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Teleworking in the Brazilian Health Regulatory Agency and innovation in the import of medical devices

Teletrabalho na Agência Nacional de Vigilância Sanitária e a inovação na anuência de importação de produtos para saúde

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ABSTRACT

Introduction: The insertion of teleworking for the import process of medical devices, brought innovation to all actors involved in this process. The improvement in the quality of life of the patients, added to the centralized monitoring of the processes, were points sought by the management. **Method:** We used the trimesters from 03/01/2018 to 08/31/2018, when the harmonizations and operational procedures were already in force at the Virtual Post. We made a comparative analysis based on parameters inherent to the flow of importation of health products, such as: deadline of the analysis of the importation process and qualification of the reasons of non-compliance in the importation processes (product irregularity or procedural instruction error) to show the main results achieved in telecommuting. **Objective:** The purpose of this report is to show the main results achieved in teleworking, from 01/03/2018 to 08/31/2018, through the evaluation of indicators of the analysis period and the quality of the instruction of the import processes. **Results:** The centralization of the consenting parties in teleworking sought as a result harmonizing the consent procedures as well as guaranteeing to those involved the predictability of the analysis of the import processes; a productivity increase that was beneficial to Anvisa's efficiency was also sought. As a result, predictability was the most representative. The centralization of the processes in a virtual post, managed by a leader, has brought significant results regarding the harmonization and the possibility of data extraction. **Conclusions:** The extremely positive results of the survey brought other issues; it was verified that the constant improvement in the process is necessary. It is also necessary to formalize the import as an effective control of pre-market, using these data to guide sectoral policies.

KEYWORDS: Brazilian Health Regulatory Agency; Import; Teleworking; Productivity; Medical Device

RESUMO

Introdução: A inserção do teletrabalho para os anuentes de processos de importação de produtos para saúde trouxe inovação a todos os envolvidos na importação. A melhoria na qualidade de vida dos anuentes somada ao acompanhamento centralizado dos processos foram pontos almejados pela gestão. **Método:** Utilizou-se o corte temporal de 1º de março a 31 de agosto de 2018 trimestre no qual as harmonizações e procedimentos operacionais já estavam vigentes no Posto Virtual. Assim, procedemos a análise comparativa baseada em parâmetros inerentes ao fluxo de importação de produtos para saúde, como: prazo de análise do processo de importação e qualificação das motivações de não anuência nos processos de importação (irregularidade de produtos ou erro de instrução processual) para mostrar os principais resultados alcançados no teletrabalho. **Objetivo:** Mostrar os principais resultados alcançados no teletrabalho, no período de 1º de março a 31 de agosto de 2018, por meio da avaliação de indicadores de prazo de análise e de qualidade da instrução dos processos de importação. **Resultados:** A centralização dos anuentes no teletrabalho buscava como resultados a harmonização dos procedimentos de anuência bem como garantir aos envolvidos a previsibilidade da análise dos processos de importação, além do incremento de produtividade benéfica à eficiência da Anvisa. Como resultado, a previsibilidade foi a mais representativa. A centralização dos processos em um posto virtual, gerenciado por um líder, trouxe resultados significativos quanto à harmonização e a possibilidade de extração de dados. **Conclusões:** Os resultados extremamente positivos do levantamento trouxeram outras questões e foi verificado que a melhoria constante no processo é necessária. Há de se propiciar a formalização da importação como um controle efetivo de pré-mercado, utilizando-se destes dados para direcionar políticas setoriais.

PALAVRAS-CHAVE: Agência Nacional de Vigilância Sanitária; Importação; Teletrabalho; Produtividade; Produtos para Saúde

INTRODUCTION

This report describes the changes that occurred in the management analysis of the processes of importation of health products subject to health surveillance, imported under the Integrated Foreign Trade System (Siscomex)[1], within the General Management of Ports, Airports, Borders and Bonded Warehouses (GGPAF) of the Brazilian National Health Surveillance Agency (Anvisa), after the implementation of teleworking regime for consenting servants, according to the innovative publication of Anvisa Ordinance n. 1.665, of October 2, 2017[2].

Institutional context of the consent to import health products

Anvisa is responsible for the sanitary inspection of products subject to health surveillance, including the procedures related to technical-administrative document analysis and physical inspection of imported goods or products, with the purpose of reducing and preventing risks to human health and intervening in sanitary problems derived from the environment, production and circulation of goods and services to protect the health of the population.

Importation is the entry into the national territory of goods or products from abroad[3]. As determined by current legislation, imported products that are subject to health surveillance and intended for trade, industry or consumption must have the consent of Anvisa for their importation. All products must be regularized with the health authority as to their obligation, as appropriate, of registration, notification, record, model authorization, registration waiver or any other form of control regulated by Anvisa.

Goods or products under health surveillance are considered all materials, raw materials, inputs, parts and pieces, finished products, bulk products, semi-finished products, fresh products and others under health surveillance, dealt with in Law n. 9.782 of January 26, 1999. These include: food, cosmetics, personal care and fragrances, household sanitizers, laboratory standard and reference materials, in vitro diagnostic products, medical and hospital health products, medicines, human cells and tissues[4].

The legal grounds that determine sanitary control of imported health products, subject to health surveillance, as Anvisa's responsibility are:

> Art. 7 The Agency is responsible for the implementation and execution of the provisions of items II to VII of art. 2 of this Law, and it should:
>
> VII - authorize the operation of companies in the manufacture, distribution and importation of the products mentioned in art. 8 of this Law and the marketing of medicines;
>
> VIII - agree with the importation and exportation of the products mentioned in art. 8 of this Law;
>
> XIV - as a health surveillance measure, close down the places of manufacture, control, importation, storage, distribution and sale of products and services related to health, in case of violation of the legislation or imminent risk to health;
>
> XV - prohibit the manufacture, importation, storage, distribution and marketing of products and inputs, in case of violation of the legislation or imminent risk to health; [...] (Federal Law n. 9.782/99 - Law that created Anvisa)[3].

Additionally, the Resolution of the Collegiate Board (RDC) n. 81 of November 5, 2008, updated by RDC n. 208, of January 5, 2018, which provides for the Technical Regulation of Imported Goods and Products for Health Surveillance purposes, rules the proceedings for importing health products subject to sanitary control in Brazil[3,5].

The process of importing health products under the consent of Anvisa has the digital format of document attachment, analysis and consent in the Siscomex modality since before the publication of the teleworking regime. The Siscomex modality was instituted by Decree n. 660, of September 25, 1992, and started operating in 1993 as the Brazilian foreign trade administrative system, in which operations began to be registered and analyzed by the management bodies: Secretariat of Foreign Trade (SECEX), Federal Revenue Secretariat (SRF) and Central Bank of Brazil (Bacen), and by the consenting agencies: Anvisa/Ministry of Health, Ministry of Agriculture, Livestock and Supply, Federal Police etc.[1] The digital process begins with the registration of the import license (IL) and verification by the importer whether the imported product requires Anvisa's consent or not. Then the importer generates an electronic dossier in a system called Integrated View and attaches all the necessary documents for procedural instruction, according to specific rules for each type of product and purpose. In the third stage, on Anvisa's website, importers generate a payment slip so that the import process is formalized through the electronic protocol and submitted to Anvisa's technical analysis after bank clearing.

Teleworking legal and conceptual grounds

According to the International Labor Organization (ILO), teleworking is "the form of work done away from the office and/or production center, which enables physical separation and involves the use of a new technology that facilitates communication"[6].

Van Horn and Storen[7] define that teleworking is done from home, away from the employer's workplace, using information technology resources like the internet, computers or telephones. For Goulart[8], it is the process of bringing work to employees rather than taking employees to work; periodic activity outside the company one or more days a week, either at home or in another intermediate work area.

Although the advantages of this type of work, when well managed, are recognized in terms of increasing workers' productivity and reducing costs, there is a strong resistance from public institutions in Brazil, as well as from civil servants themselves, in

relation to this model, with the misperception that the physical absence of servants in the organization would lead to the end of the workplace and force everyone to opt for the new modality[9].

Anvisa's Ordinance n. 1.665/2017 states that performance goals will be 20% higher than the performance goals of employees doing the same activity on the premises of the Agency. Their planning, whenever possible, should be agreed between the teleworking professional and his or her manager, prior to the start of the program. In the case of Anvisa, there should be follow-up of this planning every quarter[2]. The program development plan should include the tasks, goals and percentage of productivity that the teleworker should have for the regular performance of his or her activities, as well as a schedule with the meetings with his or her immediate leader to evaluate performance and make goal revisions and adjustments[10]. Also, according to the Normative Instruction of the Secretariat of Public Management (SEGEP) n. 01, of August 31, 2018, which regulates teleworking in federal public administration agencies, teleworking is defined as:

> the category of implementation of the management program in which the civil servant performs his or her functional duties entirely off the unit's premises, through the use of equipment and technologies that enable the full performance of his or her duties remotely, without frequency control, pursuant to this Normative Instruction[11].

It is understood that with the progress of information technology and the widespread use of the resulting resources, access becomes possible anywhere in the world, at any time. Pursuant to this conception, Costa[12] explains that, since it is now possible to work anywhere, there is no more limitation of space and time, and the organization can function anywhere on the planet, at any time of the day, during 24 hours, with workers doing their jobs online.

Teleworking advantages

Regarding the advantages of teleworking for the workers, there is no doubt that the absence of home/work commuting, the flexibility of the 40-hour workweek and improved quality of life are among the determining factors for the adoption of teleworking. Another relevant factor are the working hours, which, in this case, are determined by the workers themselves and in favor of their family routine. They can also be arranged considering the seven days of the week, whatever is best suited to the worker. If the worker is more active in the afternoon/evening, he or she can concentrate his or her working hours in these periods and meet work goals with quality and satisfaction[14].

With regard to the work done, Tremblay and Lima emphasized the improvement in quality and increased productivity, since when workers are at home, they are free of constant interruptions, noise and thus can focus more on their activities[13,14]. There is improvement in absenteeism rates and delays due to health reasons, increase in talent retention and a decrease in staff turnover, since by increasing the motivation to work at home, workers are more attracted to organizations that adopt teleworking policies in their people management and development programs. Moreover, the risks of accidents on the journey between home and workplace are eliminated[8].

The objective of this report was to show the main results achieved with the teleworking modality in the consent of importation of health products, from March 1 to August 31, 2018, through indications of specific parameters related to the time it took them to deliver the analysis and assessment of the quality of the technical analysis in import processes.

METHOD

Initially, a comparative analysis based on parameters inherent in the flow of importation of health products was presented, like the time it takes to analyze the importation process and qualification of the reasons for non-consent in importation processes (product irregularity or legal discovery errors), issues widely publicized and discussed in forums, meetings and papers that address the assessment of Anvisa's efficiency in importation consent. The timeframe we established was from March 1 to August 31, 2018. We considered the teleworkers' productivity evaluation quarter, a period when harmonization and operational procedures were already in force.

Finally, the authors considered alternatives and considerations for the continuous improvement of the sector, considering the search for the sanitary safety of the products and the protection of the health of the Brazilian population.

RESULTS AND DISCUSSION

Teleworking at GGPAF was first instituted with GGPAF/Anvisa Service Guideline n. 34 of August 14, 2017[15]. This guideline proposed to establish IL analysis centers for each product class, with each analysis center organized in a physical station, with the workers located in this center being responsible for the analysis. Thus, the new guideline provided for the rationalization of the sanitary control inspection management of imported products, distributing the importation processes to stations with fewer IL demands and more workers. With that, the analysis was no longer restricted to Anvisa units directly responsible for the bonded warehouses related to the shipping of the goods.

With the centers, we moved to the Results-Oriented Management Program (teleworking/attendance waiver - DCA) for the IL consent activity. Thus, interested workers with an appropriate profile for joining the program were selected, and the first virtual station was established on December 1, 2017, with 25 consenting workers. The station was called Virtual Health Product Analysis Post (PAFPS).

This pilot station covered health products that accounted for about 45% of the total IL under consent of Anvisa, according to

data from the Datavisa System. For entry into teleworking, a productivity increase of 20% over the metric defined as daily work at the physical station was required. As determined by Anvisa's Ordinance n. 1.665/2017[1], each teleworker's productivity would be published quarterly in the Federal Official Gazette[1]. All activities performed by the consenting workers were measured considering their complexity and time required for their completion.

After the success of the pilot project, in March 2018, other virtual stations were established with teleworkers: Medicines (Pafme), Food (Pafal) and Cosmetics/Sanitizers (Pafco). Also, to harmonize the analysis of the consenting workers, standard operating procedures (SOPs) were established for the activities of analysis, inspection and interdiction/reopening. Furthermore, a technical leader is mandatory in every virtual station for the operationalization of these SOPs. The leader appointed by the general manager of GGPAF is also responsible for providing technical support to teleworking servants; communication with other areas of Anvisa; answers/presentations and webinars (web conferencing in which communication is only one-way, i.e. one person presents while others watch) to the regulated sector; as well as the responsibility to communicate with GGPAF and pass on demands to consenting workers via virtual communication (platforms of *Teams*, e-mail, *WhatsApp* and file exchange programs).

Physical inspection of the merchandise continues to be done by the physical stations where the cargo is stored. However, since the initial analysis of the IL is done by the teleworking consenting servants, the inspection request to the post is sent by the consenting worker to the Anvisa Post that is responsible for the Shipping Unit, through the SEI System. The sanitary criteria for inspection request are determined in specific SOPs and must be correctly followed by both the teleworking servants and the servants working at the posts responsible for the physical inspections. After the inspection, the virtual process returns via SEI to the consenting servant with the physical inspection report for evaluation and completion of the technical analysis.

Normative Instruction of the Ministry of Health (MS)/Health Surveillance Secretariat (SVS) n. 1, of December 16, 1996 was the first strict formalization of the procedures to be adopted in the consent of importation of products subject to consent of importation[16]. From 1996 to November 2018, despite the normative changes, the process of analysis of importation processes in a decentralized manner remained unchanged. In this sense, the centralization of data about the dynamics of the process analysis was under the responsibility of the Anvisa post manager. Thus, data like average process analysis time, daily process entry volume, percentage of inspections, number of interdictions, sanitary infringement notices and even situations of irregular products remained restricted to local posts.

The first result achieved by telework in the consent of importation of health products was the possibility of centralizing the information of the analysis flows, and the central manager of the area can establish projects, procedures and decisions focused on the actual diagnosis of the importation environment.

The redesign of the Information Technology structure was necessary so that the centralization of processes on a single virtual file server could be done. Thus, the extraction of historical data from previous years was eventually possible in this new format.

The timeframe from March to August 2018 was compared with the same period of previous years. Data on the volume of processes filed and the analysis period could be compared, as shown in Figures 1 and 2.

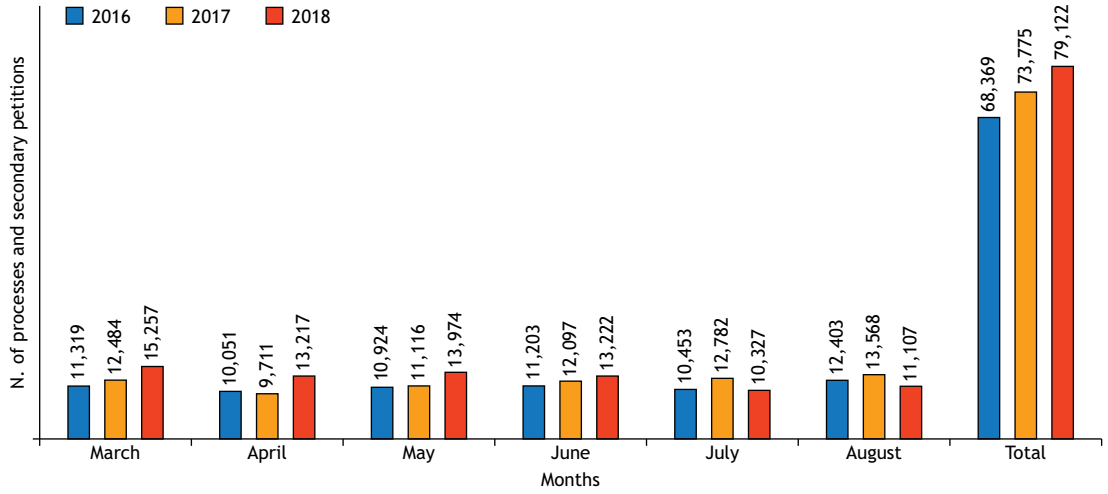
In addition to the average time needed to start the analysis of import processes being shorter than that of previous years, it is worth highlighting the possibility of forecasting process analysis with the official availability of these data on Anvisa's website - http://portalanalitico.anvisa.gov.br/importacao. In the past, this situation was poorly monitored by the importers, according to the preferred post of clearance of their products. This precariousness made importers "avoid" slower posts, with the sudden movement of large import volumes to other Anvisa posts that had smaller demands. This movement caused economic losses for both the importing company (transportation costs, warehousing etc.) as well as for the original shipping region, which that lost the customer (port, logistics companies, shipping companies etc.).

The centralization of the analysis of the importation processes also increased the security of the technical analyses. Processes that did not receive consent because of sanitary irregularities and whose release could increase the health risk to the population are now harmonized at the national level, avoiding attempts to change the post for nationalization with different interpretations of the law. From March to August 2018, PAFPS diagnosed 253 records and irregular products from 92 different companies.

Regarding the information that began to be monitored through telework, we have some strategic data to assist in process management:

- A total of 79,122 files were analyzed. Of these, 72,767 were importation processes. That is, primary petitions;
- Of the importation processes, 6% did not receive consent (were not approved);
- Considering non-consented processes, Figure 3 shows the percentage related to the banned products, which were therefore irregular, in addition to the volume of appeals filed against decisions of non-consent.

Figure 3 shows that only 6% of the non-consented processes resulted from irregular products, whereas 94% of non-consents resulted from wrong procedural instruction, such as lack of mandatory documents or non-compliance with deadlines for clarification of technical requirements formalized by Anvisa.



Source: Datavisa.

Figure 1. Volume of files (processes and secondary petitions) filed for health products from 2016 to 2018 (March to August).

This situation creates a vicious cycle, in which non-consented processes are filed again, generating process accumulation and rework to the consenting servants and burdening the importer with new inspection fees and storage costs due to the lack of speed in the importation process.

The volume of appeals filed against Anvisa's non-consent decisions – 3% - means that the sector is more mature and understands the reasons for the non-consent and the next steps to be followed in the flow of the importation process.

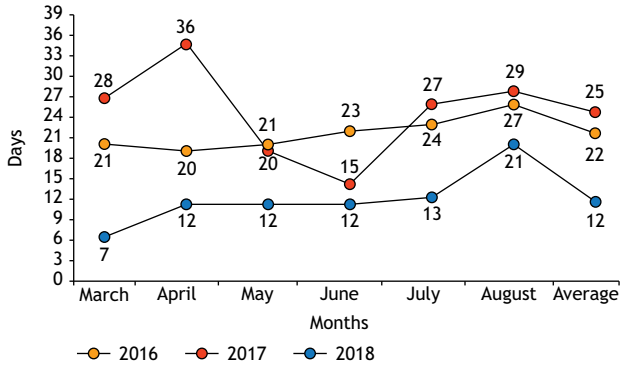
CONCLUSIONS

The unified analysis of importation processes in virtual stations by product class enabled the standardization of the analysis of these processes, with more uniform technical opinions.

However, balancing the need for fast technical analysis with quality improvement remains a challenge. Therefore, the most important point is the continuous qualification of the consenting servants, in order to avoid discrepancies in the IL analyses. Technically skilled management has also proved necessary to coordinate and strengthen the technical positioning to the detriment of diffuse interests, outside the context of health risks.

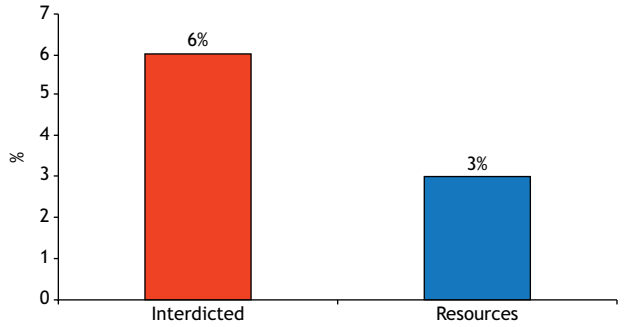
Strengthening the figure of the technical leader at virtual posts is key to ensuring suitable work processes. Since the consenting parties are scattered about the Brazilian territory, one person must centralize the points to be discussed between servants and managers. It is also necessary to ensure the standardization of procedures and verification of the performance of the consenting servants.

In order to improve and expedite the analysis of the importation processes, the risk management of the processes focusing on more careful analysis for import processes that pose greater health risks is also fundamental. However, it is necessary to define robust criteria to identify the processes, products and companies that can be considered as having more or less health risks.



Source: Datavisa.

Figure 2. Average time (percentile 90) for the start of the analysis of health products importation processes from 2016 to 2018 (March to August). Working days.



Source: Datavisa.

Figure 3. Percentage of processes of importation of health products that were not consented, interdicted and that had resources filed, referring to the processes of importation of health products from 2016 to 2018 (March to August).

Another key point in process analysis is the availability of information and the stability of the systems required to validate process information and finalize technical actions. Several systems are involved in the process of analysis of importation processes, including those from the Brazilian IRS and Anvisa, which are often unstable and thus hinder the analysis of the processes. Improvement in the availability of consent data in Anvisa's internal in-house consultation systems should be done as soon as possible in order to expedite consent.

Furthermore, there was a substantial volume of rejections motivated by inaccuracies in procedural instruction. In order to improve this process, the Manual of Process Analysis of Importation of health products was published in May 2018. This manual sets out all the points that must be observed by the importer for proper instruction of the importation process.

Finally, regarding the regularization of products, in the analyzed period we identified several divergences between the information of regularization of imported products in their processes and what was actually being imported. It is noteworthy that the regularization of a health product requires the compilation of technical information that is analyzed and validated by the areas responsible for the analysis of the registration processes, and any change can only be published after authorization by the agency.

Finally, we emphasize that it is the responsibility of companies to keep their processes updated in accordance with what is really being imported and made available to the population. This bias has shown that importing companies need to combine pre-market control of products with the importation flow, with daily checks for correction needs, thus avoiding market shortages, rejections, additional storage costs and losses to all parties involved in the life cycle dynamics of health products.

REFERENCES

1. Brasil. Decreto N° 660, de 25 de setembro de 1992. Institui o sistema integrado de comércio exterior: Siscomex. Diário Oficial da União. 28 set 1992.
2. Agência Nacional de Vigilância Sanitária – Anvisa. Portaria N° 1.665, de 2 de outubro de 2017. Boletim de Serviço Nº 46. 2 out 2017.
3. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução RDC Nº 81, de 5 de novembro de 2008. Dispõe sobre o regulamento técnico de bens e produtos importados para fins de vigilância sanitária. Diário Oficial União. 6 nov 2008.
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 União. 27 jan 1999.
5. Agência Nacional de Vigilância Sanitária - Anvisa. Resolução RDC Nº 208, de 5 de janeiro de 2018. Dispõe sobre a simplificação de procedimentos para a importação de bens e produtos sujeitos à vigilância sanitária. Diário Oficial da União. 8 jan 2018.
6. Organização Internacional do Trabalho - OIT. Convention 177: home work convention. Geneva: Organização Internacional do Trabalho; 1996[acesso 14 set 2018]. Disponível em: http://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12100:0::NO::P12100_INSTRUMENT_ID:312322.
7. Van Horn C, Storen D. Telework: coming of age? Evaluating the potential benefits of telework. In: Department of Labor (US). Telework and the new workplace of the 21 st century. Washington: Department of Labor. 2000[acesso 19 set 2018]. Disponível em: https://hdl.handle.net/2027/mdp.39015050538738
8. Goulart JO. Teletrabalho: alternativa de trabalho flexível. São Paulo: Senac; 2009.
9. Silva AMS. A aplicação do teletrabalho no serviço público brasileiro. Anais do 3º Congresso Internacional de Direito e Contemporaneidade; 27-29 maio 2015; Santa Maria, RS. Santa Maria: Universidade Federal de Santa Maria; 2015. Disponível em: http://coral.ufsm.br/congressodireito/anais/2015/1-2.pdf
10. Conselho Nacional de Justiça - CNJ. Resolução Nº 227, de 15 de junho de 2016. Regulamenta o teletrabalho no âmbito do Poder Judiciário e dá outras providências. Diário Oficial Justiça, 16 jun 2016.
11. Ministério do Planejamento, Desenvolvimento e Gestão (BR). Instrução Normativa Nº 1, de 31 de agosto de 2018. Estabelece orientação, critérios e procedimentos gerais a serem observados pelos órgãos e entidades integrantes do sistema de pessoal civil da administração federal - Sipec relativos à implementação de programa de gestão, de que trata o § 6º do art. 6º do decreto Nº 1.590, de 10 de agosto de 1995. Diário Oficial União. 3 set 2018.
12. Costa ISA. Poder/saber e subjetividade na construção do sentido do teletrabalho [tese]. Rio de Janeiro: Fundação Getúlio Vargas; 2004.
13. Tremblay DG. Organização e satisfação no contexto do teletrabalho. Rev Adm Emp. 2002;42(3):54-65. https://doi.org/10.1590/S0034-75902002000300006
14. Lima MSB. O Teletrabalho no poder judiciário brasileiro: ganhos para os tribunais e sociedade? As experiências de Santa Catarina e Amazonas [tese]. Rio de Janeiro: Fundação Getúlio Vargas; 2018.
15. Agência Nacional de Vigilância Sanitária – Anvisa. Orientação de serviço N° 34, de 14 de agosto de 2017. Boletim de Serviço Nº 37. 14 ago 2017.

16. Ministério da Saúde (BR). Instrução Normativa SVS Nº 1, de 16 de dezembro de 1996. Estabelece procedimentos para liberação de produtos importados sujeitos as normas da vigilância sanitária em terminais alfandegos instalados no território nacional. Diário Oficial União. 19 dez 1996.

Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.