

**STUDY OF SANITARY IRREGULARITIES RELATED TO THE MEDICINES
MERCHANDIZING ¹**

ESTUDO DO PERFIL DO COMÉRCIO IRREGULAR DE MEDICAMENTOS

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SUMMARY

Objective: identify the irregular sale of drugs by hawkers and peddlers on the streets of Belém (PA) from January 2009 to June 2010. **Method:** an observational retrospective study was carried out by means of data collection collected at the Department of Health Surveillance (Devisa) in Belém-PA. Data had been acquired through 24 Writs of Seizure and Sale (WSS) yielded by the DEVISA, where 18,334 seized medicines had been entered. **Results:** it was observed that of the 24 WSS's, 58% referred to the peddlers and 42% to the ambulant ones (hawkers). Amongst 18,334 medicines used in this analysis, 13,306 were in possession of 2 peddlers and only 5,028 were under control of 7 hawkers. The place with the highest incidence of irregular sale was the Cabanagem Fair with 73% of drugs seized. The pharmacological group most illegally commercialized was the anti-inflammatory one, as well as among the five more seized medicines the most found were the Diclofenac Sodium and Diclofenac Potassium (59%). Through a series of half-yearly balance sheet, it became evident that the number of half-yearly raids increased with decreasing of the quantity of confiscated drugs. **Conclusion:** this study demonstrates the risk that the population is exposed to through the possibility of irrational use of medicines, especially anti-inflammatories. The importance of other papers in this area is pointed out to determine the effectiveness of repression actions to the illegal medicines commerce, and in this way, to promote improvements in the planning of the health surveillance actions.

KEYWORDS: Health Surveillance, medicines, Writs of Seizure and Sale, self-medication.

INTRODUCTION

In accordance with the Law 5991/73, "medicine is any pharmaceutical product, obtained or prepared technically, with prophylactic, curative, palliative or diagnostic purposes". Thus, the drug is an essential ingredient to health and, for this reason there is a concern regarding compliance with health requirements governing their commercialization, distribution and transportation¹.

As to its marketing the Law 5991/73¹ under its Article 6 and 15 states that sale of medicinal products is of the responsibility of pharmacies and drugstores,

being forbidden in other trade centers. Their dispensation should be exercised or supervised by the pharmaceutical professional. All these requirements are intended to ensure the quality of drugs offered to the population¹.

The medicinal product quality must be ensured for it reaches its goal. According to the World Health Organization (WHO)², the drug stability ensures that this should meet the microbiological, physicochemical and biopharmaceutical reference standards throughout the period of its validation.

Some factors can alter drugs stability. Kommanaboyina and Rhodes (1999)³ state that the loss of stability of a

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drug can result ineffective products, which would retard the treatment, or generate toxic products and consequently cause morbidity or mortality.

National Health Surveillance Agency (ANVISA), a regulatory body under the Ministry of health⁴ in order to ensure the quality of medicines commercialized in Brazil, publishes specific standards for the marketing of drugs based on national and international consensus^{5,6,7,2}.

The Board Resolution (RDC) No. 44 was issued on 17 August 2009 and provides for the Pharmaceutical Good Practices for the functioning of settlements and pharmacies drugstores⁸, aiming at the quality of pharmaceutical products and services. According to this norm, there must be standardized conditions for the sale of medicines, with minimum requirements since the reception, storage and dispensing of pharmaceuticals.

However, the drug was incorporated into the dynamics of consumer society, being subject to competition and interests of any other market sector. It's illegally sale by peddlers and hawkers, as can be seen on the streets of Amazon cities, such as Belém. Air and sunlight exposure can change the quality of the product and make it inactive or toxic³, causing risk to health of the person who is buying.

Thus, actions for inspection and control of sanitary surveillance are essential to guarantee the safety in public health and through its performance there is the repression of irregularities, avoiding or minimizing risks to public health.

METHODS

Was conducted an observational retrospective cross-sectional study, by collecting documentary data disposed by the Department of Health Surveillance of the city of Belém/PA (DEVISA). The documents on which it was based the data collection consisted of Writs of Seizure and Sale (WSS) that have been prepared by fiscal agents during the sanitary activities when there is apprehension of pharmaceutical products.

They are related to the illegal drugs sale by peddlers and hawkers on Belém streets from January 2009 to June 2010. Was used a total of 24 WSS's, and when there is a complete filling of fields destined for the description of seized products a new document of seizure is opened with new number. Thus, in large seizures are plowed more than one WSS for the same offender.

This study included hawkers, vendors capable of moving without a fixed point of sale. Sellers with fixed point of sale were considered street peddlers.

The drugs seized were counted in dosage units being considered each tablet, bottle, tube and envelope as a unit. For the analysis it was used 18,334 units of seized drugs. Were excluded from the calculation of pharmacological group and from the five most seized products 2,803 medicines, since 2,049 of them missed relevant information, such as the Brazilian Common Denomination DCB and the product active ingredient; and 754 for being prohibited their commercialization by the ANVISA.

The collected data were tabulated in Excel ® worksheet and the results presented in percentage or absolute number. According to the ethical principles in research, this study obtained authorization from DEVISA for its realization.

RESULTS

24 WSS's had been collected referred to the illegal sale of drugs by hawkers and peddlers in the city of Belém during the period from January 2009 to June 2010. Of these writs, 58% made reference to peddlers and 42% to hawkers, but individually it was met a total amount of nine offenders including two hawkers and 7 peddlers. The fact of the majority of AAR's to be of the peddlers is justifiable by the greater capacity of medicines storage they have. This can be proven by the fact that among the 18,334 medicines that had been seized in the evaluated period and that were used in this analysis, 13,306 (73%) were in possession of 2 peddlers and only 5,028 (27%) proceeded from 7 hawkers.

Among the five places with incidence of irregular sales, the Cabanagem Fair stood out with 73% of seized

medicines, followed by seizure on buses (10%), the Telegraph Fair (8%) and the Ver-o-Peso Fair (7%) (Figure 1).



Figure 1: Places of seizures of drugs from January 2009 to June of 2010, in Belém/Pa.

The quantities of medicines commercialized irregularly point out that through the entire sample, the pharmacological group most seized was the anti-inflammatory ones (26%), followed by antibiotics (15%) and analgesics / antipyretics (12%). Other drug groups that showed no significant percentage were grouped and covered a total of 28%, representing other 22 different pharmacologic groups sold (Figure 2).



Figure 2: Pharmacological group mostly seized from January 2009 to June 2010 in Belém/Pa.

Among the most impounded medicines, one observed that Diclofenac Potassium (33%) and Diclofenac Sodium (26%), both belonging to the group of anti-inflammatory drugs were more seized, followed by Metoclopramide (16%) and 2 antibiotics, Sulfamethoxazole + Trimethoprim (13%) and Tetracycline (12%)(Figure3).



Figure 3: 5 mostly impounded drugs from January 2009 to June of 2010, in Belém/Pa.

A series of half-yearly balance of the Raids and the quantities of seized dosage units was carried out. In the first six months of 2009 there were two raids with just over 2,000 units of drugs seized from hawkers and peddlers. In the second half of 2009 there was only one raid with large seizures of medicines units (around 12,000), mainly in the possession of peddlers. In the first half-year of 2010 there was an intensification of operations on hawkers and peddlers (6 raids), however with decreasing in the quantity of seized medicines. In this way, it became evident that the number of raids in each six month increased and that the amount of impounded medicines has decreased (Figure 4).

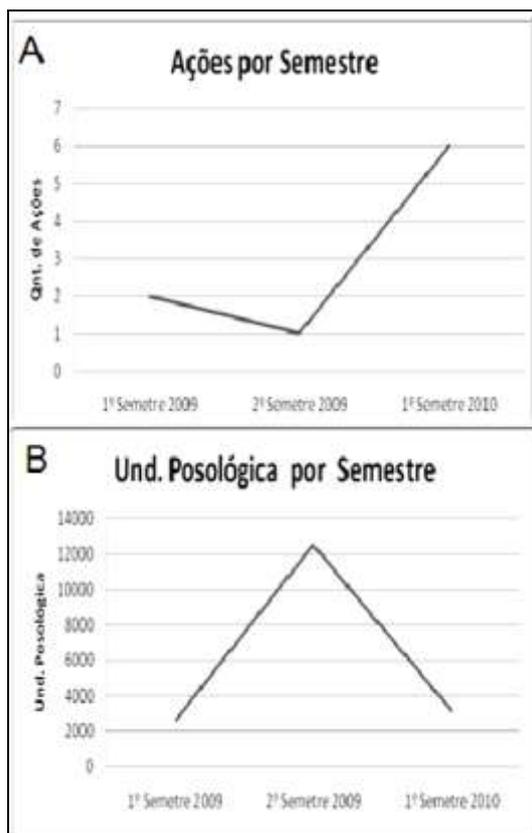


Figure 4: A) Number of raids per semester. B) Number of dosage units per semester, from January 2009 to June 2010, Bethlehem / Pa.

DISCUSSION

Of the 24 raids realized by the DEVISA, the place of highest incidence was the Cabanagem Fair where two peddlers had been sued, proving that despite more hawkers commercializing medicines, the peddlers selling-power is greater due to fixed-commercial point, allowing a greater storage.

Other authors have demonstrated the occurrence of medicines sale in inappropriate places and not allowed by law, such as warehouses, supermarkets and bares^{9,10}; however the commercialization by peddlers and hawkers is recent and not yet described in the literature and it evidences the self-medication.

Self-medication in Brazil and in the world is increasing¹¹, mainly in more devoid regions. This affirmation confirms the results found in this paper because the places where occurred a great incidence of medicines seizure are in outlying areas and of great flow of people with lower income.

In accordance with Campos et al. (1985)¹², the difficulty in accessing the health care system can be associated to high indices of self-medication. However, studies showed that self-medication is not exclusive to lower social-class but it is also associated to higher social-class individuals with a great prevalence of high education level¹².

Self-medication is considered as a potential risk to the public health. In Brazil, drug intoxication accounts for 29% of deaths, mainly caused by self-medication¹³. Arrais *et al*¹⁴. Showed that the most popular drug groups searched for the practice of self-medication were: analgesics (17.3%), nasal decongestants (7.0%), anti-inflammatories/anti-rheumatic (5.6%) and anti-infectives for systemic use (5.6%). The pharmacological group mostly found in this study was the anti-inflammatory represented by Diclofenac Sodium and Potassium, corroborating with the results found in literature, however with prominence for the high consumption of anti-inflammatory, that they can cause severe poisoning when used inadequately^{15,16}. It should be noted that medications are the first cause of poisoning in Brazil and in many developed countries, occurring in all age groups^{17,18}, signaling to the public institutions need for control.

In such a way, in accordance with some authors^{19,20}, it behooves the Sanitary Surveillance to restrain practices that expose the population to health risks, preventing disease or injury that people who perhaps do not use quality-assured drugs are liable to.

This paper showed that risks related to medicines occurred in the streets of a capital of the Amazonia region, requiring actions related to sanitary vigilance and that had been effective in reducing risks, since the number of raids increased with the decrease of seized-drugs quantity. Thus, the importance of other papers in the area is stood out to identify the effectiveness of repression actions to the irregular medicine commerce, and in this way promote improvements in planning in health surveillance activities in order to safeguard public health.

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RESUMO

ESTUDO DO PERFIL DO COMÉRCIO IRREGULAR DE MEDICAMENTOS

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Objetivo: identificar a venda irregular, por ambulantes e camelôs, de medicamentos nas ruas de Belém (PA) no período de janeiro de 2009 a junho de 2010. **Método:** realizado um estudo retrospectivo, por meio de coleta de dados realizada no Departamento de Vigilância Sanitária (DEVISA) do município de Belém-PA. Os dados foram adquiridos através de 24 Autos de Apreensão e Remoção (AAR) cedidos pelo DEVISA, onde foram contabilizados 18.334 medicamentos apreendidos. **Resultados:** foi observado que dos 24 AAR's, 58% faziam referência à camelôs e 42% à ambulantes. Dentre os 18.334 medicamentos utilizados nesta análise, 13.306 estavam em posse de 2 camelôs e apenas 5.028 estavam no poder dos 7 ambulantes. O local com maior incidência de venda irregular foi a feira da Cabanagem, com 73% dos medicamentos apreendidos. O grupo farmacológico mais comercializado irregularmente foi o anti-inflamatório, assim como dentre os 5 fármacos mais apreendidos, os mais encontrados foram o Diclofenaco sódico e potássico (59%). Através de um balanço da série histórica semestral, ficou evidente que o número de Ações por semestre aumentou e que a quantidade de medicamentos apreendidos diminuiu. **Conclusão:** este estudo demonstra o risco que está exposto a população, através da possibilidade do uso irracional de medicamentos, principalmente anti-inflamatórios. Ressalta-se a importância de outros trabalhos na área para identificar a eficácia das ações de repressão ao comércio irregular de medicamentos, e desta maneira promover a melhoria no planejamento nas ações de vigilância sanitária.

DESCRITORES: vigilância sanitária, medicamentos, auto de apreensão e remoção, auto-medicação.

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