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Health regulatory actions in community pharmacies: Analysis of a national survey

Ações da vigilância sanitária em farmácias comunitárias: análise de uma consulta nacional

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ABSTRACT

Introduction: Law No. 13.021, August 8, 2014, revised the concept of pharmacy in Brazil boosting Brazilian Health Regulatory Agency (Anvisa) to review RDC No. 44/2009, a local regulation for this service. An immediate action was conducting a consultation directed to the National Health Regulatory System about this rule. **Objective:** To identify health regulatory actions related to health services in community pharmacies. **Methods:** This is a descriptive cross-sectional study carried out with secondary data from the consultation addressed to local Health Regulatory System representants (Visa) promoted in 2019 by Anvisa. The responses of the 349 respondents were organized in the following blocks: 'General Considerations', 'Structure', 'Process' and 'Monitoring' and categorized according to the question format (open or closed) and content, using health assessment parameters. **Results:** To share pharmaceutical dispensing with other healthcare activities reflected a health risk regarding structure. Waste management was the most cited process, surpassing those related to pharmaceutical assistance. As for monitoring, the document named Statement on Pharmaceutical Care proved to be a good instrument for recording activities performed, while notifications of adverse events and technical complaints did not appear as a routine. The decentralization in Visa actions is well established, but has evolved unevenly for regulated products and health activities, so that the role RDC No. 44 of 2009 proved to be useful, but outdated about health services. **Conclusions:** The delimitation of health activities in pharmacies is a challenge for Brazilian health regulatory agency, either by the adjustment of sanitary regulation, either by the technologies of products and services that are updated faster than the analysis of the risks involved in the its exposure to the population.

KEYWORDS: Health Surveillance; Community Pharmacy; Health Services; RDC No. 44/2009

RESUMO

Introdução: A Lei nº 13.021, de 8 de agosto de 2014, renovou o conceito de farmácia, impulsionando ações da Agência Nacional de Vigilância Sanitária (Anvisa) para a atualização da RDC n° 44, de 17 de agosto de 2009, como a realização de uma consulta dirigida ao Sistema Nacional de Vigilância Sanitária sobre a resolução. **Objetivo:** Identificar ações de vigilância sanitária relacionadas aos serviços de saúde em farmácias comunitárias. **Método:** Trata-se de um estudo transversal descritivo realizado com dados secundários da consulta dirigida às Vigilâncias Sanitárias (Visa) municipais promovida em 2019 pela Anvisa. As respostas das 349 respondentes foram organizadas nos blocos "Considerações Gerais", "Estrutura", "Processo e Monitoramento" e categorizados conforme o formato de pergunta (aberta ou fechada) e o conteúdo, utilizando-se parâmetros de avaliação em saúde. **Resultados:** O compartilhamento do local da dispensação com outras atividades de saúde refletiu um risco sanitário quanto a estrutura. O gerenciamento dos resíduos foi o processo mais citado, superando aqueles relacionados à assistência farmacêutica. Quanto ao monitoramento, a Declaração de Serviços Farmacêuticos mostrou-se um bom instrumento para o registro das atividades realizadas, enquanto notificações de eventos

adversos e queixas técnicas não apareceram como rotineiros. A descentralização nas ações de Visa está bem estabelecida, mas evoluiu de forma desigual para produtos regulados e atividades de saúde, de forma que a RDC n° 44 de 2009 mostrou-se útil, mas desatualizada nos aspectos impactantes aos serviços de saúde. **Conclusões:** A delimitação de atividades de saúde em farmácias é um desafio para a vigilância sanitária, seja pelo ajuste do regulamento sanitário, seja pelas tecnologias de produtos e serviços que são atualizadas mais rapidamente do que a análise dos riscos envolvidos na sua exposição à população.

PALAVRAS-CHAVE: Vigilância Sanitária; Farmácia Comunitária; Serviços de Saúde; RDC nº 44/2009

INTRODUCTION

Health surveillance, an integral part of public health[1], uses different tools to fulfill its objective of safeguarding the Brazilian population from the risks arising from the consumption of products and services[2,28] that can alter the state of health of the individual[3], the main ones being: legislation, inspection, monitoring and health communication actions[1]. These services are provided by establishments licensed by the Health Surveillance Agency (VISA) to sell products directly, such as restaurants and supermarkets, as well as in health services that provide assistance to individuals or the human population.

The pharmacy follows a mixed path between a commercial establishment and a health establishment, which has specific characteristics for its health regulation in Brazil. The production of medicines on an industrial scale from the 1930s onwards led the pharmacy into an expressively commercial context[4], connecting the dispensing of medication more to the sale of products than to an integral process of patient care[5]. This was characterized both by Law No. 5.991, of December 19, 1973, which conceptualizes pharmacy as commerce[6] and by its very organization, which would promote productivity and profitability (the latter, for private pharmacies), especially around medicines, rather than humanized user care.[7]

The commercial transaction for the acquisition of medicines continued to be one of the main focuses of health surveillance actions in these establishments, until the publication of Collegiate Board Resolution (RDC) No. 44, of August 17, 2009, by the National Health-Regulatory Agency (Anvisa)[8]. The health regulation describing good practices in pharmacies and drugstores included pharmaceutical services as permitted activities in these establishments, which at the time were limited to the administration of medicines, pharmaceutical care (including home care) and earlobe piercing for earrings.

Discussions on health services in pharmacies continued with the Federal Pharmacy Council (CFF), which, in 2012, set up a working group on the role of pharmacists in patient care, giving the profession a new meaning with concepts such as pharmaceutical care and pharmaceutical care[9]. The pharmaceutical care policy promoted by the Ministry of Health since 2004 has also reviewed the position of pharmaceutical services in Primary Care, so that in 2014 it published the Pharmaceutical Care series.

In Primary Health Care[10]. The first booklet in the collection, called Pharmaceutical Services in Primary Health Care, in addition to considerations of the financing of the policy's programs, highlighted clinical pharmaceutical services and actions for the rational use of medicines (now renamed safe use of medicines) as a point of patient care, going beyond the focus on the logistics of distributing medicines. There was also a historical revival of the term community pharmacy, which was used to define pharmacies that did not provide hospital pharmacy or clinical pharmacy services[11].

However, the biggest innovation regarding health services in pharmacies was yet to come. In 2014, Federal Law No. 13,021 of August 8 was published, which provides for the exercise and supervision of pharmaceutical activities. The law updated the concept of pharmacy described in 1973 to "a service unit designed to provide pharmaceutical care, health care and individual and collective health guidance"[12]. The scope of activity of this establishment in health care was thus broadened. Doubts about the licensing and operation of the vaccination activity, explained in the law as an authorized activity for pharmacies, and others not described in RDC 44/2009, began to reach Anvisa[13], from various social actors, including state and municipal Visa.

As one of the actions to capture evidence of the need to revise RDC No. 44/2009, Anvisa proposed and carried out a consultation directed at municipal VASAs[14]. The responses to the consultation were the starting point for this research, which aimed to identify the health surveillance actions related to health services carried out in community pharmacies based on the panorama presented in this national consultation.

METHOD

This is a descriptive cross-sectional survey that used as its data source the report of the consultation directed at municipal Visa on health care services in community pharmacies, carried out by Anvisa in 2019.

The data for this study was collected from the responses to the questionnaire drawn up for the targeted consultation, which was made available to municipal Visa from June 17 to August 21, 2019. The forms completed and considered valid by the LimeySurvey platform (forms with the mandatory fields filled in and which triggered the Send command) resulted in 349 Visa respondents.

The survey started from this point, taking advantage of the organization into blocks of questions proposed in the form: (1) General Considerations, which took into account the way in which Visa is organized to deal with issues relating to community

pharmacies; (2) Structure, characterized by the "physically determined and specialized space for the development of certain activity(ies), characterized by different dimensions and facilities"[15] and by the stable elements of a health service[15], such as material, human and organizational resources; (3) Process, a block that assesses the quality of the health service through the relationship between health professional and service user[16]; and (4) Monitoring, by Silva[16] as the systematic monitoring of certain characteristics of the service.

For each block, the answers to the closed and open questions were considered. Microsoft Excel, software for creating and editing spreadsheets, was used to organize the data captured from all the answers.

In dealing with the closed questions, only those actually selected by the respondents were considered. The results were organized in tables.

When dealing with the open questions, answers described as yes, no, acronyms, random words or phrases or disconnected from the question or the research objective were excluded. The answers considered for analysis were categorized into groups according to content, considering words, texts or similar contexts, which were also used to name and quantify the groups, allowing them to be organized in tables.

For the content analysis, we used the logic of delimiting the focus of the analysis of the evaluation suggested by Silva[16], with the object of evaluation being the surveillance actions in community pharmacies carried out on the basis of RDC No. 44/2009, verifying how the technical-scientific components, effectiveness and usefulness of the standard, after the change in the concept of pharmacy by Law No. 13.021/2014.

RESULTS

As can be seen in Table 1, only two states (Sergipe and Roraima) did not register municipalities that responded to the survey. The states with the most municipalities responding were

Table 1. Geographical distribution of the sample with absolute and relative frequencies of the responding Health Surveillances.

Regions	States	Responding municipalities (n)	Absolute Frequency (n)	Relative Frequency (%)
North	Acre (AC)	1	25	7.16%
	Amapá (AP)	3		
	Amazonas (AM)	1		
	Pará (PA)	8		
	Tocantins (TO)	3		
	Rondônia (RO)	9		
	Roraima (RR)	0		
North East	Ceará (CE)	3	74	21.20%
	Maranhão (MA)	2		
	Alagoas (AL)	17		
	Paraíba (PB)	2		
	Pernambuco (PE)	2		
	Piauí (PI)	1		
	Rio Grande do Norte (RN)	5		
	Sergipe (SE)	0		
	Bahia (BA)	42		
Midwest	Mato Grosso (MT)	4	14	4.01%
	Mato Grosso do Sul (MS)	8		
	Federal District (DF)	1		
	Goiás (GO)	1		
South East	Espírito Santo (ES) n = 24	24	128	36.68%
	Rio de Janeiro (RJ) n = 17	17		
	São Paulo (SP) n = 66	66		
	Minas Gerais (MG) n = 21	21		
South	Santa Catarina (SC) n = 17	17	108	30.95%
	Rio Grande do Sul (RS) n = 27	27		
	Paraná (PR) n = 64	64		
Total		349	349	100.00% (n = 349)

Source: Prepared by the authors based on the technical report: targeted consultation on health care services in community pharmacies, 2021.

São Paulo (66), Paraná (64) and Bahia (42). Twenty-one capital cities participated[14], with an estimated population of 45,100,405 inhabitants[17], characterizing a relevant sample of the Brazilian population served by municipal Visa. Capital cities such as São Paulo, Rio de Janeiro, Curitiba and Florianópolis had more than one Visa unit. In contrast to these situations, the Federal District has administrative regions, but the inspection organization is based at the head office, which was the one that responded to the survey. There was one response from the Rio Grande do Norte State Visa.

For the majority of participants, community pharmacy is a general responsibility of health surveillance, with no subdivision for dealing with the subject[14]. In the places where it is specifically dealt with, it was noted that the inspection activity is linked to the area of products[14], which may be an indication that Visa connects the issue more to the inspection of the regulated product than to the health service provided in this establishment.

With regard to the federative entity responsible for inspecting and licensing pharmacies (the state, the municipality itself or both), 71.35% of the responding municipalities assumed responsibility for these tasks[14]. There was an imprecision in the answers to the subsequent questions in the questionnaire, which were intended to capture whether health services are part of the routine attributions of community pharmacies within the current concepts of pharmaceutical assistance presented in Law 13.021/2014, which made it impossible to tabulate this data.

The types of healthcare services must be licensed by the local Visa[6]. Table 2 shows the services listed in RDC No. 44/2009 and CFF Resolution No. 499 of December 17, 2008[18] and others captured by Anvisa in the questions received about the permission to perform these services in community pharmacies between 2016 and 2019[14]. According to the respondents, all of the services listed are carried out to a greater or lesser extent, and the most commonly performed are: measuring physiological parameters (85.96%), administering medication (82.52%), measuring biochemical parameters - blood glucose (69.34%) and pharmaceutical assistance (59.89%), all of which are provided for in RDC 44/2009.

The "other" field, selected by 14.04% of the Visa respondents in Table 2, was developed into an open question, which asked for a description of these other services. The breakdown of this data indicated that the Visa registers the expansion of the health services listed in RDC 44/2009 after ten years of the standard being in force[14]. It is important to point out that vaccination services in healthcare establishments such as pharmacies are regulated in RDC No. 197, December 26, 2017[21], so there is no irregularity in the health regulations for carrying out this activity in community pharmacies.

This service, as well as aesthetic procedures[19] and acu- puncture[20], are currently regulated by the CFF, so that pharmacists are authorized by their professional council to perform them. The measurement of biochemical parameters other than glycemia had a considerable representation among the Visa, suggesting that the legal restriction on checking only glycemia should be rethought. As for the regulations used to inspect these services, approximately 90.00% reported using RDC no. 44/2009 supplemented by state or municipal regulations[14].

Table 2. Types of health care services offered in community pharmacies in the responding municipalities and citation in legislation.

Healthcare service/activity	Absolute frequency (n)	Relative frequency (%)	Expressed in RDC No. 44/2009	Expressed in RDC No. 499/2008 from CFF
Measurement of physiological parameters (body temperature and blood pressure)	300	85.96%	X	X
Administration of injectable medicines	288	82.52%	X	X
Measurement of biochemical parameters (blood glucose)	242	69.34%	X	X
Pharmaceutical assistance (consultation with the pharmacist)	209	59.89%	X	X
Administration of non-injectable medicines	99	28.37%	X	
Measurement of physiological parameters (other than body temperature)	88	25.21%		
Small dressings	67	19.20%		X
Nebulization	60	17.19%		X
Others	49	14.04%		
Vaccinations	42	12.03%		
Measurement of biochemical parameters (other than blood glucose)	31	8.88%		
Extramural vaccination by private services	14	4.01%		
Dressings, regardless of size	6	1.72%		
Total	349	100.00%		

Source: Prepared by the authors based on the technical report: targeted consultation on health care services in community pharmacies, 2021.
CFF: Federal Pharmacy Council.

Aspects related to the structure of the health service in community pharmacies

Almost 50.00% of the participating VAS responded that the location for pharmaceutical guidance could be shared with dispensing; 30.09% considered that guidance could be carried out alongside other health care activities; and approximately 18.00% felt that there should be an exclusive room for pharmaceutical guidance (Table 3). The most frequent justifications of the Visa respondents who said that sharing was prevented for technical reasons were: confidentiality, ethics, safety, privacy and patient comfort[14], in line with article 15 of RDC no. 44/2009.

Carrying out dispensing activities in the same place as health care activities (disregarding pharmaceutical guidance in this question) is not acceptable to the majority of local Visa (only 4.58% said that the activities could share space). On the other hand, the sharing of areas between health care activities and pharmaceutical guidance was considered acceptable by almost 35.00% of the respondents and a specific area for these health care activities is essential for 51.86% of the VAS surveyed, as can be seen in Table 3.

The technical impediments to sharing health care activities with others carried out by community pharmacies pointed out by some of the Visa respondents involved, for example, the promotion of good practices related to hygiene, infection control, safe drug administration and patient care[14].

The legal basis most cited to justify the infrastructure requirements was RDC No. 44/2009 and the the technical basis was safety and quality of service, described in general terms in the RDC[14].

Aspects related to the processes involved in community pharmacy services

They were looking for elements that could provide a record of this relationship, including the safety in which the service is practiced. Respondents had to select the documents that are usually available in a health surveillance action. The results are shown in Table 4. The procedures for managing health service waste were the most cited in the survey (80.23%).

It is noteworthy that procedures such as the updated list of health establishments and protocols related to pharmaceutical care are below 50.00% of the documents made available to Visa, which may indicate that health services are not yet viewed in this way by this pharmaceutical sector. The procedures relating to the vaccination service[21] are not the subject of this research and were not included in the analysis, but are reported in Table 4 as they are part of the list of responses.

Aspects related to health surveillance monitoring and health services in community pharmacies

For this research, the characteristics highlighted were the records and notifications that should be made available to Visa, including those directed at Anvisa's institutional monitoring systems, such as Notivisa 2.0 (patient-related adverse events) and Vigimed (drug-related adverse events, including adverse reactions). The under-reporting of the occurrence or suspicion of adverse events and medication errors was evident in Table 5, with the Declaration of Pharmaceutical Services, a document that reports the services provided, being the most cited instrument. Once again, data on vaccination services was not analyzed, as it is linked to specific legislation on the subject and not to RDC 44/2009.

DISCUSSION

The first important result of this study is the decentralization of health surveillance actions in community pharmacies, which is an advance on the panorama reported by Brito[22] on the National Health Surveillance System (SNVS), even if there is still no niche dedicated to the subject in most municipalities. However, the proximity of these actions to the inspection of products, rather than regulated health services, as evidenced

Table 3. Sharing of premises between the activities carried out in a community pharmacy, according to the respondent Health Surveillance agencies.

Pharmaceutical guidance	Absolute frequency (n)	Relative frequency (%)	Health care activities	Absolute frequency (n)	Relative frequency (%)
Can be carried out in the same place as the dispensing of medicines	160	45.85%	Does not occur in the pharmaceutical guidance environment or in the dispensing area	181	51.86%
Can be carried out with other health care activities (e.g. administration of medication, nebulization, dressings)	105	30.09%	Can be shared with the pharmaceutical guidance area	121	34.67%
There must be an exclusive place for this activity (it does not occur in the dispensing area or in the environment of other health care activities such as administration of medication, nebulization, dressings)	62	17.77%	Can be shared with drug dispensing	16	4.58%
No reply	22	6.30%	No reply	31	8.88%
Total	349	100.00%	Total	349	100.00%

Source: Prepared by the authors based on the technical report: targeted consultation on health care services in community pharmacies, 2021.

Table 4. Quality documents made available to Health Surveillance by pharmacies during inspections.

Documents provided by community pharmacies to Health Surveillance during routine inspections	Absolute frequency (n)	Relative frequency (%)
Written procedures on health service waste management	280	80.23%
Procedures on the administration of medicines when administered in the pharmacy	232	66.48%
Records of periodic maintenance and calibration of the equipment used to measure parameters physiological and biochemical parameters allowed by RDC No. 44/2009	193	55.30%
Records relating to health care activities, with information on the user, the guidance and pharmaceutical interventions carried out and the results thereof, as well as information on the professional responsible for carrying out the service.	182	52.15%
Up-to-date list identifying the nearest public health establishments, containing the address and telephone number	142	40.69%
Protocols related to pharmaceutical care, including bibliographical references and indicators	135	38.68%
Recording the maximum and minimum temperatures of the equipment used to store vaccines	114	32.66%
Record of training for vaccination activities	75	21.49%
Procedure for dealing with vaccine-related complications	56	16.05%
Total	1.409	100.00%

Source: Prepared by the authors based on the technical report: targeted consultation on health care services in community pharmacies, 2021.

Table 5. Notifications and records made by pharmacies.

Records and notifications	Absolute Frequency (n)	Relative Frequency (%)
Registration of use of the Pharmaceutical Service Declaration	234	67.05%
Notifications of occurrences or suspicions of adverse events related to healthcare activities to the health authorities	76	21.78%
Reporting of medication errors according to Anvisa's reporting system	43	12.32%
Notifications of occurrences or suspicions of technical complaints related to health care activities carried out in the pharmacy to the health authorities	50	14.33%
Recording information on vaccines administered in the Ministry of Health's information system.	47	13.47%
Recording information on the origin of the vaccine	44	12.61%
Notification of the occurrence of adverse events following immunization (AEFI) as determined by the Ministry of Health	32	9.17%
Procedures for investigating incidents and failures that may have contributed to the occurrence of errors vaccination	25	7.61%
Total*	551	100.00%

Source: Prepared by the authors based on the technical report: targeted consultation on health care services in community pharmacies, 2021.
*The question allowed for multiple choice, which is why the total value was higher than the number of respondents (349).

by the distribution of the topic in both the surveillance and the standards used, is a strong indication that basic work needs to be done so that the basic concepts of health services are worked on with these actors in order to redefine and broaden the focus of inspection[23].

In this sense, Anvisa, as the coordinator of the SNVS and with a more general view of the subject, should help local VASAs[23], not only by updating RDC 44/2009 on these issues, but also by better disseminating the current rules on health services. Another action that could help adapt to the new framework is to promote alignment between health surveillance and the Ministry of Health's primary care policy.

In a general assessment of the responses, the federal health regulation appeared to be the regulatory tool most used by the respondents, so that RDC 44/2009 represents a normative pillar for states and municipalities in their inspection and surveillance of pharmacies. In this sense, its updating in relation to the new concept of pharmacy is also necessary so that inspection actions do not conflict with what is currently being defined and practiced as pharmaceutical care and, in a broader sense, health care, a recurring challenge for health surveillance of health services[24]. This is confirmed by the answers to the questionnaire about the services currently offered in pharmacies, which shows an expansion of the activities provided for in RDC 44/2009, such as dressings and beauty services (provided for in specific CFF resolutions) or nebulization and the performance of tests close to the patient for biochemical parameters other than glycemia.

One possible way to update the Visa on the dynamics of health services in pharmacies would be to reformulate the concept proposed by Correr and Ribeiro[11] for community pharmacies,

including the specific characteristics of these establishments, which serve a specific territory by dispensing and, in the case of private pharmacies, selling medicines and offering health services aimed at primary care in that community. This also gives them an identity with the region they serve, making it possible to construct public policies for the pharmacotherapeutic care of that population.

There is an additional reflection on this result: should the health regulations on health services in community pharmacies list the health activities that can be carried out by health professionals in this location, or should these activities be defined by the professional council responsible for the qualification of the health professional carrying out the service[25], leaving it up to surveillance to observe and inspect the quality of this service? Given that the first option does not apply to any other health establishment and that the number of activities may vary, this does not seem to be the best option. Allied to this, there is the example of the failure to implement Normative Instruction No. 9 of August 17, 2009, which proposed a positive list of products other than those regulated that could be sold in pharmacies and which was not implemented in most Brazilian states due to the impediment arising from lawsuits filed by representatives of pharmaceutical establishments precisely because of the restriction on the sale of products[26].

The sharing of environments for health care activities deserves a more careful discussion, since for almost 50.00% of the Visa respondents, the pharmacist's guidance can be practiced in the same place as the dispensing of medicines, despite the fact that RDC 44/2009 recommends an environment for individualized care that guarantees privacy and comfort for the service user, which, according to Leite et al.[27], favors service and interaction between the pharmacist and the pharmacy user, and it is therefore desirable that this remain a guideline for the physical structure. On the other hand, sharing dispensing activities with other health care activities is not acceptable to more than 50.00% of the Visa, who believe that there should be an exclusive room to carry out these activities. This data seems to confirm the distance between dispensing in pharmacies and pharmaceutical care, as also pointed out in the study by Leite et al.[27].

The pharmacist's intervention in primary care[29,30,31], including the monitoring of chronic diseases[32,33], is widely discussed in the literature and should also affect health surveillance's discussion of best practices in the community pharmacy, both in terms of physical structure and processes that bring it closer to a health service.

As for the pharmaceutical care protocols related to the health care process, this study found that they are less common than the waste management protocol, despite the fact that they represent the guiding activity for other care actions that have already been standardized, such as measuring physiological and biochemical parameters. It is therefore understood that an integrated movement by the SNVS to update new pharmaceutical care practices is necessary to support the Visa in the transition from looking only at the surveillance of the marketed product to the surveillance of the health service also offered.

With regard to monitoring the health activities carried out in the pharmacy, there was a similar impression to the process: although the Pharmaceutical Services Declaration is a document presented by more than 60.00% of pharmacies, the records and notifications that are involved in the activities referred to in the Declaration are under-reported by the establishments. It is necessary to check whether the information in the Pharmaceutical Services Declaration is still relevant to Visa in the format proposed when RDC 44/2009 was published, without the changes demanded by the legal innovations and pharmaceutical practice that have taken place in the ten years the regulation has been in force.

The study was carried out with a significant number of surveillance agents, but it is recommended that the sample be expanded in future studies to get a closer look at the reality of health surveillance activities in pharmacies. Another point that deserves attention in terms of data processing is that this research format is new to the Regulatory Agency and it is possible that the way in which the data is captured and organized could be improved.

CONCLUSIONS

The identification of health activities carried out in community pharmacies is neither objective nor easy for Visa to highlight, due to the various crossings exposed in the research. From the analysis of the understanding and application of the standard, the aspects linked to structure seem to be more understood and applied than those of process and monitoring. Some points that may be linked to this perception are: the health regulatory profile is more directed at the structure of the service; risk identification is more objective in this respect; updating and communication between the regulatory body and VASIs on technological innovations are deficient, so that the information is not temporally adjusted for those involved in the actions.

The adjustment between specific health legislation and the object of care is a permanent challenge for the regulatory agent: in general, technological innovation, both in terms of the product and the health professional, precedes and provokes the updating of the Visa, a situation that has long been diagnosed in discussions involving the activities of this sector. RDC 44/2009 followed this path, and the provocation to update it comes not only from a law specific to the activities carried out by the pharmaceutical professional, but also from the practice identified for this service by the local VAS themselves, who reported the innovations in their answers to the survey. This is a setback generally faced by technical standards. Specifically for Visa, the object of action requires a constant analysis of risk and benefit and it is essential that the other instruments of action and intervention of health surveillance are integrated and tuned in such a way as to complement the management of the risk of innovation until the specific regulation is updated.

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Authors' Contribution

Jubé TA - Conception, planning (study design), acquisition, analysis, data interpretation and writing of the work. Barreto JOM - Conception, planning (study design), 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.