EXPERIENCE REPORT
https://doi.org/10.22239/2317-269x.02106

E-commerce surveillance project of irregular products: Anvisa's experience report

Projeto de fiscalização de *e-commerce* de produtos irregulares: relato de experiência da Anvisa

Leidy Anne Alves Teixeira*

Agência Nacional de Vigilância Sanitária (Anvisa), Brasília, DF, Brasil

* **E-mail:** leidyunb@gmail.com

Received: 10 Aug 2022
Approved: 26 Sep 2022

How to cite: Teixeira LAA. E-commerce surveillance project of irregular products: Anvisa's experience report. Vigil Sanit Debate, Rio de Janeiro. 10(4):54-58, novembro 2022. https://doi.org/10.22239/2317-269X.02106

ABSTRACT

Introduction: Electronic commerce, called e-commerce, has been driven by expanded access to the internet, smartphones and marketing strategies to reach new consumers. However, products subject to health surveillance must comply with legal requirements to be marketed in a way that ensures their quality and safety. **Objective:** To report Anvisa's experience of applying an automated search platform to monitor e-commerce of products under its jurisdiction. **Method:** Anvisa has hired an automated search platform to verify the regularity of products advertised via electronic commerce. These are: medicines, medical devices, food, cosmetics, sanitizing products, and smoking products. Search terms were chosen considering the product categories and the health risk. The platform identifies irregular products and notifies the advertiser to remove the ad. **Results:** In 8 months of implementation of the pilot project, 50,636,985 million signals were collected. Of these, 64,767 corresponded to irregular ads in which advertisers were notified to withdrawal. **Conclusions:** Innovative actions for monitoring products subject to health surveillance is a necessity given the large volume of data present in commercial operations and the reach of e-commerce.

KEYWORDS: Anvisa; Surveillance; Electronic commerce

RESUMO

Introdução: O comércio eletrônico, denominado *e-commerce*, tem sido impulsionado pelo acesso expandido à internet, *smartphones* e estratégias de *marketing* para alcance de novos consumidores. Contudo, produtos sujeitos à vigilância sanitária devem cumprir requisitos legais para serem comercializados de forma que garantam sua qualidade e segurança. **Objetivo:** Relatar a experiência da Anvisa no emprego de plataforma de busca automatizada para monitorar o comércio eletrônico de produtos sob a sua tutela. **Método:** Foi contratada uma plataforma de busca automatizada para a verificação da regularidade de produtos anunciados via comércio eletrônico. São estes: medicamentos, dispositivos médicos, alimentos, cosméticos, saneantes e produtos fumígenos. Elegeu-se termos de buscas considerando as categorias de produtos e o risco sanitário. A plataforma identifica os produtos irregulares e notifica o anunciante para a retirada do anúncio. **Resultados:** Em 8 meses de implantação do projeto-piloto, 50.636.985 milhões de sinais foram coletados. Destes, 64.767 corresponderam a anúncios irregulares em que os anunciantes foram notificados para retirada. **Conclusões:** Ações inovadoras para o monitoramento de produtos sujeitos à vigilância sanitária é uma necessidade visto o grande volume de dados presente nas operações comerciais e de alcance do *e-commerce*.

PALAVRAS-CHAVE: Anvisa; Fiscalização; Comércio Eletrônico

INTRODUCTION

Electronic commerce (e-commerce) is a modality in which sales and financial transactions occur in a virtual environment through electronic platforms, such as virtual stores (webshops), marketplaces, social networks, and applications. The health-related e-commerce market mainly covers the sale of medicines, medical devices, cosmetics, and food. Approximately 2.8 million searches are performed daily on topics related to health on Google[1].

This type of trade is booming. It is estimated that the global e-commerce market will reach US$ 4.23 trillion in 2022[2]. The health-related e-commerce segment reached US$ 261.25 billion in 2021. It is expected that, in 2022, it will reach a possible US$ 309.62 billion with a compound annual growth rate (CAGR) of 18.5%[3]. In Brazil, surveys show that e-commerce grew 27% in 2021, totaling US$ 34,531 billion in sales[4]. This growth was mainly driven by isolation measures resulting from the fight against the COVID-19[5] pandemic, combined with expanded access to the internet and smartphones[6].

However, there are requirements to market products under sanitary protection. According to Law No. 9,782, of January 26, 1999, the Brazilian National Health Surveillance Agency (Anvisa) has the institutional purpose of promoting the protection of the population's health, through sanitary control of the production and sale of products. Thus, products subject to health surveillance must be duly registered with Anvisa and establishments must have a Business Operating Authorization for manufacturing, importing, distributing, and/or marketing activities, including e-commerce. It should be noted that health regulation provides that electronic commerce and the dispensing of medicines take place under the responsibility of duly authorized and licensed pharmacies and drugstores[7].

Sanitary inspection is an instrument for verifying compliance with legal standards aimed at ensuring the quality and safety of regulated products and services. It is Anvisa's responsibility to carry out, at the national level, articulating with the state, district and municipal levels, sanitary inspection activities to investigate deviations, as well as to promote the inspection of advertising, publicity, and promotion of products subject to sanitary surveillance8. Irregular products are considered, among other criteria, those without registration/notification/registration at the Agency. Complementarily, the Consumer Defense Code, Law nº 8.078, of September 11, 1990, describes products unfit for use and consumption as those that are in disagreement with the regulatory norms of manufacture, distribution, or presentation. Altered, adulterated, damaged, counterfeit, corrupted, defrauded, harmful to life or health, and dangerous items are included. That is, all products that, for whatever reason, prove to be unsuitable for the purpose for which they are intended. In addition, electronic commerce must observe, among other requirements, the quality and suitability of the products offered, as determined by Decree No. 7962, of March 15, 2013, which regulates Law No. 8,078/1990, to provide for contracting in electronic commerce.

The use of irregular products can cause contamination, infections, ineffective treatments, surgical complications, physical damage, among others. Therefore, actions to curb the sale of these products are important measures to ensure the protection of the population's health. However, with the advent of the internet, irregular products can be disseminated to a wider audience and with a certain degree of concealment from those responsible for making such products available. E-commerce is allied with technologies to reach potential customers aided by artificial intelligence that challenges regulatory bodies to act articulately throughout the supply chain.

In addition, the irregularities of products subject to health surveillance go beyond the borders of countries and, for efficient health action, it is necessary to collaborate with entities and authorities from other countries, not only related to health surveillance. While there are regulatory differences between countries in terms of registration and trade, global cooperation solutions are desired.

In Brazil, Anvisa, together with the United Nations Development Program (UNDP), through a contract per product under the Technical Cooperation Project, designed the pilot project to monitor products sold irregularly on websites and Brazilian e-commerce platforms. The contract extract was published in the Brazilian Federal Register, No. 22, of February 1, 2022, Section 3, p. 102. The project expands the Agency's capacity to act through active monitoring of signs of irregularity in products subject to sanitary surveillance, aided by artificial intelligence tools. This experience report brought the preliminary results of the project achieved in 8 months of implementation.

METHOD

The contracted search platform carried out the daily automated monitoring of sales of irregular assets on the internet based on the terms and rules pre-established by the areas of the General Management of Inspection and Sanitary Inspection at Anvisa. The history of technical complaints, irregularities, and health risk was considered.

In this study, the product under health surveillance regime that is not regularized at Anvisa is considered to be an irregular active. The content of the advertising piece in its entirety is not evaluated, only elements that indicate therapeutic benefits previously defined by the rules.

The categories of products subject to health surveillance contemplated in the project were:

a. Medicines: is the pharmaceutical product, technically obtained or prepared, with prophylactic, curative, palliative, or diagnostic purposes, according to Law No. 5,991, of December 17, 1973.

b. Health products: also known as medical devices, are materials for use in health, equipment, or *in vitro* diagnostic devices intended for medical, dental or laboratory use,

or application, with the aim of preventing, diagnosing, treating, rehabilitating human beings, according to Resolution of the Collegiate Board of Directors (RDC) No. 185, of October 22, 2001 and RDC No. 36, of August 26, 2015.

c. Food: any substance that is ingested in its natural state, semi-elaborated or elaborated, intended for human consumption, including drinks and any other substance used in its elaboration, preparation, or treatment, excluding cosmetics, tobacco, and substances used solely as medicine, according to RDC nº 259, of September 20, 2002.

d. Sanitizing agents: are substances or preparations intended for household cleaning, disinfection or disinfestation, in collective and/or public environments and in water treatment. There are those that are over-the-counter products and those for professional use or for sale restricted to a specialized company, according to Law nº 6.360, of September 23, 1976 and RDC nº 59, of December 17, 2010.

e. Personal hygiene products, cosmetics and perfumes: these are preparations consisting of natural or synthetic substances, for external use on the various parts of the human body, skin, capillary system, nails, lips, external genital organs, teeth, and mucous membranes of the oral cavity, with the sole or main purpose of cleaning them, perfuming them, changing their appearance, and/or correcting body odors, and/or protecting or keeping them in good condition, as per RDC No. 7, February 10, 2015.

f. Smoking products: those derived from tobacco, any manufactured product that contains tobacco in its composition, having the following classification: combustible product derived from tobacco, non-combustible product derived from tobacco, and electronic nicotine delivery device, according to RDC No. 559, of August 30, 2021.

The search platform scans electronic websites in order to collect signals related to products subject to health surveillance. Once the product advertisement (active) is identified, the attributes are automatically checked based on pre-established rules. One of the verified attributes, for example, is the regularity of the product in Anvisa. When the ad is classified as irregular, the platform sends an email (notificacao@anvisa.gov.br) to the person responsible for the ad requesting its withdrawal (also called takedown). The deadline for expressing any doubts or clarifications is 5 days. The response can be sent to the same e-mail address as the notification and is evaluated by Anvisa technicians. After this period, if there is no withdrawal of the ad or justification presented, it is classified as unresolved and, then, forwarded so the appropriate health measures can be taken.

Ad monitoring is continuous in order to avoid their return under irregular conditions.

The exploratory analysis of the data presented in the experience report was carried out from January 27, 2022 to August, 2022. The Microsoft Power BI tool was used for data synthesis and analysis.

RESULTS

Monitoring results, updated on August 30, 2022, were: 50,636,985 million signals collected. These signals are any word found on the internet that refers to the terms indicated. After checking the regularity of the products, 307,344 thousand potential threats were detected. Non-validated threats, quarantined threats, and discarded threats were excluded from this total, totaling 65,351 registered incidents.

From the recorded incidents, 64,767 ads were taken down by advertisers from e-commerce platforms. The percentage of groups that had more ads identified for removal is represented in the Figure. Anvisa provides a panel with program data at: Anvisa portal > Content Center > Publications > Certification and Inspection > E-Commerce Inspection Panel.

DISCUSSION

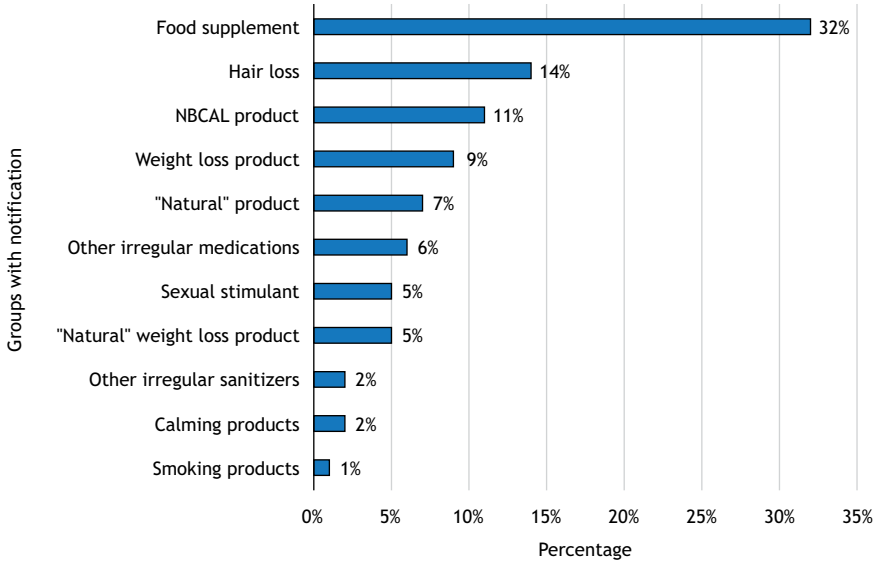
The pilot project consisted of surveying the terms and rules and evaluating the sensitivity of the search platform in detecting the sale of irregular assets. Regarding nomenclatures, it is identified as necessary to improve the terminology for searches in view of the irregular advertising of products subject to health surveillance. Commercial names with population appeal do not always reflect the technical names of products but meet the needs of the population, with a clear appeal to commercialization in spite of sanitary regulation, such as, for example, “50 herbs”, which is on the list of irregular weight loss products released by Anvisa[9].

Medical device terms are similarly difficult due to the plurality of existing names, in contrast to the pharmaceutical ingredients that are described and standardized in the Brazilian Pharmacopoeia. Anvisa still does not adopt a standardized nomenclature for medical devices. With the implementation of the Unique Device Identification (UDI) for medical devices in the coming years, the adoption of the Global Medical Device Nomenclature (GMDN) is expected.

From the point of view of regulation, there is a need to improve the federal health legislation to monitor the characteristics related to e-commerce and inspection. As the project progresses, more information is expected to enable propositions by the Agency, which may support changes in current legislation, publication of normative acts, and adoption of educational actions, based on an open dialogue with all sectors of society.

The pilot project has the benefits of expanding and automating the monitoring of products subject to health surveillance in the context of e-commerce. In this way, it is possible to make an agile decision by notifying the advertiser and removing the irregular ad in a few days. It should be noted that non-compliance with the notification leaves the offender subject to the administrative penalties provided for in Law No. 6,437, of August 20, 1977, without prejudice to other sanctions to be applied at the judicial level.

Without the help of the search platform, possible irregularities are identified in monitoring programs during the performance of



Source: Anvisa Portal (https://app.powerbi.com/view?r=eyJrIjoiZ jM0MmE4NzItNzM0OS00YzRiLTgyYWYtMjg5ZmVlNjMyNDU1IiwidCI 6ImI2N2FmMjNmLWMzZjMtNGQzNS04 MGM3LWI3MDg1ZjVlZGQ4MSJ9).
NBCAL: Brazilian Standard on The Marketing of Children's Foods, tips, pacifiers, and bottles.

Figure. Main groups with notifications sent for advertisement takedown from e-commerce platforms.

programmed activities or as a result of the evaluation of complaints and technical complaints arising from Anvisa's service channels. The usual process requires more steps for its execution and, consequently, a longer response time. In addition, the whistleblower's notification is educational in nature, since most advertisers are micro and small companies protected by Complementary Law No. 123, of December 14, 2006, regarding the criterion of double visit for drawing up the infraction notice.

Even with the actions of Anvisa and other entities of the Brazilian National Health Surveillance System, irregular practices, fraud, or intentional misinformation continue to occur. Thus, the actions developed by the other actors involved, distributors, financial service providers, and e-commerce companies, are also essential[7], so that, with the use of various mechanisms concomitantly, actions are effective in combating irregular products. Websites and platforms can seek ways to block the dissemination of irregular products, as well as users can verify information so that irregular products offered in these environments are not purchased.

International efforts are being made to discourage e-commerce of irregular products. Operation Pangea XIV is an action coordinated by the International Criminal Police Organization (Interpol) since 2008 and has the participation of health regulatory, police, and customs authorities from 92 countries to combat the illegal sale of medicines and health products over the internet.

Operation Pangea XIV (2021) resulted in the closure or removal of 113,020 web links, in addition to the seizure, in the United Kingdom, of three million fake medicines and devices[10].

In 2011, the European Council drafted the MEDICRIME Convention: an international criminal law treaty aimed at regulating the crime of counterfeiting medicines and health products. It was primarily motivated by e-commerce and currently has 47 European member states.

Interpol accounted for an increase of more than 60% in piracy crimes, during 12 months from April 2020, motivated by the COVID-19 pandemic. In response, it launched Project I-SOP (2021 to 2026) in collaboration with South Korea to support enforcement, capacity building, research, and public awareness of online piracy and intellectual property crimes[11].

In 2022, the Organization of Economic Co-Operation and Development (OECD) and the Food and Drugs Administration (FDA) began publicizing the broader approach initiative to combat irregular products, called whole-of-governments, to encourage cooperation between the multiple actors involved, considering the current complexity associated with the trade in irregular products. The case study of Operation Lascar was presented to illustrate the concept and raise possibilities for this new approach. Operation Lascar consisted of a bilateral agreement between the FDA and the United Kingdom focused on the movement of irregular products from the United Kingdom to the United States. As a more recent result, more than 3,000 shipments of irregular products destined for the United States were detected, with around 80 criminal investigations being opened to identify those responsible and comply with legislation[12].

In 2021, Anvisa concluded more than 2,500 sanitary investigation dossiers, and more than 700 preventive and/or precautionary measures were published regarding medicines, pharmaceutical supplies, health products, sanitizers, food, cosmetics, personal hygiene products, and perfumes[13]. With the support of new technological tools, the Agency is expected to have a greater reach both in propositions of educational and inspection measures.

CONCLUSIONS

It is concluded that the originality in terms of automation of searches for irregular products sold via e-commerce in Brazil is a necessary advance to keep up with market and consumption changes. The results demonstrate the need for monitoring and rapid and timely regulatory actions to ensure the quality of the products offered.

REFERENCES

1. Bakhur N. Healthcare trends: digital transformation in healthcare. Neklo Blogs. 2020[acesso 10 ago 2022]. Disponível em: https://neklo.com/digital-transformation-in-healthacre/
2. Statista. Ecommerce worldwide. Statista Digital Markets. 2022[acesso 21 maio 2022]. Disponível em: https://www.statista.com/outlook/dmo/ecommerce/worldwide
3. The Business Research Company. Healthcare e-commerce global market report 2022 – by type (drug, medical devices), by application (telemedicine, caregiving services, medical consultation), by end user (hospitals, clinics) – market size, trends, and global forecast 2022-2026. Global Healthcare E-Commerce Market. abr 2022[acesso 21 maio 2022]. Disponível em: https://www.thebusinessresearchcompany.com/report/healthcare-ecommerce-global-market-report
4. NielsenIQ. Webshoppers. 45a ed. Chicago: NielsenIQ; 2022[acesso 21 maio 2022]. Disponível em: https://nielseniq.com/global/pt/landing-page/ebit/nielseniq-ebit-brasil/webshoppers/
5. Verdon J. Adobe: pandemic shift is permanent, e-commerce to hit $1 trillion in 2022. Forbes. 21 mar 2021[acesso 21 maio 2022]. Disponível em: https://www.forbes.com/sites/joanverdon/2021/03/15/adobe-pandemic-shift-is-permanent-e-commerce-to-hit-1-trillion-in-2022/?sh=7d7b6ac344ce
6. PayPal. A grande mudança no comércio eletrônico mundial: relatório comércio sem fronteiras 2021. São Paulo: PayPal; 2021[acesso 21 maio 2022]. Disponível em: https://www.paypalobjects.com/marketing/web/br/business/borderless-commerce/Borderless-Commerce-Report-2021.pdf
7. Agência Nacional de Vigilância Sanitária – Anvisa. Resolução RDC Nº 44, de 17 de agosto de 2009. Dispõe sobre as boas práticas farmacêuticas e dá outras providências. Diário Oficial União. 18 ago 2009.
8. Agência Nacional de Vigilância Sanitária – Anvisa. Resolução RDC Nº 585, de 10 de dezembro de 2021. Aprova e promulga o regimento interno da Agência Nacional de Vigilância Sanitária - Anvisa e dá outras providências. Diário Oficial União. 15 dez 2021.
9. Agência Nacional de Vigilância Sanitária – Anvisa. Anvisa divulga lista de emagrecedores irregulares. Brasília: Agência Nacional de Vigilância Sanitária; 2022[acesso 14 ago 2022]. Disponível em: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2022/anvisa-divulga-lista-de-emagrecedores-irregulares
10. International Criminal Police Organization – Interpol. Thousands of fake online pharmacies shut down in Interpol operation. Lyon: International Criminal Police Organization; 2021[acesso 21 maio 2022]. Disponível em: https://www.interpol.int/News-and-Events/News/2021/Thousands-of-fake-online-pharmacies-shut-down-in-INTERPOL-operation
11. International Criminal Police Organization – Interpol. Project I-SOP: Interpol stop online piracy. Lyon: International Criminal Police Organization; 2021[acesso 21 maio 2022]. Disponível em: https://www.interpol.int/Crimes/Illicit-goods/Project-I-SOP
12. US Food and Drug Administration – FDA. Global uptade, June 2022. Silver Spring: US Food and Drug Administration; 2022[acesso 25 jul 2022]. Disponível em: https://www.fda.gov/media/159479/download
13. Agência Nacional de Vigilância Sanitária – Anvisa. Fiscalização de produtos irregulares na internet. Portal da Anvisa. 2022[acesso 25 abr 2022]. Disponível em: https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2022/produtos-irregulares-resultados-do-projeto-de-fiscalizacao

Acknowledgment

Ana Carolina Moreira Marino Araújo, General Manager of the General Management of Sanitary Inspection and Surveillance (GGFIS), for suggesting the theme and conducting the project at Anvisa, contributions from Benefran Junio da Silva Bezerra, manager of the Inspection and Surveillance Management of Health Products, Tatiana Cambraia Sá Lowande, employee of the Coordination of Inspection and Surveillance of Health Products, and Carolina Vedana Pasquetti, GGFIS advisor.

Author's Contributions

Conception, planning (study design), acquisition, analysis, data interpretation, and writing of the work. The author approved the final version of the work.

Conflict of Interests

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