

Analysis of the medicine sales on the Internet: the case of the phosphodiesterase-5 inhibitors

Análise da venda de medicamentos pela Internet: o caso dos inibidores da fosfodiesterase-5

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ABSTRACT

Context: The e-commerce of medications is one of the most recent expressions of irrational drug use, as part of the “medicalization of the society” process. Medicines with high marketing appeal, such as the 5-phosphodiesterase inhibitors (5PDEI), represent the extreme cases of this contemporary public health problem. **Objective:** The objective of this study was to analyze the features of legal and illegal 5PDEI e-commerce websites in Portuguese language, according to the Brazilian medicine marketing regulation benchmark. **Methods:** Websites containing advertisements of legal and illegal presentations of 5PDEI were searched using the Google™ search engine. Data regarding adherence to the ANVISA recommendations were collected and statistical analysis was performed to compare the variables between legal and illegal presentation advertisements. **Results:** The study found 497 advertisements, 310 legal and 187 illegal. Both types of sites showed few differences regarding the analyzed variables, as well as low adherence to the ANVISA recommendations. **Conclusion:** This study shows that the regulation of medicines e-commerce in Brazil is incipient. Thus, beyond the regulation benchmark, more general public health interventions are important and needed.

RESUMO

Contexto: O comércio eletrônico de medicamentos é uma das mais recentes expressões do uso irracional de medicamentos, como parte do processo de “medicalização da sociedade”. Medicamentos com alto apelo mercadológico, tais como os inibidores da 5-fosfodiesterase (5PDEI), representam casos extremos deste problema de saúde contemporâneo. **Objetivo:** O objetivo deste estudo foi analisar as características de endereços eletrônicos para 5PDEI legais e ilegais em português, de acordo com o marco regulatório do mercado de medicamentos brasileiro. **Métodos:** Endereços eletrônicos contendo anúncios de venda de apresentações legais e ilegais de 5PDEI foram buscados pelo uso da ferramenta de busca Google™. Os dados relativos à adesão às recomendações da ANVISA foram coletados e uma análise foi realizada de modo a comparar as variáveis presentes nas propagandas das apresentações legais e ilegais. **Resultados:** o estudo encontrou 497 anúncios, 310 legais e 187 ilegais. Ambos os tipos de endereços eletrônicos apresentaram poucas diferenças referentes às variáveis analisadas, assim como baixa adesão às recomendações da ANVISA. **Conclusão:** Este estudo demonstra que a regulação do comércio eletrônico de medicamentos no Brasil é incipiente. Assim, para além do marco regulatório, intervenções de caráter mais genérico em saúde pública são importantes e necessárias.

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INTRODUCTION

The e-commerce has driven the attention of global healthcare decision-makers, due to its potential risks to the population. One of the main problems related to the e-commerce of medications is the absence of a healthcare professional, either a physician or a pharmacist, mediating the purchase of the product. Another element that could increase those risks is the supply of forbidden medications, without proper registration according to the countries' regulatory agencies. Thus, the websites that offer those drugs are illegal, not taking any responsibility on any aspect related to quality or safety of the drug being offered to the "web surfer patient"⁽¹⁻²⁾.

The World Health Organization (WHO), in its 50th Annual Assembly, in 1997, had already stated a warning about the possible damages related to the remote medication sales⁽³⁾. In the United States (US), the Food and Drug Administration (FDA) estimates that more than 10% of the medicines globally sold are counterfeit, although this number might overpass 25% in peripheral countries⁽⁴⁾. In 2006, the WHO estimates, in the first official meeting of the International Medical Products Anti-Counterfeiting Taskforce, that 50% of the medications commercialized on the Internet were fake, and people in the developing countries are at especial risk of using fake drugs purchased on the Internet⁽⁴⁻⁶⁾. In Latin America and Africa, it is estimated that 30% of the medications are counterfeit. In some former socialist countries, this estimation would be 20%, and in developed countries, this number would reach to 1%⁽⁴⁻⁶⁾. According to the United Nation's International Narcotics Control Board (INCB), this situation tends to get more severe due to the virtual medication commerce. It is estimated that the profit from the global counterfeit medication commerce surpasses 32 billion dollars a year^(2,4).

In Brazil, the medication e-commerce was recently regulated by the Board of Directors' Resolution (BDR) ("*Resolução da Diretoria Colegiada – RDC*") no. 44, published on August 17th, 2009, by the National Agency of Hygiene Surveillance ("*Agência Nacional de Vigilância Sanitária – ANVISA*"), which established rules for the licensing and operation of virtual pharmacies or other modalities of remote care. Some examples of the requirements that the virtual pharmacies must be compliant to are: only pharmacies and drugstores that are open to the public, with a pharmacist present all through the establishment's open hours, are allowed to sell medications ordered remotely; it is mandatory for the presentation and the analysis of the prescription by the pharmacist before the delivery of prescription-only drugs; the website must adopt a domain ended with ".com.br", and it must contain, on its homepage, information about the pharmacy or drugstore in charge of the delivery and about the pharmacist who is technically responsible

for the pharmacy or drugstore, and must provide direct links to: data about the pharmacist who attended the customer, alert messages and hygiene recommendations determined by ANVISA, and warnings about prescription-only drugs, which will only be delivered by the presentation of the prescription, including the method by which it should be sent to the establishment (fax, e-mail or others)⁽⁷⁾.

The use of Phosphodiesterase Inhibitors (5PDEI) drugs, used for Erectile Dysfunction (ED), may generate several side effects such as headache, facial flush, nasal congestion, dyspepsia, back pain or visual disorders. Those drugs might increase the risk of cardiac diseases as well, especially by maximizing the hypotensive effect when associated to nitrate-based anti-hypertensive drugs⁽⁸⁻¹⁰⁾.

It is often observed the use of those drugs without a prescription, thus characterizing a recreational and abusive use. One fact that increases the severity of the situation is the occurrence of 5PDEI abuse by illicit drug users, especially ecstasy and amphetamines, which have ED as a side effect, thus leading the users to take 5PDEI to avoid the sexual impotence, which generates a vicious cycle of combined use of potentially harmful substances in the search for entertainment each at a cost. Another problem associated with the indiscriminate use of 5PDEI is the increase of risky sexual practices, with great potential of disseminating sexually transmitted diseases⁽¹¹⁻¹²⁾.

Thus, with the intent to inform the debate on the global medication e-commerce, this study performed an exploratory analysis of the information published on websites that sell legal and illegal 5PDEI drugs, targeted to the Brazilian customer market.

METHODS

The study followed a cross-sectional design. The research was performed for each one of the 5PDEI drugs on a single search, in a single day, prior to the publication of the RDC 44/2009 regulation. The selection of the web pages was made by searching the Google? website and selecting "pages in Portuguese". The legal drugs that were searched were: Viagra[®] (sildenafil citrate), Cialis[®] (tadalafil), Levitra[®] (vardenafil); and the illegal drugs, according to the Brazilian legislation, were Pramil (sildenafil citrate) and Eroxil (tadalafil).

The search was performed with the keywords mentioned above, followed by the word "reais" or the symbol "R\$", separately. Those keywords were used since those are the names adopted by the legal medicines in Brazil, and the known names of the illegal ones. The use of the terms "reais" or "R\$" was justified because there was an intention to restrict the search to the advertisements that showed the price in Reais, the Brazilian currency, and therefore demonstrably targeted to the Brazilian customer market. The methodology

of search for healthcare information on the Internet proposed by Sajid *et al.*⁽¹³⁾ was adopted, by analyzing all Internet pages, published on different websites.

Information was collected from the websites on a proper form built on Appnitro™ pForm™, including variables related to the website and vendor location. The presence of information about indication, contraindication and dosage, the words “safety”, “confidence”, “quality” and “guarantee” (“segurança”, “confiança”, “qualidade” e “garantia” in Portuguese), were also selected due to their prevalence in advertisements, and the website’s compliance to the Brazilian RDC 44/2009 legislation.

A univariate and bivariate descriptive analysis was performed, showing the absolute and relative (in percentage) frequencies of the categorical variables and adopting Pearson’s Chi-square hypothesis test for differences between proportions, and odds ratios were adopted as measurements of association. The confidence level of the estimations was set to 95%. The BrOffice’s “Assistente de Dados” tool, similar to the OpenOffice’s Data Pilot, was used for database tabulation and table formatting; the Chi-square test was calculated using the statistical analysis application R version 2.9.2; odds ratios and its respective confidence intervals were estimated by using the Statcalc tool from the epidemiological analysis

application EpiInfo version 3.4.2.

RESULTS

A total number of 497 advertisements were found after the search was performed. For legal medicines, a higher number of advertisements was found (n = 310; 62.4%) and for illegal medicines, 187 advertisements were found (37.6%).

Regarding the website and vendor features, it was found that for legal medicines advertisement published by legal entities (46.1%) were in higher proportion than those posted by individuals, and in a proportion of those sites (17.7%) it was not possible to identify the type of vendor. On the other hand, no advertisements from legal entities were found for illegal medicines, just from individuals (82.3%).

The most frequent way of contact found on the websites, for both types of medicines, was the “contact us” style of message form (73.4%), although it was noticed that the e-mail and telephone contacts showed similar frequencies for legal medicines, which doesn’t happen in the illegal ones. Nevertheless, the differences found on the proportional distribution of those variables did not show statistical significance (Table 1).

Few sites, both selling legal and illegal medicines, showed information about drug indication (18.9%),

Table 1 - Website and vendor features by type of medicine (legal and illegal).

Variable	Legal medicines		Illegal medicines		Total	
	n	%	n	%	n	%
Type of vendor						
Not identified	55	17.7	33	17.7	88	17.7
Individual	112	36.1	154	82.3	266	53.5
Legal entity	143	46.1	0	0.0	143	28.8
Total	310	100.0	187	100.0	497	100.0
Type of contact						
E-mail	36	10.5	73	30.3	109	18.7
Message form	274	80.1	154	63.9	428	73.4
Telephone	32	9.4	14	5.8	46	7.9
Total*	342	100.0	241	100.0	583	100.0

* The total value of the variable “type of contact” is higher than the total number of sites, since it was found more than one type of contact on some websites.

Table 2 - Information on indication, counter-indication and dosage by type of medicine (legal and illegal).

Variable	Legal Medicines		Illegal Medicines		Total		Odds Ratio (95% CI)*
	n	%	n	%	n	%	
Presence of information on indication							
Yes	76	24.5	18	9.6	94	18.9	3.05
No	234	75.5	169	90.4	403	81.1	(1.71-5.50)
Total	310	100.0	187	100.0	497	100.0	
Presence of information on counter-indication							
Yes	20	6.5	19	10.2	39	7.9	0.61
No	290	93.5	168	89.8	458	92.1	(0.30-1.23)
Total	310	100.0	187	100.0	497	100.0	
Presence of information on dosage							
Yes	35	11.3	42	22.5	77	15.5	0.44
No	275	88.7	145	77.5	420	84.5	(0.26-0.74)
Total	310	100.0	187	100.0	497	100.0	

* 95% CI = 95% Confidence Interval.

but the sites selling legal drugs had a chance three times higher than the illegal ones of providing that information. The same was observed for the information on counter-indication (7.9%), and there was no statistically significant difference between legal and illegal medicine websites regarding this variable. Information on dosage was

seldom observed as well (15.5%). The websites selling legal medicines showed a statistically significant lower chance of 56% of showing dosage information than the illegal ones (Table 2).

The word "Safety" ("Segurança" in Portuguese) occurred on 21.7% of the websites, and there was a

Table 3 - Distribution of the websites with the words "Safety", "Quality", "Confidence" and "Guarantee" ("Segurança", "Qualidade", "Confiança" and "Garantia" in Portuguese) by type of medicine (legal and illegal).

Variable	Legal Medicines		Illegal Medicines		Total		Odds Ratio (95% CI)*
	n	%	n	%	n	%	
Presence of the word "Safety" ("Segurança" in Portuguese)							
Yes	92	29.7	16	8.6	108	21.7	4.51
No	218	70.3	171	91.4	389	78.3	(2.48-8.30)
Total	310	100.0	187	100.0	497	100.0	
Presence of the word "Quality" ("Qualidade" in Portuguese)							
Yes	9	2.9	21	11.3	30	6.0	0.24
No	301	97.1	166	88.7	467	94.0	(0.10-0.56)
Total	310	100.0	187	100.0	497	100.0	
Presence of the word "Confidence" ("Confiança" in Portuguese)							
Yes	10	3.2	26	13.9	36	7.2	0.21
No	300	96.8	161	86.1	461	92.8	(0.09-0.46)
Total	310	100.0	187	100.0	497	100.0	
Presence of the word "Guarantee" ("Garantia" in Portuguese)							
Yes	2	0.6	14	7.5	16	3.2	0.08
No	308	99.4	173	92.5	481	96.8	(0.01-0.38)
Total	310	100.0	187	100.0	497	100.0	

* 95% CI = 95% Confidence Interval.

Table 4 - Frequency of the RDC 44/2009 requirements by type of medicine (legal and illegal).

Variable	Legal Medicines		Illegal Medicines		Total		Odds Ratio (95% CI)*
	n	%	n	%	n	%	
Website's domain name ended in ".com.br"							
Yes	43	13.9	68	36.4	111	22.3	0.28
No	267	86.1	119	63.6	386	77.7	(0.18-0.45)
Total	310	100.0	187	100.0	497	100.0	
Presence of the pharmacy's brand name							
Yes	147	47.4	7	3.7	154	31.0	23.19
No	163	52.6	180	96.3	343	69.0	(10.15-55.71)
Total	310	100.0	187	100.0	497	100.0	
Presence of the drug's active principle name							
Yes	159	51.3	30	16.0	189	38.0	5.51
No	151	48.7	157	84.0	308	62.0	(3.44-8.87)
Total	310	100.0	187	100.0	497	100.0	
Presence of the pharmacy's complete physical address							
Yes	67	21.6	-	-	67	13.5	NE**
No	243	78.4	187	100.0	430	86.5	
Total	310	100.0	187	100.0	497	100.0	
Presence of the pharmacist's name							
Yes	18	5.8	-	-	18	3.6	NE**
No	292	94.2	187	100.0	479	96.4	
Total	310	100.0	187	100.0	497	100.0	
Presence of the pharmacist's CRF registration number							
Yes	18	5.8	-	-	18	3.6	NE**
No	292	94.2	187	100.0	479	96.4	
Total	310	100.0	187	100.0	497	100.0	
Presence of the operating authorization issued by ANVISA							
Yes	18	5.8	-	-	18	3.6	NE**
No	292	94.2	187	100.0	479	96.4	
Total	310	100.0	187	100.0	497	100.0	

* 95% CI = 95% Confidence Interval. ** NA = Not evaluated (due to the presence of zero value cells).

4.5 times higher chance of finding that word on legal than illegal medicine websites. The words “Quality”, “Confidence” and “Guarantee” (“*Qualidade*”, “*Confiança*” and “*Garantia*” in Portuguese) presented low frequency and statistically significant lower chances of being present on legal medicine websites compared to the illegal ones (Table 3).

Regarding the compliance of the advertisements to the Brazilian RDC 44/2009 legislation, it was observed that only a minority of websites adopted domain names ended in “.com.br” (22.3%), and there is a statistically significant 72% lower chance of finding the “.com.br” extension on legal medicine websites than on the illegal ones.

The proportion of websites showing the pharmacy’s brand name was 31.0%, with a 23 times higher chance of finding this information on legal medicine websites.

The information about the name of the active principle of the drug, according to its common denomination in Brazil, was present only on 38.0% of the advertisements, and the chance of that occurrence was 5.5 times higher, with statistical significance, for legal compared to illegal medicine websites.

In addition, only on legal medicine websites the information about the pharmacy’s complete physical address and the operation authorization issued by ANVISA, the pharmacist’s name and registration in the Regional Pharmacy Council (*Conselho Regional de Farmácia – CRF*), was found, in low proportion (Table 4).

The present search did not find any website showing information about other requirements from RDC 44/2009, such as the pharmacy’s corporate name, legal entity registration number (“*Cadastro Nacional de Pessoa Jurídica*” – *CNPJ*), business hours, hygiene licensing or authorization, and alert messages or recommendations.

DISCUSSION

The Internet provides easy access to any type of information about healthcare, including drug purchase, even those whose commerce is forbidden within each country, depending on local legislation.

The first finding that drives the attention in this study is the similarity of basic features between legal and illegal medication e-commerce websites. There were no statistically significant differences for any of those features, thus showing the lack of regulation before the publication of the RDC 44/2009 legislation, which made it difficult to discern the behavioral differences between the legal and illegal vendor. The general lack of advertisement normalization for the Internet allows the occurrence of several illegalities that puts the generic Internet purchaser in jeopardy⁽¹⁴⁾. The heterogeneity of results regarding the information about indication (more frequent on legal medicine websites), counter-indication (no statistic difference) and dosage (more frequent on illegal medicine websites) highlights this

lack of definition of the thresholds between what is legal and illegal in a situation of fragile regulation.

The low proportion (18.9%) of advertisements presenting information about drug indication found in this study was not expected, since the hypothesis was that the vendors would promote the drug sales through its indication. Nevertheless, those results suggest that the 5PDEI indication is well known and widespread among the general public. Regarding the study results about drug dosage, which are apparently counter-intuitive, the individual analysis of each advertisement has suggested that because of the fact that the leaflet of illegal medications; when present was written in foreign languages.

By the analysis of the expressions used by the advertisements it is possible to see that the illegal medicine websites show a higher frequency of typical advertisement expressions. The exception is for the use of the word “safety” (“*segurança*” in Portuguese) more were found on legal medicine websites. Those results are expected since the use of terms that manipulate the customer’s understanding of reality is a traditional strategy of advertising in general, only to lead ultimately to false advertising⁽¹⁵⁻¹⁶⁾.

Regarding the compliance of the websites to the RDC 44/2009 regulation, it is important to stress the fact that this study was performed before its implementation. This provided the ability to develop an analytical baseline for further follow-up studies. The results show that the majority of the 5PDEI advertisements included in this study was not published on websites whose domain name ended in “.com.br”, which challenges the RDC goals. It is interesting to notice, however, that the domain extension was more frequent for illegal medicine websites, which suggests the sense of impunity of the advertisers. Therefore the advertisers may feel protected by the dynamics and fluidity of information posted on the Internet⁽¹⁷⁾.

On the other hand, the advertisements for legal 5PDEI drugs had more chance to show information on the brand name and active ingredients, compared to the illegal ones. That result was expected, since the legal advertisers have more interest in showing compliance to the norm than the illegal ones. The latter, by the nature of their activity, do not feel obligated to following regulations. For the same reasons, only on legal 5PDEI websites, information about the pharmacist name and registration and the pharmacy’s operation authorization issued by ANVISA was found.

The total nonexistence of information on the websites about other RDC 44/2009 requisites shows that the process of adjustment in order to comply with the legislation, in the case of the websites selling legal medications, will be long, as is expected for cultural change. Especially in a conservative social sector such as healthcare⁽¹⁸⁻¹⁹⁾.

Like other studies based on Internet search^(9-11,13),

the present study showed some limitations.

In the first place, the exclusive use of the Google? search engine is an example. Because other web-based search engines could have retrieved different results. Nevertheless, the Google? search engine is currently acknowledged as the most efficient in terms of answers to queries. In a recent comparison to concurrent tools (Yahoo! ? Search?, Microsoft? Live Search?) and with some seldom used engines (Yahoo!? Search?, Microsoft? and Live Search?) beside some specialized search services (Blogdigger?, Picsearch? and TubeSurf?), Google? has achieved the best performance (except for specific text search), compared to the other competitors⁽²⁰⁾. Also there was an interest in this study, to imitate the Internet user's searching behavior. In this case the choice for the most popular searching tool was an important decision, since it would allow the investigation to get closer to the reality experienced by the common user on his or her searching. Therefore choosing Google? was coherent with the interest of this research, since this search engine is the preference of 78% of the Internet users in the United Kingdom, and of 63% in the United States, although there are no studies about the Brazilian reality on this subject⁽²¹⁾.

In addition, by restricting the search using the name of the drug, added to the term "R\$" or "Reais", the search was exclusively targeted in principle, to the Brazilian purchaser. Nevertheless, this search restriction excluded from the results the advertisements that did not show the price of the product. Thus, this exclusion criterion, since it was directly implemented on the search algorithm, might have restrained the universe of pages analyzed by this study. Thus, it is possible to suggest that there is a selection bias affecting the results, as long as the advertisements that do not show the price of the drug in Brazilian Reais in text form (a price as part of an image might be excluded).. This is

not unlikely, since fake advertisements tend to be less informative about the price of their products²². Despite those limitations, this study was able to shed some light on the public health problem of medication e-commerce, and it establishes a baseline for further studies.

CONCLUSIONS

This study showed that it is necessary to establish a baseline and maintain a constantly updated database of the regulatory compliance of medication sales on the Internet. Especially for those that present a huge marketing demand, such as the 5PDEI. The National States should be aware of the need for the enforcement of the regulations, otherwise it will be even more difficult to prevent the irregular or illegal medication e-commerce, given the relative ease of advertisement, the increased access to the Internet and the impossibility of the total prohibition of this media for medicine commerce.

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