judiciary

One of the forms in which the Welfare State can intervene in guaranteeing social rights is by issuance of rules and laws – from the Constitution down to the regulations under laws passed by Congress – and by strengthening of jurisdictional control of application of this legislation by the constitutional courts[29]. The latter is one of the determinants of feverish action by Congress members today.

Today's technological society demands quick answers to new or very specific questions. A formidable quantity of technologies, continuously produced, need to undergo assessment of the risks that are involved in their process of production, use or consumption. And they need systematic monitoring, because many of their effects are only revealed after long use and studies. Thus, the State is increasingly taking action with other legal instruments than the law, with increasingly technical contents[29], to regulate issues that cannot and should not wait for the completion of long and difficult processes of decision which are typical of the Legislature. They cannot wait, because the history of public health has proven that absence of timely health regulation and inspection is a basic cause of numerous tragedies. And they should not wait, because these are specific issues, of technical-scientific content, in which the debate is not appropriate for the rules of a generalist nature that a Legislature is likely to formulate. A great part of this regulatory authority is, thus, exercised by regulatory agents – agencies, institutes, commissions, councils – made up of specialists who use science to propose technical criteria of argumentation.

The regulatory attribution of HS, especially of Anvisa, has always been a subject for controversy and strong reactions when it exercises its regulatory functions, sponsored by corporate and parliamentary groups which, in reaction to one-off situations and corporate interests with a strong power of pressure on other powers of the State, disagree with the decisions of the health authority. In many cases these disagreements are drawn out into negotiations between the regulatory agents of the state and the sector being regulated, and do indeed find their way into the judiciary and the legislature in the form of contestation and even lawsuits. They question, firstly, the role of the regulatory agencies, not only that of Anvisa, in the legal exercise of their attributions, with arguments of extrapolation outside their area of competency. Second, they try to confuse public opinion on a supposed deviation of the agencies' function and invasion of spheres that are exclusively within the competence of the Legislature. Third, they point to the Judiciary, on the pinnacle of its supposed political neutrality and as guardian of the precepts of the Constitution, to resolve any doubts that may exist on the scope and scale of the legal limits delegated to the Agencies in their prerogative of protection of health. The public power must not inhibit the constitutional right of access to the judiciary for rights supposedly denied to the citizen or to entities representing common interests. But this right

Ciência & Saúde Coletiva, 23(6):1953-1962, 2018

should be guaranteed through instruments that respect and obey the harmony of and the mutual independence between the powers which, although interdependent between themselves, have duties and competencies clearly spelt out in the Constitution[30].

The most high-profile case – for the social convulsion that it caused – was that of synthetic phosphoryl ethanolamine. Popular prejudices have been a strong fuel and motive force for politicians' interests in meeting the population's demands without taking into account the health legislation. To this, in this case, were added action by sectors of the Judiciary and even of the Executive in supporting decisions that are outside the scientific parameters applicable to the case[31]. The association, in this case, between the Ministry of Science, Technology and Innovation (MCTI) and the National Committee on Research Ethics (Conep) gave rise to justified doubt on its appropriateness: the former, by allocating significant amounts for a survey on the effects of a supposed drug, and the second, for approving formal clinical studies without proof of pre-clinical data to justify them. And the Judiciary comes into question, for a single-judge decision by one of the Justices of the Supreme Court, which ordered delivery of the "drug" to the patients that demanded it, without any scientific evidence of efficacy that might justify such a decision. In Congress, there were grotesque scenes of politicians at public hearings called to discuss the subject, and approval, in record time, of Law 13269 of April 13, 2016, currently repealed by an injunction by the Federal Supreme Court, in effect until that court gives its final decision. From the Executive, there was sanctioning of this law without vetoes, by the President of the Republic, in spite of an opinion statement to the contrary by Anvisa and the Health Ministry. The environment of political disturbance at the time is the most plausible explanation for the full approval of the text received from Congress.

Other highlight cases of litigation against regulations of Anvisa were the cases opposing Anvisa Directorate Resolutions 14/2012, which restricts the use of aromatic substances in cigarettes, and 52/2011, which prohibited the use of the substances *fenproporex* and *mazindol*, and set controls on prescription and dispensation of medications that contain *sibutramine*.

These are examples of the tense relationships with the regulatory agents and the Legislative and Judiciary powers of Brazil. It is a relationship that is in general a conflict-ridden one, in which arguments for protection of health do not always prevail, and which can retard or obstruct materialization of the right to health specified in the Federal Constitution – which strengthens another fundamental juridical asset of the population: human dignity.

Challenges and perspectives

In spite of the significant progress that has been achieved, especially after the creation of Anvisa, SNVS needs constant assessment as to the effectiveness of its theoretical and practical fundaments and of its model; it also needs to be systematically planned, in the quest to overcome the difficulties and deficiencies. SUS and its context of need is the basic point of reference.

In this direction, certain challenges, among so many, arise for all the components of SNVS[32]:

a) Formulation of a national HS policy, one of the components of promotion of health and prevention of damage in the SUS, which would: define objectives and targets, the major lines of structuring of the SNVS and the strategic principles; orient the activity to the needs of the SUS, to improvement of the quality of health services, and to confrontation of the chronic diseases; and would rethink the organization and management of the SNVS, and decentralization as a priority to strengthen the other entities.

b) Definition of and decision on a model for identification of the main risks to health, in each region and locality. In a situation of constant scarcity of resources, it is essential to work with priorities, in spite of a significant part of the work of the HS being demanded by regulated segments, by force of law. There is a need to build a conception of risk that is appropriate to the singularity of the objects of action, that will help to think through the review of the traditional instruments of control; and to be guided by the health situation of the population, with the work coordinated with the agencies of surveillance in epidemiology, environment and workers' health, and with instances that work with assessment of risks to health.

c) To confront the question of inequality, so as not to treat equally those that are unequal; a regulation that differentiates the risks to health related to small businesses from those of immense transnational corporations; progress in regulation with productive inclusion, getting closer to the entities of small producers; finding alternatives to make artisanal production of food viable, and traditional practices and cuisines,

which preserve the culture, biodiversity and autonomy of the regions of the country.

d) Consolidation of HS in its status as a field of research, an academic discipline that produces knowledge, a space for reflection and dissemination of knowledge; decision on a research agenda also at the state and municipal levels, to strengthen postgraduate studies in the area.

e) Debate on careers for the workforce of HO in the states and municipalities, similar to that of other state areas of regulation and inspection; expansion and strengthening of the qualification of the workers with a focus on acting on risks to health in the many territories.

f) Maintenance of participation in the efforts of international regulation, in identification of global risks and in strategic regulatory actions that can add effect to the national resources. Such efforts to be principally directed to the needs of the SUS, its structuring and sustainability.

g) Effort in communication of risk, to help with the health consciousness of the Brazilian public, and to strengthen the technical and scientific arguments vis-à-vis the mostly economic interests of the great business corporations and their powerful mechanisms of pressure on the powers of the republic.

Over the thirty years that the SUS has existed, health surveillance has emerged as its institutional 'ghetto', seen as essentially bureaucratic, serving formal demands of the regulated segments with little or no linking with the health system. It became more visible, especially at the end of the 1990s, when there were veritable health tragedies caused by the impotence of the State to deal with them. The creation of Anvisa and better structuring of SNVS in its linkage with the SUS have been decisive factors, which have strengthened the visibility of health surveillance, and the perspectives for its organization in SUS.

Collaborations

JAA Silva, EA Costa and G Lucchese participated equally in the conception, drafting, critical revision and approval of this article.

References

1. Rosen G. *Uma história da Saúde Pública*. São Paulo: Unesp-Hucitec-Abrasco; 1994.
2. Costa EA, Souto AC. Área Temática de Vigilância Sanitária. In: Paim JS, Almeida Filho NA. *Saúde Coletiva: Teoria e Prática*. Rio de Janeiro: Artmed; 2014. p. 327-341.
3. Costa EA. Fundamentos da vigilância sanitária. In: Costa EA, organizadora. *Vigilância Sanitária: Temas para Debate*. Salvador: EDUFBA; 2009. p. 11-36.
4. Brasil. Lei nº 9.782, de 26 de janeiro de 1999. Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária e dá outras providências. *Diário Oficial da União* 1999; 27 jan.
5. Brasil. Lei nº 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. *Diário Oficial da União* 1990; 20 set.
6. Di Pietro MSZ. *Direito Administrativo*. 13ª ed. São Paulo: Atlas; 2004.
7. Lucchese G. A vigilância sanitária no Sistema Único de Saúde. In: De Seta MH, Pepe VL, Oliveira GO, organizadores. *Gestão e vigilância sanitária: modos atuais do pensar e fazer*. Rio de Janeiro: Fiocruz; 2006. p. 33-47.
8. Almeida Filho N. *A clínica e a epidemiologia*. 2ª ed. Salvador: APCE-Abrasco; 1997.
9. Almeida Filho N. O conceito de saúde e a vigilância sanitária: notas para a compreensão de um conjunto organizado de práticas de saúde. In: Costa EA, organizadora. *Vigilância sanitária: desvendando o enigma*. Salvador: EDUFBA; 2008. p.19-43.
10. Leite HJ, Navarro MVT. Risco potencial: um conceito de risco operativo para vigilância sanitária. In: Costa EA, organizadora. *Vigilância Sanitária: Temas para debate*. Salvador: EDUFBA; 2009. p. 61-82.
11. Buss PM. Uma introdução ao conceito de promoção da saúde. In: Czeresnia D, Freitas CM. *Promoção da saúde: conceitos, reflexões, tendências*. 2ªed. rev. amp. Rio de Janeiro: Editora Fiocruz; 2009. p. 19-42.
12. Nogueira E, Vecina Neto G. Falsificação de medicamentos e a lei nº 11.903/09: aspectos legais e principais implicações. *Revista de Direito Sanitário* 2011; 12(2):112-139.
13. Costa EA. Regulação e Vigilância Sanitária: Proteção e defesa da Saúde. In: Rouquayrol MZ, Silva MGC, organizadores. *Rouquayrol – Epidemiologia & saúde*. 8ª ed. Rio de Janeiro: MedBook; 2018. p. 461-486.
14. Brasil. *Plano Diretor da Reforma do Aparelho do Estado*. Brasília: Presidência da República, Câmera da Reforma do Estado, Ministério da Administração Federal e Reforma do Estado; 1995.
15. Paim JS. Prefácio. In: Souto AC, organizador. *Saúde e Política: a vigilância sanitária no Brasil. 1976-1994*. São Paulo: Sociedade Brasileira de Vigilância de Medicamentos (SOBRAVIME); 2004. p. 13-14.
16. Lucchese G. *Globalização e Regulação Sanitária: os rumos da vigilância sanitária no Brasil* [tese]. Rio de Janeiro: Escola Nacional de Saúde Pública/Fiocruz; 2001.
17. De Seta, MH, Silva, JAA. A gestão da vigilância sanitária. In: De Seta MH, Pepe VL, Oliveira GO, organizadoras. *Gestão e vigilância sanitária: modos atuais do pensar e fazer*. Rio de Janeiro: Fiocruz; 2006. p. 195-217.
18. Moreira EMM, Costa EA. Avaliação de desempenho da Agência Nacional de Vigilância Sanitária no modelo de contrato de Gestão. *Cien Saude Colet* 2010; 15(Supl. 3):3381-3391.
19. Silva JAA. *Fala na Comissão de Assuntos Sociais do Senado Federal durante sabatina para aprovação ao cargo de Diretor da Anvisa*. Brasília, 18 de abril de 2007.
20. Vecina Neto G, Marques MCC, Figueiredo AM. Vigilância Sanitária no Brasil. In: Campos GWS, Minayo MCS, Akerman M, Drumond Júnior M, Carvalho YM, organizadores. *Tratado de Saúde Coletiva*. São Paulo, Rio de Janeiro: Hucitec, Fiocruz; 2006. p. 702-704.
21. Instituto de Estudos sobre Saúde Suplementar (IESS). [homepage da internet]. *Erros acontecem*. [acessado 23 nov 2017]. Disponível em: https://www.iess.org.br/?p=publicacoes&id=806&id_tipo=15
22. Brasil. Ministério da Saúde (MS). [homepage da internet]. *Painel de Monitoramento da Situação de Saúde*. [acessado 23 nov 2017]. Disponível em: http://svs.aids.gov.br/dashboard/situacao/saude.show.mtw
23. Gøtzsche PC. *Medicamentos mortais e crime organizado*. Porto Alegre, São Paulo: Bookman Editora Ltda.; 2016. p. 1.
24. Angell M. *A verdade sobre os laboratórios farmacêuticos*. São Paulo, Rio de Janeiro: Editora Record; 2007.
25. Carneiro FF, Augusto LGS, Rigotto RM, Friedrich KB, Búrigo AC, organizadores. *Dossiê ABRASCO: um alerta sobre os impactos dos agrotóxicos na saúde*. Rio de Janeiro, São Paulo: Expressão Popular, EPSJV; 2015.
26. Lucchese G. A vigilância sanitária no Sistema Único de Saúde. In: *Conferência Nacional de Vigilância Sanitária. Caderno de Textos*. Brasília: Anvisa; 2001. p. 53-69.
27. Foreman Junior CH. *Plagues Products & Politics – emergent public health hazards and national policymaking*. Washington: The Brookings Institution; 1994.
28. Nethis. *Programa de Pesquisa e Comunicação: Perspectivas bioéticas da regulação de produtos de uso humano vinculados a fatores de risco das doenças crônicas, no contexto das relações internacionais do Brasil*. Brasília: OICH/Nethis; 2013. [acessado 23 nov 2017]. Disponível em: http://bioeticaediplomacia.org/wp-content/uploads/2014/03/TR-Programa-Nethis-Oich.pdf.
29. Cléve EM. *Atividade Legislativa do Poder Executivo*. São Paulo: Editora Revista dos Tribunais; 2000.
30. Silva JAA. *Conferência proferida no 3º Encontro Nacional do Ministério Público de Defesa da Saúde – Ampasa*. Florianópolis, 30 de agosto de 2006.

31. Paumgartten FJR. Sobre a alegada eficácia anticâncer da pílula de fosfoetanolamina, fragilidade da evidência científica e preocupações éticas. *Vig. sanit. debate* 2016; 4(3):4-12.
32. Associação Brasileira de Saúde Coletiva. *GT Vigilância Sanitária. Referencial de Trabalho para o GT Vigilância Sanitária*. Rio de Janeiro: Abrasco; 2014. [acessado: 07 dez 2017]. Disponível em: https://www.abrasco.org.br/site/wp-content/uploads/2015/03/GT-VISA-REFERENCIAL-DE-TRABALHO.pdf

Article submitted 05/01/2018
Approved 30/01/2018
Final version submitted 27/02/2018