

REGULATING INTERNET PHARMACY – A COMPARISON OF LEGAL POSITION IN UNITED STATES, UNITED KINGDOM AND MALAYSIA

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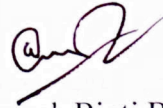
AUTHOR DECLARATION

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

I hereby declare that the work in this academic project is my own except for quotations and summaries which have been duly acknowledge.

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(In the name of Allah, most gracious, most merciful)

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Firstly, I would like to thanks to Allah The Most Graceful for his everlasting and his Messenger Muhammad p.b.u.h, so that this Academic Project Paper that title “Regulating Internet Pharmacy –A Comparison of Legal Position in U.K U.S And Malaysia” was completed. I wish to extend my sincere thanks to all who made this Academic Project Paper possible.

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ABSTRAK

Dalam kajian ini, penulis membincangkan bagaimana kedudukan undang-undang, prinsip-prinsip yang diguna pakai dan panduan-panduan dalam menggunakan Internet farmasi di tiga negara iaitu Amerika Syarikat, United Kingdom dan Malaysia. Pada masa yang sama, ia juga membincangkan cabaran-cabaran yang dalam Pengaturan Internet Farmasi dan mengemukakan persoalan sama ada pembelian melalunya menjamin keselamatan atau memberi keburukan terhadap diri pengguna. Kajian ini bertujuan untuk mengenal pasti adakah wujud perbezaan peruntukan atau undang-undang mengenai Internet farmasi di antara tiga Negara. Untuk memperolehi data dan maklumat, beberapa teknik kajian telah digunakan. Antaranya ialah kajian perpustakaan, jurnal, Internet dan meneliti dokumen yang berkaitan. Hasil kajian telah menunjukkan bahawa resiko dalam penggunaannya adalah lebih besar berbanding keberkesanan kerana maklumat yang diperolehi darinya adalah samara-samar. Dapatan dari hasil kajian ini juga telah menunjukkan bahawa terdapat juga laman web yang menyediakan maklumat yang tepat dan memenuhi keperluan pengguna. Ianya bergantung kepada kesahihan laman web tersebut.

ABSTRACT

This project paper addresses the principle and practice of online pharmacy and its legal position in United States, United Kingdom and Malaysia. At the same time, it will access the challenges in regulating Internet Pharmacy and adduce the question whether the purchasing through Internet can guaranteed the safety or risky among consumers. The study sought to identify is it exist different provision or legal position regarding Internet Pharmacy in three countries. Library research, Internet, Journal and related document were the tools and methodology employed for data gathering purposes. The findings indicates that the risk is largest than effective because quality of information is doubtful. And finally, the study concludes with a discussion there is web sites provided the assurance of safety and protect the patient's right. It's all depends to a legal web sites.

الملخص البحث

هذا البحث يناقش عن مكان القانون ومبادئ تستخدم في ثلاثة البلاد يعني أمريكا شريكات، يونيتد كندم والماليزيا. إضافة إلى ذلك، أنه يناقش عن التحديات في تنظيم الإنترنت الصيدليّة وصدر السؤال إما اشتره يضمن السلامة أو المفسدة لدى المجتمع. يهدف هذا البحث ليعرف هل موجود الاختلاف في القانون عن الإنترنت الصيدليّة بين ثلاثة البلاد. ومن حيث طريق في جمع تحليل ورتيب المعلومات، قد استخدام القواعد الدراسة وهو الإنترنت، والكتب المتعلقة بالبحث. حصلت الباحثة على المفسدة أكبر من المصلحة لأن المعلومات اوقع في ريب. فالنتيجة من هذا البحث حصلت موجود أيضاً عنوان الكهراء التي استعداد المعلومات صحيحات ويملاء احتياجات المجتمع. كله يعتمد على صحيح عنوان الكهراء في كل البلاد.

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ABBREVIATION

AG	Attorney General
AMA	American Medical Association
CBP	Customs and Border Protection. Canadian Council for Accreditation of Pharmacy Programs
CCAPP	
DCA	Drug Control Authority
DCA	Drug Control Authority
DEA	Drug Enforcement Association.
DHS	Department of Human Services
EU	European Union.
FDA	Food Drug Act
FDCA	food, Drug, Cosmetic Act
FTC	Federal Trade Commission.
GMC	General Medical Council
Ibid	From Latin Language (ibidem): the writer, title, pages. International Federation Pharmaceutical Manufacturer and Association.
IFMA	
MA	Medical Act
MAB	Medicine Advertisements Board
MDA	Medical Devices Agency
MHRA	Medicines Healthcare product Regulatory Agency.
MMA	Malaysian Medical Association
n.a	No author
n.d	No date
n.pb.	No Publisher
NAAG	National Association of Attorney General
NABP	National Association of Boards of Pharmacy National Association of Pharmacy Regulatory Authorities
NAPRA	
NCPA	National Community Pharmacists Association
OTC	Over The Counter
PEBC	Pharmacy Examining Board of Canada's
PGD	Patient Group Direction
PhAMA	Pharmaceutical Association of Malaysia
RHSGB	Royal Pharmacies Society of Great Britain
U.K	United Kingdom
U.S	United States
VIPPS	Verified Internet Pharmacy Practice Site.

CHAPTER ONE

CHAPTER 1

INTRODUCTION

1.1 Background Information

The provision of Internet Pharmacy services is an area of rapid growth. This undoubtedly improves patient access to and choice of pharmacy services, but the regulatory framework must ensure public protection and confidence in the profession. The public is entitled to expect the same quality of pharmaceutical care irrespective of whether the service is provided online or face to face on the pharmacy premises.¹

The internet has resulted in medicines being available from online suppliers who have no professional qualifications or healthcare expertise, and this carries a risk to patient safety. It is essential therefore; that the pharmacy profession can demonstrate a real difference in the quality of services provided from registered internet pharmacies, with appropriate safeguards to ensure patient safety. This will also help to increase public awareness about the sites they are using and their understanding of the need to obtain medicines from a qualified healthcare professional.²

1.2 History and Nature of the Internet

The Internet is not a physical or tangible entity, but rather a giant network which interconnects innumerable smaller groups of linked computer networks. It is thus network of networks. Some networks are “closed” meaning that computers within the network are not linked to other computers or networks. Many networks, however, are connected to other networks, which are in turn connected to other networks in a manner which permits

¹n.a. 3 Aug 05 “Guidance on Internet Pharmacy Services. www.rpsgb.org.uk/pdfs/raisingconcernsguid.pdf.
p: 3

² ibid

each computer in any network to communicate with computers on any other network in the system. This global web of linked networks and computers is referred to as the Internet. However, the term “Internet” is also used to refer to the wide range of applications that can be accessed through this networks infrastructure.³

The Internet was born about 20 years ago, out of an effort to connect together a USA defence Department network called the ARPANET and various other radios and satellite networks. It was intended for use as a research vehicle for the US military, a way to find out how to build persistent network that could withstand the wages of war, as it evolved over a few years; this electronic highway was then aimed at providing a pipeline for electronic mail services and on-line libraries for universities and government agencies. In 1992, the number of registered Internet had doubled to 727000. Today there are millions of computers connected to Internet providing direct access for up to 40 million people. In Malaysia, Internet can be accessed through two Internet providers which are TM net from Telecom Malaysia Berhad and JARING from MIMOS (Malaysia Institute of Microelectronic System). Both of them have links to the proper plan to give due attention to educational institution and rural areas through a well-coordinated programmed so that both the Internet service providers in Malaysia do not duplicate each other in the pursuit of such efforts. Their main objective is to provide the most effective, easy to use and cost efficient service possible.⁴

1.3 Definition

1.3.1 Internet

The Internet is more than networks of computers. It is really network of network. Some people define Internet as a combination of computers- millions of them connected by a variety of wires, phone lines, radio signals, and satellite connections. Beyond that internet is also a network of services consisting of libraries, databases, and communities of

³ Alan M. Gathan. *Internet Law: A Practical Guide for Legal and Business Professional*. Kuala Lumpur: Thomson Professional publishing. p. 1-2

⁴ Mohd Asri Mohd Zain. 18 May 2004. “Internet and Islam”. *Teaching of Islam through Internet*. <http://www.islamonline.net>. p. 36

people. We can use Internet to send and receive electronic mail. We can write message and post them on a host computer, where they are then routed to the proper destination a little later. We can participate in real time on-line discussion with people from all over the world and we can conduct research by reading what other people have written about almost any topic. To get the sense of the nature of the Internet you can log on to and Internet node (a computer connected directly to the Internet that offers at least some Internet features) and begin to explore its features.⁵

The Internet was, for a long time, a world reserved for academic and the US military. In the early 1990, a new application called the World Wide Web and the development of integrated user-friendly browser programs with graphical user interfaces made it possible for business and the world at large to participate in this phenomenon. The Internet is many things to many people. In order to fully exploit the emerging opportunities, business professional need to understand how the law applies to their activities on the Internet.

1.3.2 Pharmacy

"Pharmacy" means any place within the State where Drugs are Dispensed and Pharmaceutical Care is provided and any place outside of a State where Drugs are Dispensed and Pharmaceutical Care is provided to residents of the State.⁶

1.3.3 Internet Pharmacy

Pharmaceutical services provided to the public via the internet include the dispensing of prescriptions, the sale of medicines and the provision of information on web site pages. The term 'Internet Pharmacy' is often used by the media and the public to describe both registered pharmacies and other commercial suppliers who offer to sell medicines on-line. This can lead to confusion and uncertainty. For the purpose of pharmacists' professional

⁵Mohd Asri Mohd Zain. 18 May 2004. "Internet and Islam". *Teaching of Islam through Internet*. <http://www.islamonline.net>. p. 35

⁶Rockville. 27 April 2004. "Pharmacists Services and the Internet pharmacy" <http://www.rpsgb.org.uk/pdfs/internetpharmservguid>

requirements, the RPSGB defines internet pharmacy as: A registered pharmacy which offers to sell or supply medicines (or other pharmaceutical products) and/or provides other professional services over the internet, or makes arrangements for the supply of such products or provision of such services over the internet.⁷ This is not a legal definition, but is intended to help pharmacists and others identify the legal and professional requirements applicable to the internet services pharmacists provide.

1.3.4 Other Definitions

The definition of online pharmacy is a legitimate pharmacy site on the Internet that provides consumers with a convenient and private way to obtain prescribed medications, sometimes at a more affordable price than regular pharmacies. Online pharmacies provide the elderly and persons in remote areas quick access and an easy and convenient way to purchase medications (FDA, 2001). Reputable Internet pharmacies allow patients to consult with a licensed pharmacist from the privacy of their homes. Legitimate online pharmacies only fill prescriptions prescribed by physicians and they use safe and legal medications.⁸

An “Internet pharmacy” is defined as an Internet site that is used primarily to sell prescription drugs in interstate commerce.⁹

1.4 International Federation Pharmaceutical Manufacturers and Association (IFPMA)

- (i) The ethical promotion of prescription medicines is vital to the pharmaceutical industry’s mission of helping patients by discovering, developing, and marketing new medicines. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines

⁷ n.a. 3 Aug 05 “Guidance on Internet Pharmacy Services”. www.rpsgb.org.uk/pdfs/raisingconcernsguid.pdf. p: 3

⁸ Henney & Shurren, 1999. *Online Pharmacies: Breach Ethical Principles*. East Tennessee State University. http://www.eaa-knowledge.com/ojni/ni/6_1/article5.htm.

⁹ Amalie L. Tuffin. “Internet Pharmacy Consumer Protection Act”. *Congress Attempts to Crack down On Internet Pharmacies*.

they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.¹⁰

- (ii) IFPMA and its members are committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the practice of medicine. IFPMA also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines to patients. The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines. Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients. Pharmaceutical companies must maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory, and professional requirements. Through the promotion of this Code, IFPMA seeks to ensure that ethical promotional practices are established worldwide.¹¹

- (iii) The IFPMA Code of Pharmaceutical Marketing Practices (the “IFPMA Code”) sets forth standards for the ethical promotion of pharmaceutical products to healthcare professionals, and for member companies’ interactions with them. Effective January 1st, 2007, this Code replaces the IFPMA Code of Pharmaceutical Marketing Practices (Update 2000). Member associations of IFPMA must incorporate this Code into existing national codes no later than January 1st, 2007.¹²

- (iv) IFPMA acknowledges the role of relevant codes of ethics developed by the World Medical Association, International Council of Nurses and the International

¹⁰ n.a. 2006. “IFPMA Code of Pharmaceutical Marketing Practices”. <http://www.ifpma.org/>. p:1

¹¹ *ibid*

¹² *ibid*

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¹⁰ n.a. 2006. “IFPMA Code of Pharmaceutical Marketing Practices”. <http://www.ifpma.org/>. p:1

¹¹ *ibid*

¹² *ibid*

Federation of Pharmacists. IFPMA also recognizes the role of Ethical Criteria for Medicinal Drug Promotion provided by the World Health Organization in 1988.

- (v) The IFPMA Code contains provisions relating to scope, applicability and guiding principles (Articles 1-2), the content of promotional material (Articles 3-6); interactions with healthcare professionals (Articles 7-8); company procedures and responsibilities (Article 9); and operation and enforcement (Article 10). It also includes a Q&A section to assist in interpretation of the IFPMA Code.
- (vi) It is a requirement of IFPMA membership that member associations accept the conditions of the IFPMA Code and, subject to local laws and regulations, adopt codes that meet local requirements but are consistent with, and as comprehensive as, the IFPMA Code.
- (vii) It is accepted that where there is an established framework of stringent regulatory and/or legal controls which are effectively as comprehensive in their provisions and application as the IFPMA Code, it may be more appropriate for a national member association not to establish new duplicative provisions and procedures. IFPMA also acknowledges that many IFPMA member associations have already established their own codes of conduct, which, together with local laws and regulations, fully embody the principles set forth in the IFPMA Code.
- (viii) IFPMA member companies must comply directly with applicable national codes of member associations where such codes exist. In all other territories, i.e. where there are no local codes or appropriate laws and regulations, or where a member company is not a member of local/regional association, the IFPMA Code acts as a default code for the activities of member companies and the IFPMA operating procedures apply.¹³

¹³ *ibid*

- (ix) IFPMA member companies are accountable for addressing and correcting infringements under relevant codes. They should also ensure that internal structures and procedures (including adequate training of employees) are created to ensure responsible and ethical promotional activities. Companies not in membership with IFPMA may elect to be subject to the IFPMA Code and its complaints handling processes.
- (x) The IFPMA is open to receive genuine complaints from any source on any aspect of the IFPMA Code, in accordance with its operating procedures. Where it is determined that there has been a breach of the IFPMA Code, the objective is to correct the matter as rapidly as possible.
- (xi) The IFPMA is a non-profit, non-governmental organization representing industry associations and companies from both developed and developing countries. Member companies of the IFPMA include major global research-based pharmaceutical companies. Companies are committed to the ethical standards set out in this Code.¹⁴

1.4.1 GENERAL PRINCIPLES

Below are the important general principle explained under IPMA code.

a) Basis of Interaction

Member companies' relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education.¹⁵

¹⁴ ibid

¹⁵ ibid p: 6

b) Independence of Healthcare Professionals.

No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practices.

c) Appropriate Use

Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

d) Local Regulations

In all cases, all relevant laws, local regulations and industry codes must be observed and companies have a responsibility to check local requirements, in advance of preparing promotional material or events in any specific country.

1.4.2 STANDARDS OF PROMOTIONAL INFORMATION.

The standard of promotional information are provided below:

a) Consistency of Product information.

It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with locally approved product information. Healthcare

professionals in developing countries should have access to similar data to those being communicated in developed countries.¹⁶

b) Accurate and Not Misleading.

Promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Descriptions such as 'safe' and 'no side effects' should generally be avoided and should always be adequately qualified.

1.4.3 IFPMA CODE OPERATING PROCEDURE

a) Principles

- i. The IFPMA Code and the operating procedure of the IFPMA Code shall apply directly in territories where no national code has been adopted by the respective member association.¹⁷
- ii. The IFPMA Code and its operating procedure shall also apply in all cases where a member company commits a breach of the IFPMA Code in territories where there are national codes adopted by the respective member association but the member company in alleged breach is not a member of that association.

¹⁶ *ibid.* p: 8

¹⁷ n.a. 2006. "IFPMA Code Operating Procedure". <http://www.ifpma.org/>. p:17

- iii. IFPMA shall ensure that its website contains information on codes and provisions organized by member associations, including details of where case reports may be viewed.
- iv. If a complaint is received by IFPMA that is not covered by this operating procedure, IFPMA will refer it to the company concerned. In addition, a copy will be sent to the relevant member association, if the association has a process for complaints.
- v. Should IFPMA receive a complaint about an alleged breach which is already under investigation by one of the member associations (or relevant body thereof or equivalent regulatory body), it will not process the complaint but will inform the sender of the fact that the complaint is being handled elsewhere.
- vi. Likewise, if IFPMA during its processing of a complaint is informed that the same alleged breach is being investigated elsewhere, it shall suspend the process and inform the complainant thereof.¹⁸

1.4.4 THE PROCEDURE FOR CODE COMPLAINTS

a) Validation.

When a complaint, alleging a breach of the IFPMA Code, is received by the IFPMA Secretariat, it is first validated to ensure that:

- a) It appears to be a genuine matter, submitted in good faith;
- b) There is sufficient information to enable the complaint to be processed.
- c) The alleged breach concerns a country where this operating procedure applies; and
- d) It is not evident that the same alleged breach is being or has been investigated by a member association (or relevant body thereof). If the

¹⁸ *ibid.*

complaint cannot be validated, it will not be processed under this operating procedure and, where possible and/or appropriate, the complainant will be notified accordingly. In appropriate cases, IFPMA may refer the complainant or forward the complaint to an appropriate member association. A single complaint may cover more than one “case”, e.g. the complaint may refer to several advertisements from different companies and/or for different products. Each “case” is handled separately by IFPMA under the main complaint reference. The first action in each case is to identify the company cited in the case and the head office or parent company, and its location, if different.¹⁹

b) Responsibilities of IFPMA

IFPMA designates a member of its staff to undertake all necessary activities in relation to this operating procedure. IFPMA also establishes the IFPMA Code Compliance Network, comprised of individuals experienced in the application of industry codes from member companies and associations. This network has the following roles:

- a) To exchange best practices in code compliance and implementation;
- b) To facilitate prevention of breaches by encouraging communication and networking among companies and associations officers;
- c) To create a forum for positive communication around industry self-regulation activities;
- d) To create a resource pool of experts in code compliance for needs of the IFPMA complaints procedure as described in 2.6 and 2.7 (only experts from associations);
- e) To stimulate discussions about new challenges related to industry’s promotion and marketing practices. Periodic reports on the operation of the IFPMA Code

¹⁹ n.a. 2006. “IFPMA Code of Pharmaceutical Marketing Practices”. *The Procedure for Code Complaints*. <http://www.ifpma.org/>. p:18