

# Health Surveillance actions in pharmaceutical products and services in a large municipality in Northeastern Brazil

## Ações de Vigilância Sanitária na área de produtos e serviços farmacêuticos em município de grande porte do Nordeste do Brasil

### ABSTRACT

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**Introduction:** Health Surveillance acts through inspection to prevent people, establishments, or processes from producing situations of risk to individual and collective health. **Objective:** To present a situational diagnosis of the sanitary actions of the area of pharmaceutical products and services in the city of Fortaleza - Ceará, registered in the Fiscalize system, from January 2018 to December 2019. **Method:** Access to the tax system, search by registration group and registration date, with the visualization and copy of the content, individually, of each inspection. The data were stratified into notified and fined, categorized by type of establishment, neighborhood and date of occurrence, non-compliance found, and legislation used in the reasoning. The results were expressed in absolute and relative frequencies. **Results:** A total of 614 establishments were inspected, 948 inspections were carried out and 2,830 were found to be sanitary inadequacies, of which 385 (23.60%) were registered and 2,445 (86.40%) were reported. The irregularities found varied according to those inspected. Drugstore was the most frequent group among establishments (420/614; n = 68.40%) and the lack of mandatory sanitary documentation was the prevalent non-conformity (491/2,830; n = 17.30%). The legislation most used to substantiate irregularities was RDC Anvisa No. 44/2009, used in 45.20% (1,279/2.830) of inadequacies. In the distribution by neighborhoods, the city center concentrated the largest number of inspected (44/614; n = 7.20%). **Conclusions:** The results showed that most of the inspected establishments followed the legally provided sanitary standards, because only a minority of the sanitary non-conformities found were grounds for action, while the vast majority were only notified to present improvements.

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**KEYWORDS:** Health Surveillance; Health Surveillance System; Sanitary Inspection; Pharmacy

### RESUMO

**Introdução:** A Vigilância Sanitária atua por meio da fiscalização e inspeção para evitar que pessoas, estabelecimentos ou processos produzam situações de risco à saúde individual e coletiva. **Objetivo:** Apresentar um diagnóstico situacional das ações sanitárias na área de produtos e serviços farmacêuticos no município de Fortaleza, Ceará, registradas no sistema Fiscalize, no período de janeiro de 2018 a dezembro de 2019. **Método:** Trata-se de estudo descritivo, com acesso ao sistema Fiscalize, com busca por grupo de cadastro e data de registro, com visualização e cópia do conteúdo, individualmente, de cada inspeção. Os dados foram estratificados em notificados e autuados, categorizados por tipo de estabelecimento, bairro e data de ocorrência, não conformidade constatada e a legislação utilizada na fundamentação. Os resultados foram expressos em frequências absolutas e relativas. **Resultados:** Nos 614 estabelecimentos fiscalizados, foram realizadas 948 inspeções e foram constatadas 2.830 inadequações sanitárias, das quais 385 (23,60%) foram autuadas e 2.445 (86,40%), notificadas. As irregularidades constatadas variaram de acordo com os inspecionados. Drogeria foi o grupo mais frequente dentre os estabelecimentos



(420/614; n = 68,40%) e a inexistência de documentação sanitária obrigatória foi a não conformidade prevalente (491/2.830; n= 17,30%). A legislação mais utilizada para fundamentar as irregularidades foi a RDC Anvisa nº 44, de 17 de agosto de 2009, usada em 45,19% (1.279/2.830) das inadequações. Na distribuição por bairros, o centro da cidade concentrou o maior número de fiscalizados (44/614; n = 7,20%). **Conclusões:** Os resultados demonstraram que a maioria dos estabelecimentos inspecionados seguiu os padrões sanitários legalmente previstos, pois apenas uma minoria das não conformidades sanitárias constatadas foi motivo de autuação, enquanto a maioria foi apenas notificada para apresentar melhorias.

**PALAVRAS-CHAVE:** Vigilância Sanitária; Sistema de Vigilância Sanitária; Inspeção Sanitária; Farmácia

## INTRODUCTION

State interference in health issues arose from the need to protect human groups from contamination by disease at the end of the 18th century<sup>1</sup>. Interventions in healing practices, in the production of goods and services and in consumer relations have been structured over the years and are a major challenge today, with the emergence of new technologies<sup>2,3</sup>.

In Brazil, Health Surveillance (Visa), as it is known today, was conceptualized in the law creating the Unified Health System (SUS), Law No. 8.080, of September 19, 1990, as actions aimed at eliminating, reducing or preventing risks to individual and collective health, intervening in the health aspects of the environment, the production of goods and services related to health, covering the production, circulation and consumption of products and the provision of services related to health. This definition elevated Visa to a level where the practice of prevention, protection and health promotion prevails, categorically overcoming the well-known police practice of yesteryear, in conceptual terms<sup>2</sup>.

The Brazilian state, following international trends, improved its actions in the health area with the creation of the Brazilian National Health Surveillance Agency (Anvisa), positioning it within the SUS<sup>2</sup>. This agency is responsible for coordinating the National Health Surveillance System (SNVS), which is also made up of state and municipal health surveillance agencies. Among the components of the system there are so-called agreements, which mean the division of responsibilities for action between states, municipalities and the federal district<sup>4</sup>.

This system is concerned with products, technologies, processes, procedures, the transportation of cargo and people, the production, distribution and trade of goods and the provision of services that may directly or indirectly interfere with health<sup>5</sup>.

Visa acts through sanitary inspection to prevent people, establishments, or processes from producing situations that pose a risk to the health of the exposed population<sup>6</sup>. However, it can also act in a coercive manner in an attempt to reduce risks, for example, in cases of product seizure or establishment bans, based on sanitary legislation, which includes laws, decrees, ordinances, resolutions from Anvisa's Collegiate Board of Directors (RDC) and normative instructions<sup>5</sup>.

Since 2018, the municipality of Fortaleza, Ceará, has implemented an information system called Fiscalize, through which

Visa inspectors record data on their actions in the territory<sup>7</sup>. The municipality of Fortaleza covers an area of more than 312 km<sup>2</sup> and has a population of 2,703,391 people, making it the second largest in the Northeast in terms of inhabitants<sup>8</sup>.

The aim of this study was to present a situational diagnosis of health actions in the area of pharmaceutical products and services, which were recorded in the Fiscalize system in the municipality of Fortaleza, Ceará, from January 2018 to December 2019. Specifically, the objectives consisted of describing the peculiarities of health inspection, identifying the non-conformities notified and fined, correlating them to the types of establishments, as well as identifying the legal provisions infringed.

## METHOD

This is a descriptive study, which used data on the sanitary actions carried out by the inspection in the area of pharmaceutical products and services in the municipality of Fortaleza, a large municipality in the Northeast of Brazil, from January 2018 to December 2019, duly registered in the Fiscalize system.

At the start of the study period, the municipality had 1,201 establishments in the area of pharmaceutical products and services<sup>9</sup>. This area includes establishments where there is a presence of medicines or services related to the pharmaceutical profession, such as clinical analysis laboratories, for example. Other establishments that are not directly related to the area of pharmaceutical products and services, such as long-stay institutions for the elderly (ILPI), the natural products trade, *home care*, ambulance services, cosmetics distributors, grocery stores, street markets, food stores, referred to in this study as multidisciplinary establishments, were included due to the possibility of identifying illegal sales of pharmaceutical products.

The inspection actions were the result of planning such as the Annual Health Inspection Plan (PAF-Visa) and were motivated by complaints or for other reasons, such as renewing the municipal health license.

The study's variables include information taken from the notifications and infraction notices registered in the Fiscalize system, which identify: the type of establishment; the date of the incident; the location (neighborhood) of the incident; the



non-conformities found (situations that deviate from the provisions of the relevant legislation); the legal grounds for the non-conformities or legal provisions infringed; the number and type of document generated (notice or notification).

The data was collected in the Fiscalize system, which produces a table-type result, with 20 items per screen page containing: the title of the columns, the notice number, the person in demand (the inspected establishment), the classification of the group, the date of the notice, the deadline for submitting a defense, the type of notice and the annexes.

This data was stratified into notified or fined and categorized by type of establishment, neighborhood and date of occurrence, non-compliance found, and legislation used as grounds. They were compiled in a Microsoft® 2016 Excel spreadsheet, using dynamic tables with the results expressed in absolute and relative frequencies.

As this information comes from a database restricted to the service, with no public access, in accordance with Resolution No. 510 of April 7, 2016 of the National Health Council, the project was submitted to the Research Ethics Committee (CEP) via Plataforma Brasil and was approved under substantiated opinion No. 3.578.158 and CAAE 20153119.6.0000.5054.

## RESULTS

During the study period, information was obtained from 614 establishments, of which 127 (20.70%) were re-inspected. The percentage of inspections during the study period reached 15.40% (n = 185) in 2018 and 35.7% (n = 429) in 2019, considering the 1,201 establishments in the municipality at the start of the survey. Overall, there were 948 inspections and 2,830 non-conformities were found, of which 2,445 (86.40%) resulted in notifications and 385 (23.60%) in fines.

Table 1 shows that drugstores were the most inspected establishments (68.40%), resulting in 666 (70.20%) inspections and 2,015 (71.20%) non-conformities.

Table 2 shows that 1,755 drugstores (71.80%) were notified of inadequacies and 260 (67.50%) were fined.

Of the 119 neighborhoods in the city of Fortaleza, 100 (84.00%) were inspected during the study period. The 11 neighborhoods that had the highest number of establishments inspected were: Centro (n = 44; 7.20%), the upscale neighborhoods Aldeota (n = 41; 6.70%) and Meireles (n = 18; 3.00%), and the suburbs Messejana (n = 23; 3.70%), Parquelândia (n = 20; 3.30%), Jóquei Clube (n = 19; 3.10%), Presidente Kennedy (n = 18; 3.00%),

Table 1. Frequencies of establishments by total, number of inspections, and non-conformities, from 2018 to 2019, in Fortaleza, Ceará.

Types of establishments	Establishments		Inspections		Non-conformities	
	N	%	N	%	N	%
Drugstore	420	68,40	666	70,20	2.015	71,20
Laboratory collection point	34	7,00	65	7,10	216	7,60
Wholesale of medicines	43	6,00	67	5,40	180	6,30
Clinical laboratory	37	5,5	51	6,9	145	5,10
Retail trade in health products	25	4,20	36	3,20	114	4,00
Wholesale of health products	26	4,10	30	3,80	88	3,10
Medicines transporter	11	1,80	12	1,30	32	1,10
Biological material transporter	2	0,30	3	0,30	8	0,30
Medicines depot	1	0,20	1	0,10	3	0,10
<b>Multidisciplinary establishments</b>						
ILPI	4	0,60	4	0,40	10	0,40
Trade in natural products	2	0,30	2	0,20	2	0,10
Home care	2	0,30	2	0,20	5	0,20
Grocery store	2	0,30	2	0,20	2	0,10
Ambulance	1	0,20	3	0,30	5	0,20
Food trade	1	0,20	1	0,10	2	0,10
Bar	1	0,20	1	0,10	1	0,04
Street market	1	0,20	1	0,10	1	0,04
Cosmetics distributor	1	0,20	1	0,10	1	0,04
<b>Total</b>	<b>614</b>	<b>100,00</b>	<b>948</b>	<b>100,00</b>	<b>2.830</b>	<b>100,00</b>

Source: Prepared by the authors, 2022.

ILPI: Long-stay institution for the elderly.



Table 2. Types of establishments and distribution of non-conformities, according to fines and notifications, from 2018 to 2019, in Fortaleza, Ceará.

Types of establishments	Non-conformities					
	Fines		Notifications		Total	
	N	%	N	%	N	%
Drugstore	260	67,50	1.755	71,80	2.015	71,20
Laboratory collection point	35	9,10	181	7,40	216	7,60
Wholesale of medicines	31	7,80	149	6,10	180	6,30
Clinical laboratory	20	5,20	125	5,00	145	5,10
Retail trade in health products	26	6,70	88	3,60	114	4,00
Wholesale of health products	3	0,80	85	3,50	88	3,10
Medicines transporter	1	0,30	31	1,30	32	1,10
ILPI	-	-	10	0,40	10	0,40
Biological material transporter	1	0,30	7	0,30	8	0,30
Home care	-	-	5	0,20	5	0,20
Ambulance	1	0,30	4	0,20	5	0,20
Medicines depot	-	-	3	0,10	3	0,10
Grocery store	2	0,50	-	-	2	0,07
Trade in natural products	2	0,50	-	-	2	0,07
Food trade	-	-	2	0,10	2	0,07
Street market	1	0,30	-	-	1	0,04
Bar	1	0,30	-	-	1	0,04
Cosmetics distributor	1	0,30	-	-	1	0,04
Total	385	100,00	2.445	100,00	2.830	100,00

Source: Prepared by the authors, 2020.

ILPI: Long-stay institution for the elderly.

Rodolfo Teófilo (n = 13; 2.12%), Passaré (n = 13; 2.10%), Fátima (n = 18; 3.00%), and Antônio Bezerra (n = 14; 2.30%).

The highest frequencies of inspections and non-compliances, which resulted in higher percentages of fines, occurred in Parquelândia (63 inspections resulted in 182 non-compliances), Rodolfo Teófilo (57 inspections resulted in 165 non-compliances), Centro (52 inspections resulted in 142 non-compliances), Aldeota (41 inspections resulted in 130 non-compliances), Jóquei Clube (40 inspections resulted in 110 non-compliances), and Antônio Bezerra (36 inspections resulted in 123 non-compliances). These neighborhoods accounted for 30.10% of all inspections and 30.10% of all non-conformities.

Table 3 shows the 22 most frequent non-conformities of more than 1.00%, making up 85.90% of the total, and their distribution by fines and notifications. The lack of mandatory health documentation (n = 491; 17.30%), inadequate product storage (n = 226; 8.00%) and structural inadequacy (n = 213; 7.50%) were the most frequent items.

Among the ten most frequent non-conformities, four are closely related to the dispensing of medicines, as they include: delays in the movements of the National System for the Management of Controlled Products - SNGPC (n = 157; 5.50%), the lack of proof of checking the maps of controlled medicines (n = 146;

5.20%), dispensing antimicrobials in disagreement with current legislation (n = 99; 3.50%) and the need for training on the work routine (n = 11; 3.90%).

The non-conformities found in drugstores (n = 2.015; 71.20%) include, in general, the following problems: physical infrastructure and environmental conditions (n = 612; 30.40%), receiving, storing and dispensing products (n = 476; 23.60%), documentation (n = 347; 17.20%), medicines subject to control (n = 335; 16.60%) and pharmaceutical services (n = 153; 7.60%), outpatients (n = 27; 1.40%) and others (n = 64; 3.20%).

In the medicine wholesale trade, the non-conformities found (n = 180; 6.30%) refer to the following problems: physical infrastructure and environmental conditions (n = 73; 40.60%), documentation (n = 58; 32.20%), storage (n = 43; 16.10%), dispatch (n = 13; 7.20%) and others (n = 7; 3.90%).

With regard to laboratory collection points, the non-conformities found (n = 216; 7.60%) generally include the following problems: physical infrastructure and environmental conditions (n = 67; 31.00%), documentation (n = 64; 29.60%), worker health and safety (n = 21; 9.70%), professional training (n = 11; 8.00%), sanitation conditions and waste management (n = 17; 5.10%), standard operating procedures (n = 7; 3.20%) and others (n = 29; 13.40%). As for clinical analysis laboratories (n = 145; 5.10%),



Table 3. Most frequent non-conformities considering all types of establishments from 2018 to 2019 in Fortaleza, Ceará.

Non-conformities	Fines	Notifications	Total	
	N	N	N	%
Lack of mandatory health documentation	93	398	491	7,30
Inadequate storage of products	26	200	226	8,00
Structural inadequacy	16	197	213	7,50
Lack of equipment or instruments necessary for the activity carried out	13	147	160	5,60
Delay in SNGPC movements	28	129	157	5,50
Lack of up-to-date proof of delivery and checking of maps of controlled drugs	23	123	146	5,40
Organization and general cleaning	10	122	132	4,70
Pest control	13	117	130	4,60
Need for training on the work routine	4	107	111	4,00
Dispensing antimicrobials in disagreement with current legislation	27	72	99	3,50
No complete sink in the bathroom	5	67	72	2,50
No authorization for the use of advertising and publicity devices	6	62	68	2,40
Identification of areas or environments	6	61	67	2,37
No microbiological analysis of water	4	46	50	1,80
Proof of final disposal of expired medicines	3	46	49	1,70
No operating license	3	42	45	1,60
Inadequate waste storage	5	38	43	1,50
Display warning information to the public	4	35	39	1,40
Proof of immunization of professionals	5	34	39	1,40
Lack of documentation proving the regularity of the third-party service provider	5	29	34	1,20
Incompatible physical and virtual stocks	1	30	31	1,10
Equipment calibration	2	28	30	1,06

Source: Prepared by the authors, 2022.  
SNGPC: National System for the Management of Controlled Products.

the problems identified were: physical infrastructure and environmental conditions (n = 59; 40.70%), documentation (n = 48; 33.10%), worker health and safety (n = 10; 7.00%), sanitation and waste management conditions (n = 6; 4.10%), professional training (n = 4; 2.70%), standard operating procedures (n = 3; 2.10%) and others (n = 15; 10.30%).

In the wholesale trade of health products (n = 88; 3.10%), the problems were related to: physical infrastructure and environmental conditions (n = 36; 40.90%), documentation (n = 31; 35.20%), storage (n = 8; 9.10%), shipping (n = 5; 5.70%), receiving (n = 3; 3.40%) and others (n = 5; 5.70%). In the retail trade (n = 114; 4.00%): physical infrastructure and environmental conditions (n = 61; 53.50%), documentation (n = 31; 27.20%), storage (n = 12; 10.50%), receiving (n = 2; 1.80%) and others (n = 8; 7.00%).

Regarding the transportation of medicines (n = 32; 1.10%), the non-conformities were related to: physical infrastructure and environmental conditions (n = 13; 43.30%), documentation (n = 11; 36.70%), the place where the medicines are

stored (n = 4; 13.30%) and the vehicle used for transportation (n = 2; 6.70%).

Table 4 shows the frequencies of non-conformities found in other establishments: 11 types were found and 40 non-conformities were found.

The legal provisions infringed are listed in Table 5. It can be seen that RDC Anvisa/MS no. 44, of August 17, 2009, was used much more frequently than the second-placed legislation, which was Municipal Ordinance no. 18, of May 13, 2003. Of the ten pieces of legislation most used to typify the inadequacies found during the period of our study, four refer to drugstores. These are: RDC Anvisa/MS No. 44/2009, Federal Ordinance/MS No. 344 of May 12, 1998, RDC Anvisa/MS No. 22 of April 29, 2014 and RDC Anvisa/MS No. 20 of May 5, 2011.

## DISCUSSION

The development of this work has made it possible to draw up a situational diagnosis of the inspection actions of Visa in the



Table 4. Frequencies of non-conformities found in other establishments between 2018 and 2019 in Fortaleza, Ceará.

Non-conformities from other establishments	N	%
<b>ILPI</b>	<b>10</b>	<b>25,00</b>
Inadequate storage of products	2	20,00
Lack of equipment or instruments necessary for the activity carried out	2	20,00
Proof of final disposal of expired medicines	1	10,00
Inadequate dispensing of medicines	1	10,00
Inadequate fractionation	1	10,00
Identification of areas or environments	1	10,00
Structural inadequacy	1	10,00
Lack of mandatory health documentation	1	10,00
<b>Biological material transporter</b>	<b>8</b>	<b>20,00</b>
Lack of mandatory health documentation	3	37,50
Schedule an inspection of vehicles that will be transporting biological material	2	25,00
Inadequate storage of products	1	12,50
Lack of protective equipment	1	12,50
Need for training on the work routine	1	12,50
<b>Mobile emergency service (ambulance)</b>	<b>5</b>	<b>12,50</b>
Lack of mandatory health documentation	3	60,00
Lack of equipment or instruments necessary for the activity carried out	2	40,00
Home care	5	12,50
Inadequate storage	1	20,00
Identification of areas or environments	1	20,00
Structural inadequacy	1	20,00
Lack of mandatory health documentation	1	20,00
Regularize change of address	1	20,00
<b>Medicines depot</b>	<b>3</b>	<b>7,50</b>
Identification of areas or environments	1	33,30
Lack of mandatory health documentation	1	33,30
Organization and general cleaning	1	33,30
<b>Grocery store</b>	<b>2</b>	<b>5,00</b>
Illegal marketing of medicines	2	100,00
<b>Trade in natural products</b>	<b>2</b>	<b>5,00</b>
Exhibiting medicines for sale without being licensed to do so	1	50,00
Display of products for sale without registration with the Ministry of Health	1	50,00
<b>Food trade</b>	<b>2</b>	<b>5,00</b>
Structural inadequacy	1	50,00
Lack of mandatory health documentation	1	50,00
<b>Street market</b>	<b>1</b>	<b>2,50</b>
Illegal marketing of medicines	1	100,00
<b>Bar</b>	<b>1</b>	<b>2,50</b>
Exhibiting medicines for sale without being licensed to do so	1	100,00
<b>Cosmetics distributor</b>	<b>1</b>	<b>2,50</b>
Lack of mandatory health documentation	1	100,00
<b>Total</b>	<b>40</b>	

Source: Prepared by the authors, 2022.

ILPI: Long-stay institution for the elderly.



area of pharmaceutical products and services, between 2018 and 2019, in the municipality of Fortaleza, Ceará. A possible limitation lies in the fact that one of the authors works in health

inspection in the municipality analyzed in this study. They therefore had to make an effort to remove personal impressions from the logical analysis of the results.

Table 5. Frequencies of legislation infringed by non-compliance, from 2018 to 2019, in Fortaleza, Ceará.

Legislation infringed	Non-conformity	
	N	%
RDC Anvisa/MS No. 44, of August 17, 2009	1.279	45,20
Municipal Ordinance No. 18 of May 13, 2003	210	7,40
Federal Ordinance/MS No. 344 of May 12, 1998	172	6,10
RDC Anvisa/MS No. 22, of April 29, 2014	167	5,90
Municipal Law No. 8.222, of December 28, 1998	149	5,30
RDC Anvisa/MS No. 16, of April 1, 2014	134	4,70
RDC Anvisa/MS No. 20, of May 5, 2011	103	3,60
Federal Ordinance/MS No. 802 of October 8, 1998	102	3,60
Federal Decree No. 8.077 of August 14, 2013	76	2,70
Municipal Law No. 8.221, of December 28, 1998	66	2,30
RDC Anvisa/MS No. 302, of October 13, 2005	62	2,20
Municipal Complementary Law no. 93, of August 29, 2011	52	1,80
Municipal Law No. 5.530, of December 17, 1981	49	1,70
RDC Anvisa/MS No. 16, of March 28, 2013	39	1,40
Law No. 5.991, of December 17, 1973	37	1,30
RDC Anvisa/MS No. 63, of November 25, 2011	24	0,90
Municipal Law No. 8.408 of December 24, 1999 as amended by Law No. 10.340 of April 28, 2015	23	0,80
Federal Law No. 6.360 of September 23, 1976	20	0,70
Municipal Complementary Law No. 270, of August 2, 2019	13	0,50
RDC Anvisa/MS No. 197, of December 26, 2017	7	0,30
RDC Anvisa/MS No. 58, of September 5, 2007	7	0,30
Municipal Complementary Law No. 159 of December 23, 2013	5	0,20
RDC Anvisa/MS No. 20, of April 10, 2014	5	0,20
RDC Anvisa/MS No. 11, of February 16, 2012	4	0,10
Municipal Ordinance No. 137 of May 20, 2015	4	0,10
Municipal Complementary Law No. 241, of November 22, 2017	3	0,10
RDC Anvisa/MS No. 283, of September 26, 2005	3	0,10
RDC Anvisa/MS No. 320, of November 22, 2002	3	0,10
RDC Anvisa/MS No. 11, of January 26, 2006	3	0,10
Anvisa RDC No. 275, of April 9, 2019	2	0,07
Federal Complementary Law No. 123 of December 14, 2006	1	0,04
Federal Law No. 13.021, of August 8, 2014	1	0,04
Federal Law No. 6.437, of August 20, 1977	1	0,04
Municipal Ordinance No. 1.040, of November 30, 2017	1	0,04
Municipal Ordinance/SMS No. 219, of January 10, 2017	1	0,04
RDC Anvisa/MS No. 153, of April 26, 2017	1	0,04
RDC Anvisa/MS No. 123, of May 12, 2005	1	0,04
Total	2.830	100,00

Source: Prepared by the authors, 2020.

RDC: Resolution of the Board of Directors; Anvisa: Brazilian Health Surveillance Agency; MS: Ministry of Health; SMS: Municipal Health Secretariat.





There was also an increase in the recording of activities from 2018 to 2019. This was due to the fact that 2018 was the year when the Fiscalize system was (de facto) implemented, operators were being sensitized to the use of the new tool and the *expertise* of the work process seemed incipient at the time.

Overall, drugstores accounted for the majority of the establishments inspected. However, it can be seen that the nine types of establishments that were inspected the least, with the exception of biological material transporters and drug warehouses, are inspections of activities subject to Visa, which are not exclusive to the area covered by this study. These are the so-called multidisciplinary inspections, in which the pharmaceutical products and services area is also involved, when there is evidence or suspicion of the presence of medicines in these places or when there are reports of illegal activities involving medicines.

The multidisciplinary group is made up of: ILPI, natural products trade, *home care*, grocery store, ambulance, food trade, bar, street market, and cosmetics distributor. Despite the low percentage, the importance of the interventions carried out in this group cannot be overlooked, as the activities they carry out involve a high potential for damage to the health of the exposed population. As supported by the working group (WG) of the Tripartite Visa Committee - Anvisa, National Council of Health Secretaries (Conass), National Council of Municipal Health Secretaries (Conasems) - in the categorization of Visa actions, the health risk is not directly related to the vertical complexity (high or low) of the actions but may be increased in low complexity actions<sup>9</sup>.

In the cases involving a grocery store, a natural products trade, a street market, a bar, and a cosmetics distributor, there was not even a notification, all of them were fined immediately, which points to the finding of a high health risk. For these cases, health legislation also provides for precautionary bans as a risk mitigation measure<sup>10</sup>.

Since health risk is a foreseeable uncertainty of an undesired event, which can take on qualitative and quantitative meanings<sup>11</sup> and, from an epidemiological point of view, can cause harm to a given population<sup>12</sup>, more frequent monitoring of the activities of these establishments that have had a high percentage of fines becomes a must for Visa. Therefore, it is necessary to work together with other actors and bodies that can contribute to reducing these risks, such as the Public Prosecutor's Office, Epidemiological Surveillance, and public safety bodies<sup>5</sup>.

The sanitary actions during the period under study were predominantly of an advisory nature, as the percentage of notifications was much higher than that of fines, showing a less police-like approach to inspections, in line with the guidelines of the Report of the National Health Surveillance Conference of 2001<sup>13</sup>. This seems to be a common procedure in other locations, where the percentage of interventions of a technical educational nature in relation to the irregularities identified was approximately 93%<sup>14</sup>.

The geographical distribution of the inspections in the study presented a panorama that should be analyzed very carefully when drawing up routes and planning operations for inspectors, since there was a higher concentration of non-compliances in the outlying districts compared to the more upmarket areas of the city, with a higher concentration of commercial establishments. A possible explanation for this could be the fact that Regional Secretariat III, which includes neighborhoods such as Parquelândia, Rodolfo Teófilo, Jóquei Clube, Antônio Bezerra, Presidente Kennedy, Henrique Jorge, and João XXIII, was a hub for the pilot experiment to implement the recording of actions in the Fiscalize system in the second half of 2017. This may have led to greater adherence by civil servants and, consequently, to a greater number of actions being recorded in Fiscalize from 2018 onwards, a period in which some regional offices were still not carrying out the entire procedure in this system.

This trend points to the conclusion that inspecting a lot does not mean reducing risks, since the region of the municipality with the highest number of inspected establishments and the highest percentage of inspections carried out was not the one with the highest frequency of non-compliance notices, since the greatest risks were present in the peripheral region, which is less visited by inspection teams. Therefore, the frequency of inspections can generate greater procedural zeal on the part of the regulated sector. Consequently, the number of inspections in the more peripheral areas of the municipality should be increased, implanting a culture of care in risk reduction, in order to achieve a higher level of sanitary adequacy in products and services provided to the population.

There are theoretical precedents in the health literature to reinforce the prioritization of actions. Navarro et al.<sup>15</sup> affirmed the need to plan interventions that target the highest risk services, giving up the annual inspection of low-risk establishments in order to improve the system's sanitary control. However, this study has shown the opposite: low-risk establishments may be the ones that least comply with health regulations and the ones that most put people's health at risk.

The non-conformities found in drugstores are similar to those found by Costa et al.<sup>16</sup> when they analyzed the health situation of medicines in SUS primary care, in which they found that the physical infrastructure and storage conditions of medicines were insufficient, especially in the North and Northeast regions of Brazil. However, our work differed from that study in relation to health documentation, because in our case, non-compliances in this aspect amounted to only 17.20%, while in the study by Costa et al.<sup>15</sup> this dimension ranged from 6.00% to 24.00%.

There is also a similarity with the results found by Bastos et al.<sup>17</sup> when inspecting pharmacies in the capital of Bahia. These authors observed that the technicians placed greater emphasis on items related to infrastructure, the sanitary conditions of the facilities and the existence of a pest control certificate.





In a study on the penalties imposed on pharmacies (other than drugstores) in Goiânia, it was found that 58.4% of them had been fined at least once and that 29.2% of the fines were for filling a prescription in disagreement with Federal Ordinance No. 344/1998, and/or Anvisa's RDCs No. 58, of September 5, 2007, and No. 52, of October 6, 2011<sup>18</sup>.

As for the wholesale medicines trade, which is commonly referred to as a medicines distributor, the item physical infrastructure and environmental conditions was found to be the most frequent. This aspect can cause a potentially high and gradual risk to the quality of medicines, since storage is a critical stage that must guarantee the quality and safe keeping of products, avoiding physical damage, theft, conservation, stock control, contributing to the correct and rational distribution of medicines and ensuring agility and proper management of distribution<sup>19</sup>.

In the wholesale trade, documentation is a type of document that has a high potential for damaging individual and collective health, because if the distributor doesn't demand that its customers present health documentation when they aren't authorized to do so, they could be contributing to the illegal sale of these products, since those who aren't legal aren't visible to the inspection and control bodies.

In addition, the drugs that have had their cargo stolen end up going to illegal pharmacies, other distributors or being sold on the internet<sup>20</sup>. This may also be the explanation for the existence of medicines found in street markets, bars, and grocery stores in the municipality of Fortaleza, as found in this study.

Martins and Galato<sup>21</sup>, researching the notifications and sanitary measures for irregularities involving medicines marketed in Brazil between 2012 and 2017, found that these products accounted for 38.5% of all occurrences notified in the period (medicines, health products, sanitizers, cosmetics, blood and blood components). They also found that importers and distributors of medicines were among the establishments that responded to health measures in the period.

As for clinical analysis laboratories and laboratory collection points, physical infrastructure and documentation were the most frequently mentioned aspects. The documentation item includes health licenses, certificates of technical responsibility and proof of equipment maintenance and calibration.

The results are similar to those of the study carried out by Navarro et al.<sup>15</sup> in the state of Bahia, which analyzed risk control in radiodiagnostic services in which 10% of the establishments had no technical manager and equipment and practices were inadequate in 68% of the procedures.

In terms of worker health and safety, there was one occurrence related to a lack of personal protective equipment (PPE) and none related to collective protective equipment (CPE). This result is different to that found by Batista and Nascimento<sup>22</sup> who, analyzing clinical analysis laboratories in the municipality

of Campina Grande-PB, found that the lack of PPE by workers amounted to 20%.

There were few occurrences of internal and external quality controls, as part of the standardized operating procedure (SOP), which could mean that most of the laboratories inspected carried out these controls. A similar result was observed in the study by Gonçalves et al.<sup>23</sup> in which approximately 76% of the records on the subject provided information on the existence of quality controls carried out by the laboratories monitored in that study. In this area of quality control, Pessoa and Ferreira<sup>24</sup> pointed out that the use of certified materials and methods interferes with the accuracy of the results released by the clinical laboratory, which can compromise the safe interpretation of the results.

The other item in these two groups mostly refers to the lack of microbiological analysis of the water used by these types of establishments.

Non-conformities related to waste management, which are present in both clinical laboratories (4.00%) and laboratory collection points (5.00%), were also found in the studies by Batista and Nascimento<sup>22</sup>, to a lesser extent (0.8%), and by Giraldele et al.<sup>25</sup>, who observed a total lack of management and proper disposal of chemical waste and staff training on the risks of handling chemical products in pathology laboratories.

The lack of an adequate structure can directly interfere with the quality of the items sold, which is why Visa actions in these companies can contribute to reducing the risk related to health products<sup>26</sup>.

The documentation item, for both wholesalers and retailers of health products, includes the health license, the company's authorization to operate (AFE), the certificate of technical responsibility, the register of suppliers and the list of products sold, the contract with the third-party service provider and the SOPs.

The good origin of the products marketed is guaranteed by the qualifications of the suppliers and proof that the products have been registered with the competent health agency. In this respect, Nascimento<sup>27</sup>, when evaluating the rejection of registrations for high-risk medical devices, found that in many cases the reason was due to a lack of documents proving safety for users and efficacy for a particular clinical condition. He argues that this absence can cause harm to patients by preventing the use of another more appropriate intervention for the illness.

The incidents related to receiving and shipping were about the need to identify these areas. Regarding storage, the non-conformity was the temperature above that recommended by the manufacturers. The results are similar to those found by Braga et al.<sup>26</sup>, who assessed good practices in the distribution and import of health products from companies in the municipality of Curitiba. These researchers found that 34% of the



companies were non-compliant in terms of physical structure, 28% lacked organization and 18% did not have a product traceability system. These three items are included in this study, in the description of infrastructure, adding up to 41.00% in the case of the wholesale trade and 54.00% in the case of the retail trade.

The importance of working on the requirement for establishments to acquire systems that allow traceability is well described in the work by Morais et al.<sup>28</sup>. According to the authors, the simple delay in notifying a technical complaint or an adverse event in the Notivisa system can compromise sanitary practices and create a risk to human health. In this context, if companies don't have systems in place to enable the traceability of notified products, there could be a break in the chain of actions designed to promote health protection, which is so well defined in the Brazilian concept of Visa.

Among the multidisciplinary establishments, the ILPIs are the ones with the most inadequacies. The non-conformities accounted for in this study refer mainly to the inadequate storage of products and the lack of equipment or instruments necessary for the activity carried out.

The results of the ILPI survey highlight the need for more frequent action, more constant vigilance on the part of the public authorities regarding these institutions. In the municipality of Fortaleza, several inspections were prompted by letters from the State Public Prosecutor's Office, which accompanied the inspections through the presence of prosecutors interested in the issue of protecting the elderly<sup>29</sup>.

Biological material transporters appear as the second most frequent of this group in terms of inadequacies found. These transporters take human materials such as blood and blood products, anatomopathological specimens and other items from their collection points to the support laboratory that carries out the analysis. The non-conformities observed in this type were of a documentary nature and related to the inspection of the vehicles used in transportation.

Of the ten pieces of legislation most used to classify inadequacies, four refer to drugstores, which coincides with the fact that they are the establishments most visited by Visa inspectors. The fact that Municipal Ordinance no. 18/2003 appears in second

place is not surprising, as it refers to both clinical laboratories and laboratory collection points.

Despite the various pieces of municipal legislation used by the inspectorate, the municipality of Fortaleza still does not have a Municipal Sanitary Code and since 1981 has based its sanitary actions (in addition to Federal Laws) on the Code of Works and Postures, which was replaced by the City Code (Complementary Law no. 270, of August 2, 2019). The practice of using the Municipal Code of Ordinances in the absence of the Sanitary Code was also observed in a municipality in the recôncavo region of Bahia<sup>30</sup>.

Finally, the use of secondary data represented a limitation of the study, as the data was recorded manually and coincided with the first years of implementation of the Fiscalize system, so there is a possibility of errors in entering the information or not recording occurrences, despite the obligation to fill it in. The information is also restricted to the years 2018 and 2019, when the system began to be used, which made it impossible to make comparisons with other years. Despite this, the system has provided official, systematized data that has made it possible to draw up a diagnosis of the situation.

## CONCLUSIONS

The percentages of notifications and fines pointed to a tendency for inspection procedures to be carried out mostly to make those responsible for the regulated segments aware of the need to promote technical improvements and legal adjustments.

Although there are small percentage differences in the results of notices compared to other work, it can be said that the actions of health inspection agents followed the health standards observed in other Brazilian municipalities. The starting point for this analysis was that the lower risk situations (notified) were treated as guidelines for improving behavior, as they did not give rise to more drastic interventions such as fines and bans.

As a continental country, Brazil should encourage studies that portray the health reality of its other large municipalities, because knowing the actions taken and their results can encourage targeted planning of interventions that result in the provision of better quality products and services for its citizens.

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#### Authors' Contribution

Mendes GL, Arrais PSD - Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. All the authors approved the final version of the work.

#### Conflict of Interest

The authors inform that there is no potential conflict of interest with peers and institutions, political or financial, in this study.



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