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Evaluation of Brazilian online pharmacies

ABSTRACT

The growing number of Internet users brought forth an increase in the search for Brazilian online pharmacy services. Aiming at evaluating the validity of information disseminated in these websites, a descriptive study was carried out in 18 virtual pharmacies concerning legal aspects, accessibility, sources of information and drug advertisements. It was found 15 pharmacies did not have authorization of the Brazilian National Health Surveillance Agency; the manager pharmaceutical officer's name could not be found in 17 of them; 17 pharmacies marketed drugs with no registration, especially herbal medicines, and did not show either information on adverse drug reactions or this agency's alerts and health recommendations. Since health control and drug commerce in Brazilian online pharmacies have not been yet regulated by proper government agencies, these gaps found in the sites can pose risk to the users' health.

KEYWORDS: Drug commerce. Internet. Standards. User-computer interface. Drug. Legislation. Health surveillance.

INTRODUCTION

Online pharmacies are computerized systems having the potential role of real pharmacies and handling business transactions remotely with no physical proximity between consumers and drug retailers.* These pharmacies' business is modest in Brazil compared to that in developed countries where online drug retail services are regularly available.¹ The growing number of Internet users in Brazil can bring forth an increased demand for these drug retail services.

Health control and drug commerce in Brazilian online pharmacies have not yet been regulated. In 2001, the Brazilian National Health Surveillance Agency (ANVISA) published a public consultation* with the purpose of regulating the operations of online pharmacies. Nonetheless, their operation has not yet been regulated as this is still a subject of strong discussions among ANVISA, representatives of pharmaceutical companies, civil society, and the Brazilian Pharmacy Board, which is the agency that regulates pharmaceutical occupation. The objective of the present study was to evaluate Brazilian online pharmacies aiming at assessing the validity and potential gaps in the information provided.

METHODS

A descriptive study was carried out to evaluate Brazilian online pharmacies.

The inclusion criterion was drug retail websites with *Uniform Resource Locators* (URL) ending in ".br". The exclusion criteria were as follows: websites that only made information available on drugs and price lists; institutional websites of

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pharmacy businesses; sites of drug distributors; sites of online veterinary pharmacies; and sites of manipulation pharmacies. A total of 18 Brazilian online pharmacies were evaluated between March and May 2005.

Data was collected from each website using a form comprising 13 items grouped according to five variables:

- Legal issues – approval of operation; drug company's complete geographical address; states where the drug retail company is licensed for drug commerce, name of the manager pharmaceutical officer providing assistance to consumers; and logs of contacts with prescribers to assure prescription dispensing;
- Drug information – comprehensible by consumers; reference of the body providing the information available or of any entity supporting the publication of this information;
- Forms of communication – types of contact for providing drug information or for asking questions to the manager pharmaceutical officer; and means facilitating contact with consumers and, if needed, prescribers;
- Drug commerce – drugs registered at ANVISA; drug advertising or marketing of prescription drugs found anywhere in the website; and controlled drugs; and
- Communication with ANVISA – mechanisms of prompt communication of adverse drug reactions and communications with the National Pharmacovigilance Service, alerts and health recommendations.

RESULT ANALYSIS

There were evaluated 18 online pharmacies that were almost distributed nationwide. Of them, ten were based in São Paulo and Rio de Janeiro in the Southeastern region, six in the Southern region (three in the state of Paraná, two in the state of Rio Grande do Sul, and one in the state of Santa Catarina), and of the remaining, one was based in the state of Mato Grosso do Sul in the Midwestern region, and one in the state of Ceará in the Northeastern region.

In regard to ANVISA's approval of operation, 15 online pharmacies have not yet been approved, which can in-

dicating the lack of specific regulations for this pharmacy. According to the Public Consultation No. 20/01,* as for the basic requirements for approval of operation, online pharmacies should comply with the current law, Law No. 6,360/76, granting drug companies authorization to market their products subject to health control.** However, these legal requirements have not yet been regulated. It could be verified this information is not available in the websites of online pharmacies.

Seventeen pharmacies did not make available the name of the manager pharmaceutical officer providing consumer assistance and responsible for the website operation. Law No. 5,991/73 establishes that the pharmaceutical officer is solely accountable for drug dispensing.*** Therefore, many online pharmacies operate unlawfully in Brazil as they are not accountable for drug dispensing and drug assistance.

The information on the pharmacy's or drug company headquarter's geographical address should be available in the website's home page and there should also be specified the Brazilian states where the pharmacy is licensed for drug commerce. The address information was provided by two pharmacies and only one of them specified the state where it can operate in a secondary page of the website. Of three pharmacies licensed to operate, only one provided its complete geographical address but none of them specified either the states where they are licensed for drug commerce or the name of their manager pharmaceutical officers.

As indicated by the Public Consultation No. 20/01, online pharmacies should have a toll-free phone number (0-800) making the contact between consumers and the pharmacy easily accessible for questions on drug use or other specific questions to the manager pharmaceutical officer through their site. Of 18 pharmacies studied, only four had a toll-free phone number, 12 had direct dial long-distance numbers, and two did not provide any contact phone number. The four pharmacies that made available their toll-free phone number had also communication through e-mail and two of them had webchats available. It was found that all pharmacies did not provide consumers means of communication (phone, e-mail, webchats) to request information after drug purchase.

As for drug shipping by the Brazilian Mail and Telegraph Company (ECT), 17 pharmacies reported using this service nationwide. Of them, two were not approved to market drugs directly to consumers: one was

* Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Consulta Pública No 20, de 21 de março de 2001. Brasília: MS/Anvisa, mar. 2001. Available at: [http://www4.anvisa.gov.br/base/visadoc/CP/CP\[2946-1-0\].PDF](http://www4.anvisa.gov.br/base/visadoc/CP/CP[2946-1-0].PDF) [Accessed on Dec 2, 2004].

** Brasil. Lei nº. 6.360, de 23 de setembro de 1976. Dispõe a vigilância sanitária a que ficam sujeitos os medicamentos, as drogas, os insumos farmacêuticos e correlatos, cosméticos, saneantes e outros produtos e dá outras providências. Brasília, 1976. Available at: <http://e-legis.bvs.br/leisref/public/showAct.php?id=16615&word=> [Accessed on May 30, 2005]

*** Brasil. Lei nº. 5.991, de 17 de dezembro de 1973. Dispõe sobre o controle sanitário do comércio de drogas, medicamentos, insumos farmacêuticos e correlatos, e dá outras providências. Brasília, 1973. Available at: <http://e-legis.bvs.br/leisref/public/showAct.php?id=16614&word=>. Accessed on Dec 2, 2004.

a drug distributor and the other one was a pharmaceutical industry; only the latter was approved to operate. Information on the drug distributor was not available on their website and they introduced themselves as a regular online pharmacy but it was verified in ANVISA's website their categorization as a drug distributor.

Drugs are required to be stored and shipped under specific temperature and humidity conditions. Administrative Rule No. 12 determines that only ANVISA-certified companies are authorized to drug shipping.* Although certified, ECT cannot assure shipping specifications for the different drugs on the way up to their delivery at the consumers' home, their physical and chemical and microbiological stability properties can be affected and they can be harmful to consumers' health. This is a challenge that needs to be addressed by proper agencies.

Only six pharmacies provided consumers information on the proper use of drugs, such as preservation specifications, dosage, contraindications, (drug and/or food) interactions, and potential adverse drug reactions. This information was provided by pharmaceutical companies through drug inserts. According to Gonçalves et al,² quality of information on these drug inserts is not reliable, once they omit or soften important information. Four pharmacies provided information such as "natural product," "no contraindications," and "no adverse effects," which constitute deceptive marketing practices.

There were identified 17 pharmacies that made available to consumers unregistered drugs, especially herbal medicines, as confirmed in ANVISA's drug registration. Six of them did not comply with the regulations on drug commerce and four violated the regulations forbidding commerce of controlled drugs.

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* Ministério da Saúde. Portaria nº. 12, de 05 de janeiro de 2005. Brasília: MS, 2005. Available at <http://e-legis.bvs.br/leisref/public/showAct.php?id=14133&word=> [Accessed on May 30, 2005].

** Ministério da Saúde. Agência Nacional de Vigilância Sanitária. Resolução de Diretoria Colegiada nº 48, de 16 de março de 2004. Brasília: MS/Anvisa, 2004. Available at URL: <http://e-legis.anvisa.gov.br/leisref/public/showAct.php?id=10230&word=> [Accessed on May 19, 2006].

Non-registration of herbal medicines indicates these drugs did not go through ANVISA's inspection procedures. These products' quality is questionable as their safety and therapeutic efficacy has not been evidenced entailing further risk to people's health.**

In addition, it was verified no pharmacy had any means of communication with ANVISA available in their websites for prompt reporting of adverse drug reactions as well as they did not provide any alerts or health recommendations.

The lack of regulations by ANVISA and state health surveillance agencies on online pharmacies became evident. This can lead to easy access to unregistered drugs and lack of control on prescription drug commerce, acting as facilitating factors for improper and indiscriminate drug use. Improper drug use can expose people's health to risks such as therapeutic inefficacy, unsafe drug use, adverse drug reactions, poisonings, and (drug and/or food) interactions.

The study findings show the need for regulations in this new modality of drug commerce in Brazil. These pharmacies should be subject to more efficient inspections by health authorities and heavy penalties should be imposed on violators, thus benefiting the community and responsible pharmacies.

For these regulations to be effective, it is crucial to stress the role of pharmaceutical officers as technical specialists responsible for online pharmacies and for providing drug information in their websites as well as being skilled providers to assist consumers. As a result, an effective service can be provided, allowing to expanding the pharmaceutical profession into a new field of operation.