

**Assessment of current status of e-pharmacies**

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Conflicts of Interest: Nil.

Abstract

Objectives: Study was conducted to assess information of e-pharmacy websites, their potential benefits and risks to the consumers and to evaluate the information available about Amoxicillin (schedule H), Alprazolam (schedule X), Codeine (over the counter).

Method: It is a cross sectional observational study. Indian websites selling Amoxicillin, Alprazolam, Codeine were selected for evaluation. Search was done by using keywords like online pharmacies, e-pharmacies, from Dec.2016 to April.2017. Websites displayed in first 7 pages of Google search were selected and screened for details deemed to be of relevance to a user and were compared to identify differences which could be used to improve patient safety. Prescriptions for above mentioned drugs were uploaded and were assessed for valid dispensing.

Result: Out of 26 accessed sites, 2 were under construction. All 3 study drugs were available on 58.84% sites. All three contact details (address, phone number and email id) were disclosed by only 45.83% sites, 45.83% sites did not provide address. All sites provided drugs only with prescription, but 29.16% sites also accepted the invalid prescription. Only 29.16% sites provided drugs as

quantity prescribed (up to 10 strips), rest of sites as per patient's demand. Both branded and generic drugs were provided by 61% sites. None of the sites asked about co-morbidities, drugs history and pregnancy. While only 37.5% provided the drug information.

CONCLUSION: Medicines are made available at doorstep to consumers by e-pharmacy. Yet, regulations are needed for the appropriate functioning of e-pharmacy and for the safe use of medicine by the consumers.

Keywords: e-pharmacy, information, regulations, valid dispensing.

Introduction

An online pharmacy is a company that sells pharmaceutical preparations, including prescription-only drugs, via online ordering and mail delivery. 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. [1] To ensure the optimal use of medicines, consumers should have appropriate usage. [2] Another aspect that is important to consider is that the Internet can facilitate access and thus support abuse of prescription drugs. [3] While some websites mention that prescriptions for the drugs order can be sent via email or

fax, fake prescriptions too could be presented as proof, and this is in no way a means to monitor sale of prescription drugs. The Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, have clear guidelines on the sale of Schedule H and Schedule X drugs. These can be sold only on prescription and there are specific rules, including for labelling. [4] These are the drugs commonly misused and have a threat of abuse liability, dependence, tolerance in patients, hence the drugs from each schedule H, schedule X and OTC (over the counter) been selected for study. In India, the growth of online Pharmacy is significantly escalating, and has become a life threatening nuisance, but Indian government has still not deemed it appropriate to tackle this problem. We have no dedicated e-commerce laws and regulations in India. [5] In a shocking turn of events, the Maharashtra Food and Drug Administration (FDA) has approached the Drugs Controller General of India (DCGI) to device an action plan for curbing the illegal online sale of medicine. According to them so far there are 86 websites operating in country engaged in sale of online drugs out of which 44 websites operate in Indian territory and rest across the borders.[6] A very simple, yet daunting solution may be needed to enforce stringent laws on all these online pharmacies, making sure that no illegal drug (not even a trace) is found. Illegal and unregulated online sale of prescribed medicines in India is still happening despite the threat of the Directorate of Drugs Control of India to punish such illegal pharmacies. Any lack of personalized, well-informed professional healthcare advice, as is the case with most online pharmacies, is therefore a concern; this is particularly so with medicines which are known to interact, such as selective serotonin reuptake inhibitors, and medicines which are liable to abuse such as benzodiazepines.[7][8] Direct access to health services, especially drugs, poses a hazard to consumers because it is

difficult to determine whether drugs purchased online are counterfeit, unapproved or illegal.[9] Besides, the inappropriate use of medicines, the limited or nonexistent opportunity for advice (which blurs the line between willful abuse and unknowing misuse), and the risk of increased antibiotic resistance arising from their misuse have also been suggested as negative consequences of online purchase of medication.[10][11]

In UK, all online pharmacies must register with the General Pharmaceutical Council (GPhC) then they may display a registered pharmacy logo that is designed to provide customers with confidence in their transactions. The logo is verifiable and may be checked against a list of GPhC registered pharmacies and pharmacists.[12] Similar procedures found in USA with the National Association of Boards of Pharmacy (NABP) organizing programme called Verified Internet Pharmacy Practice Sites (VIPPS).[13] In Canada, the National Association of Pharmacy Regulatory Authorities (NAPRA) details a set of model internet pharmacy standards[14], which is supported by the Canadian International Pharmacy Association (CIPA).[15] But no such regulatory bodies are working in India where these online pharmacy websites have to register, and they don't have even a logo which is verifiable and checked, thus there exist a need for amendment of Drugs and Cosmetics act 1940. Health professionals who prescribe or dispense medicines have professional, ethical, and legal responsibilities to provide consumers with quality information and facilitate the safe and appropriate use of medicines, we don't know whether e-pharmacies provide such information or advices.

This study will be helpful for the awareness of the uninformed consumer about the safe use of schedule H and X drugs, and also will be helpful to know the quality of e-pharmacies, whether they support the safe and

appropriate use of medicines along with factors contributing to the e-prescribing errors.

Materials & Methods

This was a cross sectional observational study. Websites selling pharmacy drugs having all three drugs i.e (Amoxicillin, Alprazolam, Codeine) with free access, designed to distribute medicines, which are accessed in India were identified and selected for evaluation. Search was done using the search key words like online pharmacies, e-pharmacies, buy online medicines, using google, google scholar, etc. Data was collected from each website.

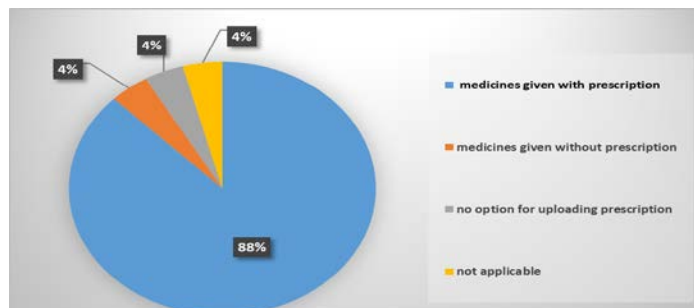
All the data obtained was evaluated in a stepwise manner for name of the site, name of the drug(brand or generic), its availability shown or not, drug information, number of other substitutes for the same drug, cost of the drug, given with prescription or not, method of uploading prescription, quantity limit, special instruction for associated diseases, drug intake, pregnancy, type of payment option, discounts offered or not, risk and benefits associated with online purchase to consumers, requirement of prescription ,contact details of the selling pharmacy websites, etc.

Statistical analysis: Data was entered into excel sheet and analyzed, results were expressed in percentage.

Results

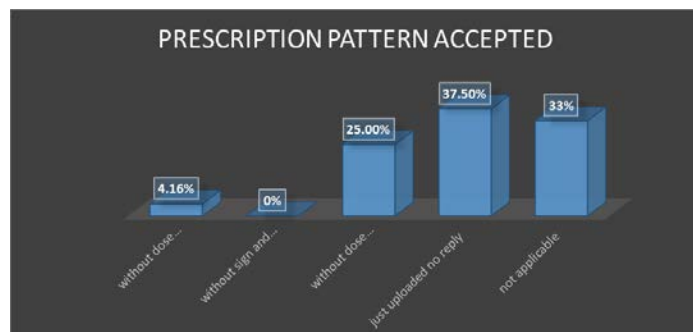
In the study total 26 sites were assessed, out of which 2 sites were under construction.

Fig1: Requirement of prescription for buying medicines



It was seen that 4.16% sites provide study drugs without prescription also while 87.50% sites provide them with prescription only.

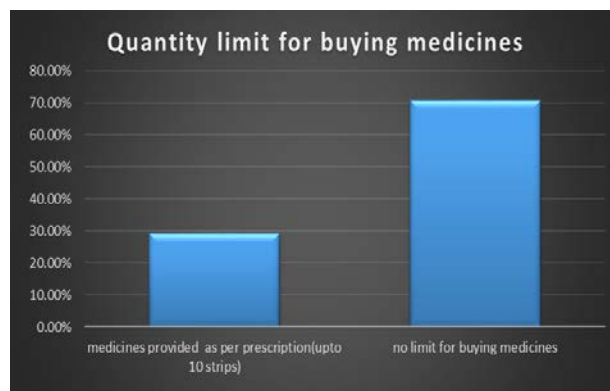
Fig.2 Prescription pattern accepted



In the study 29.16% sites accepted invalid prescription, out of which 4.16% sites accepted without dose frequency and 25% sites accepted without sign, registration number and dose frequency. No response was received from 37.5% sites. Out of those 33% mentioned as not applicable in (fig2), are as follows 25% sites did not have any of above mentioned response (4.16% online branch of brick and mortar pharmacies, 8.32% asked for prescription on delivery of medicines, 12.5% didn't have the option for uploading the prescription), whereas 8.33% sites did not accept the invalid prescription. (Fig2)

It was seen that 45.83% sites did not provide the physical address, whereas 12.55% sites provided only single contact detail (mobile number), while all the three contact details (i.e telephone no, physical address & email id) were provided by 45.83% sites.

Fig 3: Quantity limit for buying medicines



The overwhelming volume of purchase of drugs (without limit) was provided by 70.82% sites while only 29.16% sites provided the drugs as per prescribed in the prescription and maximum up to 10 strips. (fig 3) Drug Information was not provided by 62.5% sites, only 37.05% sites provided drug information. Out of the assessed sites, 25% sites provide only branded drugs, 50% provided both brand and generic drugs, whereas 25% sites didn't provide list of available drugs.

Table 1: Parameters related to the information of sites

	Availability of drugs shown	Mobile app provided	Payment option(cash on delivery and online)
Yes	58.33%	70.83%	66.66%
No	37.5%	29.16%	16.66%

For availability of the study drugs remaining 4.16% sites were the online branch of brick and mortar pharmacies, could not assess availability. Only a single option of payment was shown by 8.33% sites (Table. 1)

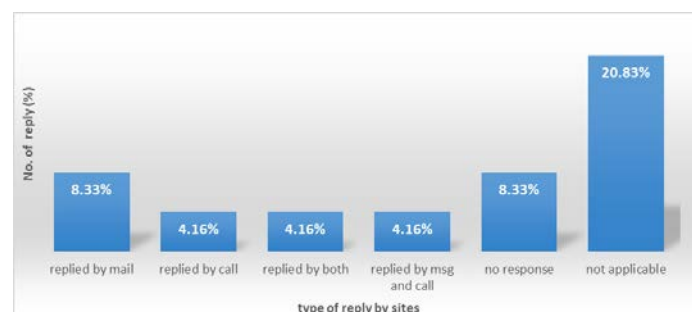
Name of all 3 study drugs were shown by 62.50% sites, while only Amoxicillin and Alprazolam was shown by 4.16% sites, and only single drug (Amoxicillin) was shown by 8.32% sites and (Alprazolam) by 4.16% sites, manual prescription was accepted by 4.16% sites, while 4.16% were the online branches of brick and mortar pharmacies. The 12.54% sites did not display the list of drugs.

Minimum number of steps in ordering a drug i.e. only a single step order was provided by 12.5% sites and 75% sites provide with an average of 1-5 steps.

Substitutes for same drug on same site were seen maximum for Amoxicillin and minimum for codeine, but

8.33% sites did not show even a single substitute. Discount of maximum 20% was shown by 4 sites (16.66%) and minimum of 5% by only one site (4.16%), rest 12 sites (50%) provide a discount of 10-15%, but 5 sites (20.83%) did not show any discount on drug purchase. The sites with online branch of brick and mortar pharmacy didn't show the shipping option, only one site (4.16%) was shipping outside Maharashtra. None of the sites ask the information about comorbidities and drug allergy nor about pregnancy status of consumer.

Fig 4: Types of reply received by sites after uploading prescription



Out of 24 sites 8.33% replied by mail, 4.16% replied by call, 4.16% replied by both, while 4.16% replied by message and call, only single site replied by mail and message and 8.33% did not give any reply. There were 20.83% sites which did not fit in any of the above criteria, and 16.66% sites did not ship in Maharashtra. (Fig4)

Discussion

Patients should have access to quality information regarding the risk, benefits and proper use of the e-pharmacies. They should be informed about the safe use of medicines.

Prescription prior to supply of drugs, helps prescriber to select appropriate drug for patient, this study shows that 87.50% sites provide drugs only with prescription, but 4.16% sites even provide the medicines without asking for the prescription. As study drugs are the prescription only drugs with abuse liability, should not be given without

prescription which may lead to misuse of drugs by consumers from the sites which provide them the drugs without prescription.

On a serious note it was observed that same prescription could be used on different sites and multiple times and by multiple persons, giving us an alarming signal and also is contravening to the definition of valid prescription.

It was also seen in our study that 45.83% sites didn't provide physical address for contact, hence the sites can't be meaningfully contacted, thus arising the question of legitimacy of site and security of consumers. As compared with previous study by Fittler A et al[16] where 22.79% sites didn't provide any contact details, all the sites had provided either of the contact details in our study.

Only 29.16% sites provide the drugs as per quantity mentioned in prescription whereas 70.82% sites provide the drugs in quantity as per consumer's demand, which may pose a threat of overuse leading to dependence, tolerance and resistance to the drugs, among the consumers. Thus lack of personalized and well informed professional healthcare advice is therefore a matter of concern.

To improve the safety, patients should be provided with proper information of drugs, not provided by e-pharmacies, which is not a case with brick and mortar pharmacies, where the pharmacist provides proper guidance about drug, thus confirming the safety of the consumers. During our study it was seen that only 37.05% sites provided the drug information while 62.5% sites had not given the complete drug information, whereas in previous study by Bessell TL et al[17] and Fittler A et al 2013[16], 60.57% and 92.64% sites had provided drug information respectively.

Only branded drugs were made available on 25% sites, but in study by Fittler A et al [16] it was 19.11% sites which provided only branded drugs. None of the surveyed sites

solely provided generic drugs, whereas in previous literature by Fittler A et al[16] 52.94% sites had provided only generic. Above findings suggests that the sites should provide more of generic drugs, for the cost effective health approach for consumers.

An inconvenience for the consumers, about which option to select among available stock of drug was faced, as 37.5% sites didn't display the availability of study drug in stock. The sites should improve and try to provide the list of availability of stock.

The mobile app which makes available the drugs at doorstep that too with few clicks, was not available for 29.16% sites, thus makes the ordering of drugs difficult for those, incapable or handicapped, even for care takers to get them at home.

Among the evaluated sites 66.66% sites had given the option for online and cash on delivery option for payment, but this was found to be (95%) in study done by Peterson A.M et al [18], above findings suggest that improvement is needed to make the online payment option available by all sites for ease in payment to the consumers.

During study it was seen that substitutes for drugs under study on the same site were not at all given by 8.33% sites so it is not possible for consumers to make a choice among available substitutes with better cost.

These e-pharmacy sites provide the drugs at doorstep with discount rate of maximum up to 20% and minimum of 5% to the consumers, these sites even provide quantity based discounts and free shipping thus provoking consumers to buy excess amount and overuse to redeem the discount. Hence stringent laws are required to curtail this quantity related discounts.

None of the above assessed sites had asked the patients about the comorbidities, simultaneous drug intake, drug allergies or the pregnancy status. May be most of the sites consider that the criteria's for POM's may be fulfilled by

the prescribers, but there are chances of mistake by practitioners in country like India, where the patient load is high, and which won't be the case in brick and mortar pharmacies where the pharmacists can explain the precautions and safe use of medicines, as may happen that consumers buying medicines online may proceed to take them without reading safety precautions.

After uploading of prescription, no response was obtained from 8.33% sites. Thus the patients requiring the medication in emergency situation may get affected. Those which were mentioned as not applicable in fig 4 were just having only a online branch of brick and mortar pharmacy or not shipping in Maharashtra hence a lot of inconvenience was noted from the side of consumers, which is the factor need to be focused.

Most of the e-pharmacies do not have the legally recognized status, so the consumers are left with no option. While purchasing medicines through these sites, consumers must be made aware of importance of regulated pharmacies and that the selling company has valid and meaningful contact information.

These e-pharmacies provide ease in access but has a risk of self-medication, hence need to create awareness among consumers and even the practitioners to educate the patients about safe use and hazards of overuse of these POM's (Prescription only medicines). Deadline must be set up for use of particular prescription. May be linking of Adhar card to particular patients account may prevent the reuse of same prescription by patient.

Limitation

No medicine purchase was completed. Hence we cannot confirm whether consumers were provided with any clinical information (package inserts). We could not even check the quality and appropriateness of drugs provided. We studied only 3 drugs, hence cannot generalize the results.

Conclusion

The e-pharmacies provides 24 hours access for drugs, only with few clicks at discount rate to our doorsteps easily by mobile app. The sale of overwhelming amount of POM's without a concern about comorbidities, drug allergy, drug interactions even pregnancy status that too by accepting invalid prescription is a matter of concern.

These e-pharmacies have no legally recognized status in our country, have no regulatory authorities as in other countries and with the advent of e-pharmacies there is a need to amend the Drugs and Cosmetics Act 1940 and enforce strong regulatory laws and guidelines for proper functioning of these e-pharmacies and for the safety of consumers.

Conflict of interest: None

This study was purely done with an intention to highlight the issue by demonstrating it practically, there was no other motive behind it.

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