

Research Article



A Comparative Study for Internet Pharmacy-Sale of Drugs in USA and UK

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ABSTRACT

In today's era of computers and supercomputers, the internet has become an indispensable part of our lives. Everything related to daily chores is available online on the internet. In a similar way, to sell medicines online (or via internet) has become a need of the time. There are increasing number of pharmacies that serve the patients via internet. With the increasing trend of online pharmacies, it has become increasingly important to establish appropriate regulations to keep check on these pharmacies. Many countries have such pharmacies that deal even with the delivery of prescription drugs. In order to control these, countries like United States of America (USA) and United Kingdom (UK) have developed strict norms that monitor and govern the business of such online pharmacies. This paper, describes in detail the use of online pharmacies and compares the rules and regulations prevalent in the USA and UK for the operations of online pharmacies.

Keywords: Internet Pharmacy, Online Pharmacy, comparative study.

INTRODUCTION

Online pharmacies or e-pharmacy is the latest trend in the pharmacy business. An online pharmacy also known as Internet pharmacy or mail-order pharmacy is a pharmacy that operates over the Internet and sends the orders to customers through the mail or shipping companies. There are plenty of online pharmacy sites that operate on daily basis to deliver number of drugs to the patients across countries. Such legalized mail-order pharmacies are similar to that of community pharmacies; the only difference being in the method of requesting and receiving the medications. Many customers find this more convenient than travelling to a community drug store. Many internet pharmacies in order to sell prescription drugs demand for a prescription, some do not require a pre-written prescription, this depends on the country specific regulations. Online pharmacies help to save a lot of money, often 90% less than the local pharmacy shops. People living in area where prescription medications are very expensive turn to online pharmacies to save money. Many websites also employ doctors or physicians to review the medication request and write a prescription accordingly. While some others offer medications without a prescription. With such pharmacies, there are a lot of risks associated. Some may not dispense through licensed pharmacies and greatly increase the chances of buying counterfeit, substandard or adulterated products. The risk of safeguarding individual's health without a prescription. Besides, the personal and financial information is at stake.

Internet pharmacy statistics in USA

US Customs have estimated 10million US citizens known to bring in medications at land borders each year. Many

others are known to arrive by international mails from Thailand, India, South Africa and other points. Factors associated with importation of drugs by U.S. residents are: age greater than 45 years, south or west region of residence, poor or near poor poverty status, lack of U.S. citizenship, travel to developing countries, lack of health insurance, fair or poor self-reported health status, prescription filling on the Internet, and using online chat groups to learn about health. A main attraction of which is the lower drug prices. A report in the journal Clinical Therapeutics found internet sale of drugs as a major reason for supply of counterfeit medications worldwide. Thus, the need for regulating the growth of online pharmacies and thus the Ryan Hatig online pharmacy Consumer Protection act was mended in 2008.

Registration of online pharmacy

The internet pharmacy to be setup in USA must meet the following criteria:

1. The internet pharmacy applicant must have a registered pharmacist licence with the Food and Drug Administration (USFDA).
2. The applicant should have a pharmacy store located in US and approved by the local state pharmacy.
3. The applicant must follow and abide by the laws and rules mentioned under the Controlled Substances Act and the Ryan Hatig Consumer Protection Act, 2008.
4. The applicant must also apply for certification by the NABP (national Association of Boards of Pharmacy).

Registration Procedure

The licence to run an internet pharmacy is provided by the local State FDA. The licence is provided by the board of pharmacy associated with the state FDA. The licence is



granted after an approval certification issued by the NABP. The total process of obtaining a licence requires about a 30 day period. For an internet pharmacy established, it is necessary to have a pharmacy licence and a pharmacy in full working condition and operating with the standards mentioned by the DEA (drug enforcement administration). The fees are to be paid annually and charge around 520 USD (\$).

Requirements of Internet Pharmacy

1. Following an approved licence by the FDA, the internet pharmacy has to abide by the laws and regulations set by the state FDA and those mentioned under 21 CFR.
2. The internet pharmacy must carry individual licences for the type of products to be dispensed. Example: license for controlled substance, injectable etc.
3. The pharmacy should register under the NABP programs and get certified by the VIPPS (verified internet pharmacy sites).
4. The domain name registration information of the pharmacy must be accurate, and the registrant must have a logical connection to the dispensing pharmacy. In order to assure safe and quality products dispensed by the pharmacy, the URL should carry a .Pharmacy address to the internet site.
5. An online pharmacy should display the VIPPS seal to assure that it has undergone thorough review of all policies and procedures as well as on – site inspections of facilities used by the site to receive, review and dispense medicine.
6. An accurate US street address of the dispensing pharmacy or corporate headquarters must be provided on the website. It should also provide on the website readily accessible and responsive phone number or secure mechanism via the website, that will allow the patients to contact or consult a pharmacist regarding concerns or in the event of a possible adverse event involving their medication.
7. The pharmacy must not engage in practices on its website that may deceive patients as to any material detail regarding the pharmacy, pharmacy staff, prescription drugs, or financial transactions.
8. The pharmacy, website, pharmacy staff, domain name registrants, and any person exercising control over, or participating in, the pharmacy business must not be affiliated with or control any other website that violates these standards.
9. The pharmacy located outside the United States cannot dispense drugs into the United States as ruled under the Drug Importation Act.
10. The sale of controlled drugs is regulated by the Ryan Hatig Consumer Protection Act, 2008. It states that any pharmacy selling controlled substances via the internet must have an authorization by the Attorney General of controlled substances and specify the quantity of controlled substances to be sold by it.
11. Controlled substances can be sold by the pharmacy only by requesting a prescription of a valid prescriber having registered with the NABP database.
12. The prescriber's information along with his registration number should be archived by the pharmacy.
13. Pharmacy authorised to sale controlled substances must have a mention on the homepage regarding the authorized sale of controlled substances. It should also mention the list of states where it is licensed to sale the controlled substances.
14. For refilling the prescription, the archive history must be referred to. In case of a prescription to be refilled by internet pharmacy not previously issued to the pharmacy, the pharmacy must verify the prescription with NABP database and possibly contact the prescriber to check its authenticity.
15. Those pharmacies not having a controlled substance license, can dispense controlled substance only in the condition of state emergency with appropriate orders from the state FDA. However, these pharmacies do not have the right to refill the prescription as per Ryan Hatig Consumer Protection Act, 2008.
16. The delivery drivers or mail services used to transport the drug orders must be registered with local state FDA.

Internet pharmacy statistics in UK

In the UK about 2 million people are known to buy drugs regularly from online pharmacies. Internet pharmacies have found a renowned place in UK since 1999. In 1999, the first online pharmacy started operating under UK regulations. Currently, there are 496 internet pharmacies attached to 453 pharmacy premises that dispense over 10,000 items per month. The delivery of drug products to the patients is generally done by local mail or couriers. However, in case of prescription drugs there are some pharmacies setting up their own delivery drivers. Looking at an enormous amount of demand for online pharmacies, the MHRA (medicines and Healthcare product regulatory agency) under the NHS (National Health Service) has set up rules and regulations to

Sale of drugs

1. The dispense and sale of drugs must comply with the rules mentioned under 21 CFR 1301.19
2. An online pharmacy registered in one state, can sale drugs in the other state only after the approval of



maintain stringent laws for operations of internet pharmacies in the UK.

Registration of internet pharmacy

For registering pharmacy on the internet, the following criteria must be fulfilled:

1. The pharmacy should be registered with GPhC (general pharmaceutical council) of the MHRA.
2. The pharmacy must hold its premises in the UK territory.
3. The internet pharmacy must have pharmacists and pharmacy technicians all registered with the GPhC.

Registration Procedure

A pharmacy premises needs to be registered with the GPhC as an active and functioning pharmacy. Premises are registered as pharmacies only if they meet the following criteria:

1. They sale pharmacy (P) medicines.
2. They supply P medicines or Prescription only medicines (POM's) against prescriptions.
3. They supply P medicines or POM's against prescriptions written by veterinary practitioners.

This criteria is checked for in case of initial registration and following any change in medical legislature. The eligibility criteria to be registered as pharmacy is set out in the Medicines Act 1968 and the pharmacy order 2010. For developing an internet pharmacy, the registration number located to its premises serves as an authentication marker. However, in case of a premises selling only those medications listed under General Sales List (GSL medicines) there is no need to register the premises as these products can be sold in other retail outlets apart from registered pharmacies when the appropriate legal conditions are met. The general fees for registration of pharmacy are 590pounds (£) with an additional cost of 221Pounds (£) as a first entry fee. Once the premises are approved by the GPhC and licence granted, the pharmacy has 6months time period to open which may be extended by period of 3 months.

Requirements of internet pharmacy

1. The foremost requirement for starting an internet pharmacy is to get the premises from where the drug dispensing and supply will be carried out to be registered with the GPhC of the MHRA.
2. The name and address of the pharmacy operating the website along with the registration numbers of the pharmacist working there.
3. The internet pharmacy logo has be located on the homepage of the website. The logo carries the unique registration number for the registered pharmacy associated with the website. By clicking on the logo, patient is directed to the online register

of GPhC having all details regarding that particular internet pharmacy.

4. From July1, 2015; anyone selling the drugs into UK need registration with the MHRA and they also need to display the EU common logo on every page of the website offering medicines for sale. This has to be in addition to the GPhC logo. The EU common logo also will be linked to the MHR list of registered online sellers.
5. The logo cannot be duplicated. For any new setup, a new logo and registration number must be applied for. A charge of 57 pounds has to be paid as an application fee.
6. The website must clearly mention its contact details long with the names of registered pharmacists.
7. There must a complaints portal linked with the website and complaints received if any must be catered to.
8. The pharmacy is supposed to maintain record of the online complaints and orders received as well as delivered.
9. The pharmacy premises catering to the website get inspected annually by the MHRA.
10. The pharmacy is expected to counter question the patient via mail or online query portal to verify that the patient is placing the order with full contentment and a valid prescription. Data records pertaining to this are to be maintained for future references.

Sale of drugs

1. The dispensing and supply of drugs by the internet pharmacy is under the control of NHS (nation Health Services).
2. NHS has set up laws and rules for dispensing of P & POM medicines.
3. In UK, it is mandatory to request prescription duly signed by the prescriber to be submitted to the internet pharmacy.
4. In case the pharmacy is involved in sale only P medicines, then that has to be mentioned on the website specifically.
5. Your pharmacy service may be associated with a medical or non-medical prescribing service. The prescribing service may be an on-line service that patients can access by a link from your pharmacy website, or one where prescriptions are ordered and collected by you on behalf of patients from a local surgery or received by your pharmacy by post or electronically.
6. You will need to be able to show that your arrangements with medical or nonmedical



prescribers do not give rise to conflicts of interest or restrict a patient's choice of pharmacy.

7. The sale or supply of medicines in an internet or distance pharmacy service presents different risks that you should consider as part of your initial risk assessment. Monitor orders for medicines to identify ones that are large or inappropriate.
8. The supply of medicines to the patient from a registered pharmacy can occur via a delivery agent at a destination selected by the patient. More recent models of distance sale and supply use automated collection machines. Manage the risks you identify. This may include how you:
 - Assess the suitability of the mode of dispatch;
 - Check the terms, conditions or restrictions of the carrier;
 - Check the legal requirements for export or import of medicines if the intended recipient is outside the UK
9. You should make sure that your pharmacy service has equipment and facilities which are specifically designed for the intended purpose. Equipment should be of sufficiently high specification, accuracy and security.
10. Pharmacies are permitted to provide online consultations, via an online form. In case the patient requires urgent POM medicine.
11. Strict laws for advertising on the internet have been imposed by the MHRA.

Similarities between USA and UK

- Both USA and UK have permitted the use of internet pharmacy.
- Both the countries focus on having an independent logo suggesting authorised internet pharmacy website.
- Both require registration with health regulating agency i.e. USFDA-State FDA in case of USA and MHRA in case of UK.
- Both the countries have stated the registration of pharmacy premises as a pre-requisite criteria to setup an internet pharmacy.

CONCLUSION

The objective of all these drug approval authorities is to ensure that drugs marketed in their country or anywhere in the world are safe and effective. These authorities play a vital role to safeguard and upsurge regulatory implementation for safety of people. Taking into account the increasing approach towards use of internet, these agencies have drafted policies to safeguard public health. Thus, it is important to understand regulatory requirement of these agencies for setting up an internet pharmacy.

This helps to create awareness among patients as to where to get a genuine and safe drug product and also helps the pharmacists to understand regulatory requirements that are must to comply. Hence, understanding of internet pharmacy is necessary for economic growth of industry and most importantly to ensure safety of people.

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