

# Medicines and the internet

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## Educational aims

- To create awareness amongst health care professionals of benefits and risks associated with the internet pharmacy
- To highlight the dangers associated with purchasing counterfeit medicines via an internet pharmacy
- to increase healthcare professionals awareness in order to reduce the potential risks to public health.

## Keywords

rogue internet pharmacy, regulatory, counterfeit, patient

**The internet has been a major revolution in enhancing the accessibility of information and goods to the public challenging well-established healthcare practices. The Internet Pharmacy is now an integral part of these searches giving enhanced access to medicines to the public. It has become a global multibillion dollar market and brings with it threats and opportunities which could not have been foreseen. A Rogue Internet Pharmacy is a very real threat to the patient and healthcare professional. Of serious concern is the increase in distribution of counterfeit medicines through these sites. The EU is currently preparing legislation to regulate Internet Pharmacy Services to protect patients.**

## Introduction

The internet has become a major tool to empower patients since it became freely accessible to the public in 1997. Accessing medical information is one of the most common reasons for people to use the web. In addition a new e-commerce market has been created which has revolutionized the public's access to goods globally.<sup>1</sup>

The internet pharmacy is a perfect example of the impact of increased access to healthcare goods offered by the newly created e-commerce market. Online pharmaceutical sales in the US alone, for example have grown from around 1% of the US pharmaceutical market to around 4% in 2007. A prime and vulnerable patient population, the elderly, use it extensively in the US to shop for cheaper prescription medicines where savings of up to 30% can be made.<sup>2</sup> Many do so confident that their purchases offer the same quality and guarantees as those medicines bought in the pharmacy.<sup>7</sup>

The number of online pharmacies have expanded exponentially in the last 13yrs. Services and fees are often associated which

are not currently effectively regulated. Of concern are the cyberdoctor and the source of the medicines sold.<sup>1,2</sup>

In Europe initial moves attempted to restrict or prohibit the movement of medicines between nations via online or Internet pharmacies. (DocMorris case: Case C-322/01 Deutscher Apothekerverband eV v 0800 DocMorris NV – 11 December 2003)<sup>6</sup> European Union Treaties, Regulations and Directives have changed the capabilities of national professional associations to challenge the restrictions of internet sales of medicines within the Europe Union but not from third parties outside of the Union. European Union treaties provide a legal framework for e-commerce thereby providing the freedom of movement of medicines.<sup>5,6</sup> The variability regarding national legislation, licensing, pricing and reimbursement has rendered the applicability of this treaty more complex and open to legal challenge particularly regarding prescription only medicines.<sup>6</sup>

Patients wish to have access to cheaper medicines or medicines which are more difficult to obtain in their nation state

because of the national legislation or simply because of lack of accessibility.

The Internet pharmacy offers them the possibility to do this across borders.<sup>1,2,3</sup>

This new enhanced accessibility presents serious challenges to well-established healthcare practice which contains benefits and threats.<sup>10</sup>

## Types of internet pharmacies and their services

Internet Pharmacies can be classified broadly into 4 types:<sup>1</sup>

1. Extensions of pharmacy chains that offer a variety of online health information and products
2. Independent pharmacies, which often use the Internet to try to compete with larger chains
3. Mail-order pharmacies that use the Internet to facilitate the ordering process
4. Pharmacies that operate exclusively online.

Benefits associated with this service are linked with the ease, convenience and increased choice offered by a 24hr service open 7 days a week where comparisons can be made between a wide range of products. Increased access to consumer information and information exchange with the service provider which offers the potential for patients to enquire about their conditions and what therapeutic options maybe available to them. This is generally done anonymously and within a framework of privacy. Finally the financial savings can be considerable particularly in certain countries such as the United States.

## Current concerns with the internet pharmacy

Currently a harmonized global regulation of these services does not exist. In the absence of appropriate harmonized laws, treaties and cooperative agreements between nation states, online sellers can evade regulation in certain jurisdiction by engaging in regulatory arbitrage (i.e. operating websites in a jurisdiction which has the least restrictive regulatory framework).

In many instances those evading regulation do so in order to engage in illegal activities. These are "Rogue Internet Pharmacies" which are involved in various illegal acts such as selling prescription drugs without a valid prescription, selling counterfeit or poor quality drugs, and providing online medical consultations (cyberdoctor) for prescribing and dispensing drugs. These "Rogue Internet Pharmacies" present a great danger to the public due to the potential harm, which can be caused by their illegal activities.

## Challenge to traditional healthcare practice

With patients directly accessing online healthcare services like the Internet Pharmacy the traditional safeguards assured by the patients physician and the dispensing pharmacist are by-passed. The patient as a result confides anonymously to a cyberdoctor who often does not know the patients current condition (in some cases this is just a questionnaire service which directs a patient to a treatment also offered by the online pharmacy). As a consequence the patient is no longer protected and becomes a consumer who is exposed to services whose aim is not to a service in the interests of public health but to obtain financial gain.<sup>6</sup>

The cyberdoctor is troubling in that the patient-doctor/patient-pharmacist relationship is threatened but when linked to the distribution of prescription only medicines this can be extremely harmful.<sup>4,5,6</sup> In particular the risk of counterfeit medicines is perhaps the greatest.<sup>5,6</sup> Counterfeit medicines have progressively infiltrated the distribution chain through the Internet pharmacy.<sup>7,9</sup> Many medicines are now manufactured in areas outside the traditional sites in the Developed World. Regulatory control is less effective and the quality of medicines more variable with counterfeit medicines being the worst end product of a now weakened system of quality control. Online pharmacies are often difficult to trace making the establishment of the Rogue Internet Pharmacy easier.<sup>9,10</sup> These sites often work from an unregulated site, have no address, are registered in China and hosted in Russia. The WHO estimates that 50% of medicines available to consumers from Internet sites which conceal their physical address are counterfeit. The internet offers them the possibility to target the wealthiest markets where connectivity is greatest; Europe and North America. This represents a direct challenge to traditional pharmacies which dispense and ensure the quality of prescription only medicines.

In the UK over the last few years there have been several serious cases of these sites distributing these drugs within the country or using the country as a warehousing transit point for other markets for example in the North America. Originally, these involved life style drugs but recently these have started to include life-saving drugs. Some of the high profile cases are reported on the UK MHRA (Medicines and Healthcare Products Regulatory Agency) website.<sup>10</sup>

## Current actions to address the threat

Governments Agencies are increasingly installing surveillance systems to monitor for the presence of Rogue Online Pharmacies. With these systems for example the MHRA recently conducted a large operation to seize

## Key points

- Various types of internet pharmacies exist, not all of which are engaged in illegal activity
- Rogue Internet Pharmacies involved in illegal activities e.g. selling prescription drugs without a valid prescription, selling counterfeit or poor quality drugs, and providing online medical consultations (cyberdoctor) for prescribing and dispensing drugs
- Online pharmacies are often difficult to trace making the establishment of the Rogue Internet Pharmacy easier
- WHO estimates that in over 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address are counterfeit
- EU working on legislation to combat counterfeit medicines

counterfeit drugs distributed through Internet Pharmacies. These approaches however are not preventative.

In the US the FDA has made efforts to set up a system of accreditation of these services so that consumer and healthcare workers can be protected and be guaranteed that a regulatory framework is in place to ensure that the quality of the service is to an adequate standard.

In the EU efforts are current on-going to draft and approve legislation which will effectively regulate and clarify the penalties imposed on those in breach of the new legislation (Euractiv 28 April 2010 Parliament takes aim at illegal online pharmacies). Indeed in July 2010 the European Parliament will have a plenary session to discuss the Falsified Medicines Directive.<sup>8</sup>

## Conclusion

The advent of the internet and its enhanced accessibility has opened a new era of e-commerce which offers benefits and risks. The Internet Pharmacy is a case in point. The services are often but not always

associated with a credible wholesale source of pharmaceutical products.

With the development of the global internet the accessibility of markets from different parts of the globe has led to a situation of regulatory arbitrage. This means that certain countries have weaker regulatory frameworks from which Rogue Internet Pharmacies can operate and access with impunity the richer markets of Europe and North America or distribute cheap counterfeit medications to poor countries. This leads to a breakdown in the traditional mechanisms of regulation of healthcare services involved in the dispensing of prescription medicines where there is a relationship between patient, physician and pharmacist. The patient becomes a consumer and is no longer protected by the healthcare professionals who are often not aware of their purchases on the internet.

Efforts are currently on going in the European Parliament to endorse a new EU Directive to improve the regulation of this online service and penalize rogue internet pharmacies.

## References

1. Weiss AM. Buying prescription drugs on the Internet: Promises and pitfalls. *Cleveland Clinic Journal of Medicine*. 2006; 73(3): 282-288.
2. Crawford S Y. Internet Pharmacy: Issues of access, quality, costs and regulation. *Journal of Medical Systems*. 2003; 27(1):57-65
3. Schafer A. Canadian Internet pharmacies: Some ethical and economic issues *CPI/RPC*.2008;141(3)191-197
4. Lineberry TW, Bostwick JM. Taking the physician out of "Physician Shopping": A case series of clinical problems associated with internet purchases of medication. *MD Mayo Clinic Practice* 2004;79(8):1031-1034
5. George C, Internet Pharmacies: Global threat requires a global approach to regulations. *Hertfordshire Law Journal*. 2006;4(1): 12-25
6. Pickering G. Internet Pharmacy in the European Union. Reed Smith Richards 2007. Available at: [http://www.reedsmith.com/\\_db/\\_documents/Internet\\_\\_Pharmacy\\_article.pdf](http://www.reedsmith.com/_db/_documents/Internet__Pharmacy_article.pdf). (Accessed 28 April 2010)
7. Henney JE, Shuren JE, Nightingale SL, McGinnis TJ. Internet purchase of prescription Drugs: Buyer Beware. *Ann Intern. Med*. 1999; 131: 861-862
8. Parliament takes aim at illegal online pharmacies. Available at: <http://euractiv.com/en/health/parliament-takes-aim-at-illegal-online-pharmacies-news-486752>.(Accessed 28 April 2010)
9. Counterfeit Drugs Kill! International Medical Products Anti-Counterfeiting Taskforce World Health Organization. Available at: <http://www.who.int/impact/about/en/> (Accessed 28 April 2010)
10. Medicines and Healthcare products Regulatory Agency (UK) Website: Counterfeit Medicines and Devices. Available at: <http://www.mhra.gov.uk/PrintPreview/DefaultSplashPP/CON019608?ResultCount=10&DynamicListQuery=&DynamicListSortBy=xCreationDate&DynamicListSortOrder=Desc&DynamicListTitle=&PageNumber=1&Title=Counterfeit%20medicines%20and%20devices>. (Accessed 28 April 2010)