DRUGS SALES IN PAKISTAN: AN ANALYTICAL STUDY WITH REFERENCE TO NATIONAL LEGISLATION & INTERNATIONAL PROTOCOLS

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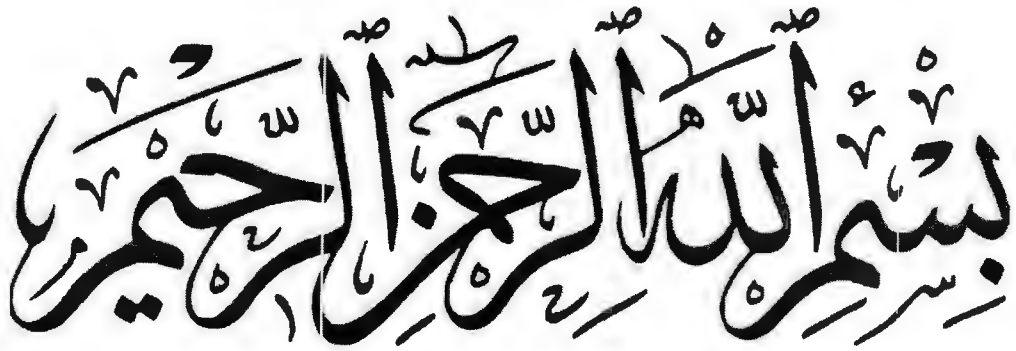
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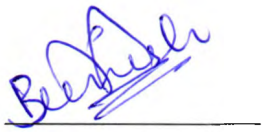

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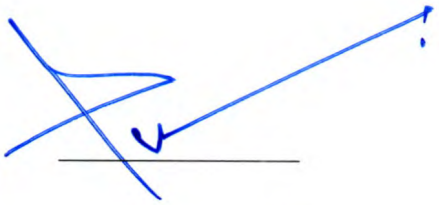

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ABSTRACT

DRUGS SALES IN PAKISTAN: AN ANALYTICAL STUDY WITH REFERENCE TO NATIONAL LEGISLATION & INTERNATIONAL PROTOCOLS

by

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Supervisor: Ms Beenish Aslam

This dissertation is basically focused on current Pakistani legislation and International drug protocols. Drug Sale Rules was carried out with the international Good Pharmacy Practices using Denobedian Model and in second phase of study 13 cases with judgments were critically analyzed against the Drug Act 1976, recommendations for offences and penalties. all provinces of Pakistan have the Drug Sale Rules in Practice, these rules specify all the conditions needed for the distribution, storage and sale of drugs so there is not much uniformity in the Drug Sale Rules of all provinces.

In the drug courts when sanctions are imposed, they are very linnet and are not serving the objective of deterrence and retributive. The current laws relating to community pharmacies in

Pakistan are inadequate to accommodate the vision of pharmaceutical care and rational drug use even in the long run

The pharmacy professional association in Pakistan needs to work together with their governing bodied and other health care associations to define the vision of pharmacy practice in the country. There is a need of professional definition of drug sales incorporated in the laws that criticized the core pharmacy activity. The U.K model of service categorization in pharmacies is a good example for Pakistan. Need of Computerized system available to drug inspectors which can be used to upload the inspection reports of different pharmacies with biometric data of the proprietor, person present or qualified persons .this system can be used to communicate with government annalist, provincial quality control board and other relevant bodies. there is a need to define Dispensing activity legally as per GPP criterion , Legislation strictly enforced in this regard sale of prescription drugs without prescription should be considered as serious violation of laws and must be categorized separately as offence with strict penalty .drug courts play their role to stop the abuse of drug sales.

TABLE OF CONTENTS

ABBREVIATIONS

ACT Drug Act 1976

DRAP Drug Regulator Authority Of Pakistan

FIP International Pharmaceutical Federation

GDP Good Dispensing Practices

GPP Good Pharmacies Practices

ICESCR International Covenant On Economics, Social And Cultural Rights

SOPs Standard Operating Procedures

WHO World Health Organization

PQCB Provincial Quality Control Board

DQCB District Quality Control Board

LIST OF TABLES

Tables

This study is dedicated to my loving husband Nasir Rashid.

ACKNOWLEDGEMENTS

Firstly I am extremely indebted to Madam Beenish Aslam for her continued guidance in writing this manuscript. I highly appreciate her intellect that becomes source of inspiration for me. Secondly my friends Sherish and Bushra for their moral support. I acknowledge my parents Mr and Mrs Saeed to whom I owe everything. And last not the least very thankful to my dear husband Nasir Rashid, whose love is light for me forever and without his support, it was impossible for me to study at this level.

PREFACE

This thesis starts with a brief background of the issue of drug sales practices in Pakistan and importance of reviewing the current legislation against international standards. Chapter 1 will elaborate the meaning of drug sales and the relevant terminology used internationally. It will provide a situation analysis of drug sales in Pakistan and detail the meaning of effective drugs sales and common malpractices worldwide. The conceptual framework of structure-process-outcome will also be introduced in first chapter. Chapter 2 will be a review of Pakistan's legislation on drug sales. A brief description of the regulations will be provided in this section. Chapter 3 will detail the critical analysis of Pakistani legislation against the international standards using the Donabedian model. It will further explore the position of the country against the guidelines for implementation of GPP in developing countries. Chapter 4 will focus on the critical analysis of 17 case judgments made by the Drug Court, Rawalpindi. Conclusion and recommendations will be detailed in the chapter 5.

LIST OF CASES

DEFINITIONS

Community pharmacy

A community pharmacy is a health care facility which provides pharmaceutical services to people. Such services can include maintaining supply chain of quality medicines, dispensing, drug information and preventive health service[1].

Dispensing

Dispensing includes all the activities which are carried out from receiving an order for drugs to the issuance of drugs. It essentially includes six activities: receiving and validating the request for medicines, understanding and interpreting the request, preparation of the medication order according to patients' needs, labeling of items for individual patients, recording the action and finally issuing the medicines to patients or intermediary with clear instructions and advice[2].

Drugs sales

The section 3 (z-a) of the Drugs Act, 1976, gives a legal definition of selling drugs as "sell" means offering, having in possession for sale, or selling drugs[3]

Drug seller

"Seller" means a person who sells drug[4] .

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[1] Management Sciences for Health. MDS-3 Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health, 2012. Available online at https://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf (last accessed on November 23, 2015).

[2] Management Sciences for Health. MDS-3 Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health, 2012. Available online at https://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf (last accessed on November 23, 2015).

[3] section 3 (z-a) of the Drugs Act, 1976

Medical store

"Medical store" means premises where drugs excluding the drugs specified in the Schedule G are stored, sold or offered for sale[5].

Pharmacy

> "Pharmacy" means premises where drugs are stored, sold, compounded, dispensed or prepared on prescription or distributed in case of authorized agent of manufacturer, indenter or importer"[6] .

Pharmacy practice

The pharmacy practice means practice and activities carried out at the community pharmacies. It includes both traditional (compounding and dispensing medications) as well as modern roles (preventive health services, clinical services, reviewing medications for safety and efficacy, and providing drug information)[7].

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[4] Punjab Drug Rules 2007;Rule 2 (1) (q)
[5] Punjab Drug Rules 2007;Rule 2 (1) (h)
[6] Punjab Drug Rules 2007;Rule 2 (1) (k)
[7] Management Sciences for Health. MDS-3 Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health, 2012. Available online at https://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf (last accessed on November 23, 2015).

CHAPTER 1

Drug sale in Pakistan, a situation Analysis

1.1. Right to Health vs Right to Qualitative and Economical Drugs

Health is considered as a basic human right worldwide. [1] It has been agreed in other international treaties like the International Covenant on Economic, Social and Cultural Rights (ICESCR)[2] and the Constitution of the World Health Organization (WHO). Concept of 'right to health' was first time formally articulated in 1946 in WHO's Constitution as "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[3] While health is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".[4] This extensive definition of health puts a lot of responsibility on Governments. Governments

[1] The Universal Declaration of Human Rights, 1948
Article 25: "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control." Available at http://www.un.org/en/universal-declaration-human-rights/ (last accessed on October 27, 2015).

[2] The International Covenant on Economic, Social and Cultural Rights, 1966
Article 12: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." Available at http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx (last accessed on October 27, 2015).

[3] The Right to Health. The WHO Fact Sheet No. 31. available at http://www.who.int/hhr/activities/Right_to_Health_factsheet31.pdf?ua=1 (last accessed on November 3, 2015).

[4] The Constitution of the WHO, 1946, available at http://www.who.int/governance/eb/who_constitution_en.pdf (last accessed on November 3, 2015).

must generate of all conditions in which everyone can be as healthy as possible.[5] These conditions include not only provision of determinants of health like nutritious food, safe drinking water, sanitation, healthy working environments, adequate housing but also the health care including medicinal remedies.[6] Pakistan being signatory of these international treaties is bound to take responsibility of providing necessary health conditions and health care to its residents.

Medicines or drugs are a vital component of health care. They play a crucial role in our lives by maintaining, improving or restoring our health. Being a vital component of healthcare, access to good quality drugs is also a basic human right. The term drug means "a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or a substance (other than food) intended to affect the structure or any function of the body" as per the definition of the United States Food and Drug Administration (FDA).[7] In Pakistan, drug refers to

> "any substance or mixture of substances that is manufactured, sold, stored, offered for sale or represented for internal or external use in the treatment, mitigation, prevention or diagnosis of diseases, an abnormal physical state, or the symptoms thereof in human beings or animals or the restoration, correction, or modification of organic functions in human beings or animals, including substance used or prepared for use in accordance with the Ayurvedic, Unani, Homoeopathic, Chinese or biochemic system of treatment except those substances and in accordance with such conditions as may be prescribed".

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[5]The WHO Fact Sheet No. 323. The Right to Health. available at (last accessed on November 3, 2015).http://www.who.int/mediacentre/factsheets/fs323/en/ (last accessed on November 3, 2015).
[6]The WHO Fact Sheet No. 323. The Right to Health. available at (last accessed on November 3, 2015).http://www.who.int/mediacentre/factsheets/fs323/en/ (last accessed on November 3, 2015).
[7]Glossary of terms, the United States *Food and Drug Administration*, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm (last accessed on November 1, 2015).

It also includes "abortive and contraceptive substances, agents and devices, surgical ligatures, sutures, bandages, absorbent cotton, disinfectants, bacteriophages, adhesive plasters, gelatin capsules and antiseptic solution". [8] Drugs come under the category of goods as well in Pakistan according to the Sale of Goods Act, 1930. This act defines goods as "every kind of movable property other than actionable claims and money; and includes electricity, water, gas, stock and shares, growing crops, grass, and things attached to or forming part of the land which are agreed to be severed before sale or under the contract of sale".[9] Drugs can be considered as goods according to the first part of the definition. Drugs, though, virtually seems to be Goods yet they actually fall under the category of services.

1.2. Drugs and Quality

Drugs play crucial roles in our lives, as apparent in the definitions given above. However, it is important to realize that a drug can produce the desired effect if and only if it is of good quality and used appropriately.[10] Any negligence on these two prerequisites can have grave consequences on peoples' lives by increasing morbidity and mortality.[11]

The issues related to the quality of drugs can range from flaws in manufacturing, through damage during transportation to inappropriate storage or mishandling during

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[8]Schedule I. *The Drugs Regulatory Authorty of Pakistan Act, 2012.* Islamabad: Government of Pakistan, 2012.
[9]Section 3 (7). *The Sale of Goods Act, 1930. Government of Pakistan.*
[10]Hogerzeil HV et al., Field tests for rational drug use in twelve developing countries. *The Lancet* 342, 8884 (1993): 1408-1410.
[11]Newton PN, Green MD, Fernandez FM. Impact of poor-quality medicines in the 'developing' world. *Trends in Pharmacological Sciences* 31 (2010):99-101. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2845817/ (last accessed on November 05, 2015).

dispensing and deliberate fraud.[12] While the issues related to inappropriate use can manifest as giving medication which is not appropriate to their clinical needs of patients. Or giving medicine in wrong dose which is not individualized, or for wrong duration or at higher costs.[13] The burden of such problems is huge with almost 50% of the patients unable to take drugs in right way.[14]

The WHO demands all countries to design and implement such drug policies which ensure quality of drugs as well as their appropriate use.[15] These efforts should focus on the entire process of drug use starting from manufacturing to distribution, storage, sales and to the drug use in communities. Present research is focused on the sales of drugs. Sale of drugs is one of the most important processes contributing to both rational use as well as quality of drugs. It is often the final and last encounter of healthcare professionals and patients. Drug sales should be carried out in a way that ensures supply of quality drugs with appropriate information and an evaluation of prescription for patients need, contributing to the rational use of drugs.[16]

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[12]http://www.who.int/medicines/services/expertcommittees/pharmprep/qual_med_promo_save-lives/en/ (last accessed on November 02, 2015)

[13]Problems of irrational drug use. Available at http://archives.who.int/PRDUC2004/RDUCD/Session_Guides/problems_of_irrational_drug_use.htm (last accessed on July 22, 2015)

[14] http://www.who.int/medicines/areas/rational_use/en/ (last accessed on October 29, 2015)

[15]How to develop and implement national drug policies. Available at http://apps.who.int/medicinedocs/en/d/Js2283e/4.html (last accessed on October 29, 2015).

[16]Role of dispensers in promoting rational drug use. Available at http://archives.who.int/PRDUC2004/RDUCD/Session_Guides/role_of_dispensers_in_rational_d.htm (last accessed on October 29, 2015).

1.3. Drug sales

The term *sale* implies the exchange of goods or services for money, the action of selling something.[17] The section 3 (z-a) of the Drugs Act, 1976, states that "*sell* means sell, offer for sale, expose for sale, have in possession for sale and distribution".[18] However, selling drugs cannot just be seen as an activity of giving away medications as other goods. It needs to be seen in a different perspective with all steps involved from ensuring safe procurement of medication to safe dispensing and rational use[19]. Sale of drugs requires special knowledge, expertise and proper dispensing process. Any compromise, negligence or malpractice at any part can have grave consequences. Considering the sensitive nature of this process, the sale of drugs is legally regulated worldwide.

To differentiate the sale of drugs from the sale of other consumer goods, the term *dispensing* is more commonly used instead of *sale*. Globally the terminologies of dispensing, pharmacy services and pharmacy practice are used.[20] Although the terminologies vary in scope, broadly they mean the activities being carried out at pharmacies/drug stores.

Dispensing is a more specific word used to denote the sale of drugs to patients or intermediaries. It clearly differentiates the nature of selling drugs and other consumer

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[17]Merriam-webster dictionary. http://www.merriam-webster.com/dictionary/sale, (last accessed on September 02, 2015)

[18]Section 3 (z-a). The Drugs Act, 1976. Islamabad: Government of Pakistan, 1976.

[19]Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012, p. 30.2.

[20]Bulajeva A. "pharmaceutical care services and quality management in community pharmacies – an international study." [Dissertation]. Division of Social Pharmacy, University of Helsinki, Finland, 2010. Available at http://europharm.pbworks.com/f/Anna_Bulajeva_Master's_Thesis.pdf (last accessed on August 12, 2015).

goods, as depicted by its definition so medicine does not fall in the category of Goods. The Management Sciences for Health (MSH) defines *dispensing* as "all the activities which are carried out from receiving an order for drugs to the issuance of drugs with sufficient counseling".[21] It further elaborates the term to essentially include six activities: receiving and validating the request for medicines, understanding and interpreting the request, preparation of the medication order according to patients' needs, labeling of items for individual patients, recording the action and finally issuing the medicines with clear instructions.[22]

The phrase *pharmacy services or practice* is relatively new and is broader in scope as compared to dispensing. It encompasses the services rendered by a pharmacy ranging from the traditional to modern ones.[23] The traditional services include compounding and dispensing medications. While modern services are patient centered, including, reviewing prescriptions for safety and efficacy, and counseling.[24]

The Drugs Regulatory Authority of Pakistan (DRAP) Act, 2012 also provides a legal definition of pharmacy services in Pakistan as "the services rendered by a pharmacist in pharmaceutical care, selection, posology, counseling, dispensing, use, administration, prescription monitoring, pharmacoepidemiology, therapeutic goods information and poison control, pharmacovigillance, pharmacoeconomics, storage, sales,

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[21]Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012. p. 30.2.
[22]Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012. p. 30.4.
[23] Wiedenmayer et al., *Developing pharmacy practice: A focus on patient care*. The Netherlands: WHO and FIP, 2006, p. 6.
[24] Wiedenmayer et al., *Developing pharmacy practice: A focus on patient care*. The Netherlands: WHO and FIP, 2006, p. 6.

procurement, forecasting, supply chain management, distribution, drug utilization evaluation, drug utilization review, formulary based drug utilization and managing therapeutic goods at all levels including pharmacy, clinic, medical store, hospital or medical institution".[25]

1.4. Changing concepts in drug sales

Decades ago, compounding was thought to be the key role performed by the pharmacies/medical stores.[26] Majority of the medicines had to be prepared extemporaneously and dispensed to the patient against prescription of a medical practitioner. This situation has changed with the scientific revolution of pharmaceutical technology. The pharmacies have lost control over so called compounding role, and the task has been changed to focus not on the medicine preparation itself but on the medicine dispensing and ultimately on their use.[27]

The shift of roles appeared quite prominent in 1960s and led to development of the concept of clinical pharmacy.[28] Clinical pharmacy is a group of patient- centered services, including prescription evaluation, therapeutic drug monitoring and counseling.[29] It is formally defined as a specialty where pharmacists are involved in promoting the rational use of medicines and devices. Clinical pharmacy can be comprehensively defined

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[25]Section 2 (xxvi) of the DRAP Act, 2012

[26]Franklin, BD, and van Mil, JWF. "Defining clinical pharmacy and pharmaceutical care." *Pharmacy World & Science* 27 (2005): 137.

[27] van Mil JWF. "Concise history of community pharmacy and pharmaceutical care in the Netherlands". In: van Mil JWF, editor. Pharmaceutical care, the future of pharmacy [Dissertation]. Groningem 1999. p. 31.

[28] van Mil JWF. "Concise history of community pharmacy and pharmaceutical care in the Netherlands". In: van Mil JWF, editor. Pharmaceutical care, the future of pharmacy [Dissertation]. Groningem 1999. p. 31.

[29]Franklin, BD, and JWF Mil. "Defining clinical pharmacy and pharmaceutical care." *Pharmacy World & Science* 27 (2005): 137.

as "a part of the practice of pharmacy that contributes directly to patient care and develops and promotes the rational and appropriate use of medicinal products and devices".[30] The ultimate focus here is the patient care. It is important to understand that the word *clinical* does not imply services rendered in hospitals or clinics, such services can be provided wherever drug sales is carried out.[31]

A more recent advance, observed in 90s, in this journey is the concept of pharmaceutical care where the focus is therapeutic outcomes.[32] The main aim of such practice is to get the best possible results from drugs through patient education, physician consultation, and patient monitoring. Pharmaceutical care is defined as "the person-focused care relating to medication, which is provided by a pharmacist and the pharmacy team with the aim of improving the outcomes of therapy".[33] Pharmaceutical care is a process in which pharmacists design, implement, and monitor a therapeutic plan for better outcomes in the patient.[34]

These emerging roles of pharmacy professionals have the potential to get maximum of any drug regimen.[35] If properly provided in low income countries, such

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[30]Franklin, BD, and JWF Mil. "Defining clinical pharmacy and pharmaceutical care." *Pharmacy World & Science* 27 (2005): 137.
[31]Wiedenmayer et al., *Developing pharmacy practice: A focus on patient care*. The Netherlands: WHO and FIP, 2006, p. 11.
[32]Wiedenmayer et al., *Developing pharmacy practice: A focus on patient care*. The Netherlands: WHO and FIP, 2006, p. 7.
[33]Franklin, BD, and JWF Mil. "Defining clinical pharmacy and pharmaceutical care." *Pharmacy World & Science* 27 (2005): 137.
[34]Wiedenmayer et al., *Developing pharmacy practice: A focus on patient care*. The Netherlands: WHO and FIP, 2006, p. 7.
[35]Hepler CD, Strand LM. *Opportunities and responsibilities in pharmaceutical care. American Journal of Hospital Pharmacy* 47 (1990):533–43.

services can dramatically improve population health.[36] Pharmacies in Pakistan also need to upgrade their potentials and provide services beyond selling medicines to meet the prestige of the profession.

1.5. Effective drug sales

Effective drug sales imply that the high quality drugs are given to the right patients, in right quantity, right dose, for right duration, with clear instructions and labels.[37] All these activities need a clean and organized working environment.[38]

The drug outlets must be legal with appropriate licenses according to local setting. The people who carry out the drug sales function must be specially trained to carry out the function of dispensing medicines. Qualified personnel must be available all the time to dispense medicines and provide patient counseling and education services.[39]

Effective sales further require procurement of high quality drugs and maintenance of their quality with necessary storage conditions within pharmacies. It also involves dispensing medicines with such packing and labeling that preserves the medication quality. Appropriate internal quality assurance mechanism needs to be operated within drug stores to ensure quality of drugs and services.[40]

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[36]Strand LM, Cipolle RJ, Morley PC, Frakes MJ. *The impact of pharmaceutical care practice on the practitioner and the patient in the ambulatory practice setting: twenty-five years of experience*. Current Pharmaceutical Design 10. No.31 (2004):3987–4001.

[37]Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012.p. 30.2.

[38]Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012.p. 30.2.

[39]Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012. P.30.2.

[40] Standards for quality of pharmacy services. The Hague, The Netherlands: International Pharmaceutical Federation; 1997. Available at: http://www.fip.org (last accessed on August 05, 2015)

1.6. Drugs sale outlets

A number of different terminologies are used worldwide to denote the premises where drugs are being sold. These include medical stores, drug sale outlets, pharmacies, chemist shops, drug stores, community pharmacies etc.

In Pakistan, pharmacy and medical store both terminologies are used. Pharmacies are allowed to sale all type of medicines and can do extemporaneous compounding as well.[41] While medical store refers to the place where selective drugs; excluding the narcotics, hormones, steroids and other controlled drugs; can be sold.[42]

Worldwide, the term of community pharmacies is more commonly used. Community pharmacies are the drugs selling outlets along with other service provisions. Community pharmacies are formally defined as "the area of pharmacy practice in which medicines and other related products are sold or provided directly to the public from a retail outlet designed primarily for the purpose of providing medicines. The provision of medicines may be either on prescription of a health care worker, or over-the-counter".[43]

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[41]Rule 2(k) The Punjab Drug Rules, 2007.
"Pharmacy means premises where drugs are stored, sold, compounded, dispensed or prepared on prescription or distributed in case of authorized agent of manufacturer, indenter or importer".
[42]Rule 2(h) The Punjab Drug Rules, 2007.
"Medical store means a premises where drugs excluding the drugs specified in the Schedule G are stored, sold or offered for sale".
[43]World Health Organization. "Good pharmacy practice (GPP) in community and hospital settings." Geneva, WHO ,1996 .Available at https://www.fip.org/files/fip/Statements/latest/Dossier%20003%20total.PDF (last accessed on August 3, 2015)

In addition, community pharmacies also provide information to patients, health professionals and public.[44]

For the purpose of this thesis, the terms medical store, pharmacy, drugs outlet, drug stores and community pharmacy are considered the same and refer to any outlet which is selling drugs to public.

1.7. Role of drugs sale outlet in community

Pharmacies are involved in maintaining and improving people's health by supplying quality drugs as well as by providing advice and information. WHO in 1994 in its publication named, *role of pharmacist in health care systems,*[45] specified the main activities of pharmacists being carried out at community pharmacies. These activities are described below.

Processing of prescriptions: Processing of prescription orders and dispensing is the prime function at these outlets. This involves verification of the legal status and therapeutic safety of the prescription, ensuring that the quantities of drugs are dispensed accurately, with appropriate labels and counseling.[46] In many countries, the pharmacy

[44]World Health Organization. "Good pharmacy practice (GPP) in community and hospital settings." Geneva, WHO, 1996. Available at https://www.fip.org/files/fip/Statements/latest/Dossier%20003%20total.PDF (last accessed on August 3, 2015)

[45]World Health Organization. *The Role of the Pharmacist in the Health Care System.* Geneva: World Health Organization, 1994. Available online at http://apps.who.int/medicinedocs/pdf/h2995e/h2995e.pdf (last accessed on August 20, 2015)

[46]Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012. P.30.4.

staff is fully aware of the patient's past and current drug history and, consequently, can provide essential advice to the prescriber as well.[47]

Responding to symptoms of minor ailments: The pharmacies receive requests from people for advice on a variety of symptoms. If the symptoms relate to a self-limiting minor ailment, the pharmacy can supply a non-prescription medicine with advice. Alternatively, the pharmacist may give advice without supplying medicine. When indicated, they can refer the inquiries to a medical practitioner.[48]

Care of patients or clinical pharmacy: The pharmacists' prime focus is patient care. They try to integrate information of patient's history, clarify the patient's understanding of the intended dosage regimen and method of administration, and advise the patient of drug-related precautions, and in some countries, monitors and evaluates the therapeutic response.[49]

Extemporaneous preparation: In some countries, including Pakistan, pharmacies are engaged in the small-scale manufacture of medicines, which must accord with good manufacturing and distribution practice guidelines. This enables them to adapt the formulation of a medicine to the needs of an individual patient.[50]

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[47]BIBLIOGRAPHY \l 1033 World Health Organization. *The Role of the Pharmacist in the Health Care System.* Geneva: World Health Organization, 1994. Available online at http://apps.who.int/medicinedocs/pdf/h2995e/h2995e.pdf (last accessed on August 20, 2015)

[48]World Health Organization. *The Role of the Pharmacist in the Health Care System.* Geneva: World Health Organization, 1994. Available online at http://apps.who.int/medicinedocs/pdf/h2995e/h2995e.pdf (last accessed on August 20, 2015)

[49]Wiedenmayer et al., *Developing pharmacy practice: A focus on patient care.* The Netherlands: WHO and FIP, 2006, p. 7.

[50]Wiedenmayer et al., *Developing pharmacy practice: A focus on patient care.* The Netherlands: WHO and FIP, 2006, p. 7.

Monitoring of drug utilization: The pharmacies also participate in arrangements for monitoring the utilization of drugs, such as analyzing prescriptions to ensure appropriate medication decision and monitoring patients' outcomes or the adverse drug reactions.[51]

Health promotion: The pharmacist can also be involved in health promotion activities both in community and in the pharmacy setting. They can educate people about substance abuse, drug use during pregnancy, antibiotic resistance, family planning etc. They may also participate in the national campaigns like the Expanded Program on Immunization, and tuberculosis, drug addiction, malaria, HIV/AIDS and blindness programs.[52]

1.8. Drug sales in Pakistan

Majority of people in Pakistan buy drugs from privately owned medical stores in the country[53]. Medical stores are the major source of drug distribution and cater the drug needs of over 80 percent of the population worldwide.[54] They are used as source of drugs, consultation and information. There are more than 60000 drugs sale outlets in the country.[55]

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[51]What are Drug Utilization Reviews. Available at HYPERLINK "https://www.prxn.com/docs/PRxN%20DUR.pdf" (last accessed on November 4, 2015)

[52] BIBLIOGRAPHY \l 1033 World Health Organization. *The Role of the Pharmacist in the Health Care System.* Geneva: World Health Organization, 1994. Available online at http://apps.who.int/medicinedocs/pdf/h2995e/h2995e.pdf (last accessed on August 20, 2015)

[53]BIBLIOGRAPHY \l 1033 Rabbani, F, et al. "Behind the Counter: Pharmacies and Dispensing Patterns of Pharmacy Attendants in Karachi." *Journal of Pakistan Medical Association* 51 (2001): 149-154.

[54]McCombie, SC. "Treatment for seeking malaria: A review of recent research." *Social Science and Medicine* 43, no. 6 (1996): 933-945.

[55]Hussai, A, et al. A Literature Review: Pharmaceutical Care an Evolving Role at Community Pharmacies in Pakistan. *Pharmacology & Pharmacy*, 4 (2013): 425-430

A medical store or pharmacy owner has to obtain a license for opening a drug sales outlet in the country.[56] Laws and regulations are in place to assure the quality of medicines provided at these outlets. Under the devolved health sector, regulation of drugs' sale is provincial government's responsibility in Pakistan[57]. The legal regime for drug sales includes the Drugs Act, 1976, the Pharmacy Act, 1967, the DRAP Act, 2012 and the provincial drug sales rules.

Despite the availability of laws and rules, the drug sales practices in Pakistan are very dismal[58]. A recent study concluded that none of the medical stores in Pakistan fully meet the legal requirements for drug sales[59]. Another study reported that less than 20 % of the drug outlets meet the licensing requirements.[60] Less than half of the outlets have the proper storage facilities for drugs which is a grave risk to the quality of drugs.[61] Sale of drugs without prescription is very common and leading to drug abuse and antibiotic resistance[62]. Pharmacist or other qualified dispensers are not available at majority of

[56]Section 14, The Punjab Drug Rules, 2007
"The licensing authority may issue a licence of a pharmacy or a licence of a medical store."
[57]Secction 6, The Drugs Act, 1976
"The Provincial Governments shall regulate the sale of drugs in the prescribed manner and may for that purpose make such orders, and issue such directions to the importers, manufacturers, stockists, retailers or other dealers of drugs, as they may deem fit."
[58]BIBLIOGRAPHY \l 1033 Rabbani, F, et al. "Behind the Counter: Pharmacies and Dispensing Patterns of Pharmacy Attendants in Karachi." *Journal of Pakistan Medical Association* 51 (2001): 149-154.
[59]BIBLIOGRAPHY \l 1033 Hussain, A, Ibrahim, MIM, and Babar, ZU. "Compliance with Legal Requirements by Community Pharmacies in Pakistan: a cross sectional survey." *International Journal of Pharmacy Practice* 20 (2012): 183-190.
[60]Butt, ZA, et al. "Quality of Pharmacies in Pakistan: A Cross-sectional Survey." *International Journal for Quality in Health Care* 17. No. 4 (2005): 307–313.
[61]BIBLIOGRAPHY \l 1033 Hussain, A, Ibrahim, MIM, and Babar, ZU. "Compliance with Legal Requirements by Community Pharmacies in Pakistan: a cross sectional survey." *International Journal of Pharmacy Practice* 20 (2012): 183-190.
[62]The Drugs Act, 1976

outlets, although the store is licensed in the name of that person.[63] Further, it is a common practice to not counsel patients on drug use. It is reported that a major fraction of patrons using these pharmacies don't even know how to use the medicines after they have bought.[64]

This poor quality of pharmacy services in Pakistan is leading to extensive morbidities and waste of resources in an already resource constrained setting. All of the technical, pharmaceutical, research and financial resources which brought the drug to treat a particular condition go in vain if dispensing/sales of drugs is erroneous.[65]

Considering the context, it is important to explore the reasons of these malpractices even in the presence of legislation and law enforcement bodies. The first step in this regard can be to analyze the current legislation on drug sales in Pakistan and compare it with internationally set standards. It is worth exploring the flaws in the legislation which are leading to extensive malpractices in the country.

1.1. Conceptual Framework for Drug Sales

The sale of drugs is not a simple activity.[66] It is a health service delivery and needs to be analyzed in broader perspective using a special analytical framework. Different models[67]

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[63]BIBLIOGRAPHY \l 1033 Hussain, A, Ibrahim, MIM, and Babar, ZU. "Compliance with Legal Requirements by Community Pharmacies in Pakistan: a cross sectional survey." *International Journal of Pharmacy Practice* 20 (2012): 183-190.

[64]BIBLIOGRAPHY \l 1033 Hussian, A and Ibrahim, MIM, "Knowledge Level of Patrons Attending Community Pharmacies in Pakistan: Is It a Threat to Rational Use of Drugs," *HealthMed* 5, No. 4 (2011): 819-825.

[65]BIBLIOGRAPHY \l 1033 Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012. Available at HYPERLINK "http://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf" (last accessed Sep 3rd, 2015).

[66]BIBLIOGRAPHY \l 1033 Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012, p. 30.2

are used worldwide to describe and analyze the complex activities related to health service delivery; however the Donabedian model best suits the pharmacy practice[68]. The Donabedian model[69] of structure-process-outcome provides a framework for monitoring and evaluation of health services and their quality. This model will be used throughout the thesis to describe and analyze the standards of drug sales practices. Avedis Donabedian, a medical doctor and researcher developed this model in 1966. According to the model, the quality of services is predicted from three categories: "structure," "process," and "outcomes." This chain of events from structure to process to outcome operates in a legal and social context.

1.1.1. Structure

Structure includes the physical factors required to deliver a health care service. This includes the physical environment, equipment, and human resources. The training of staff and payment methods are also part of structural component.[70] In the context of drug sales, structure refers to the quality of the premises of medical store, storage facilities and the

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[67]HYPERLINK"https://en.wikipedia.org/wiki/Donabedian_model"
Other models include: the HYPERLINK "https://en.wikipedia.org/wiki/World_Health_Organization" \o "World Health Organization" World Health Organization (WHO)-Recommended Quality of Care Framework, the HYPERLINK "https://en.wikipedia.org/wiki/Bamako_Initiative" \o "Bamako Initiative" Bamako Initiative and the Shewhart Cycle

[68]Nau, David P., Mary Ann Kliethermes, and Sarah McCabe. "Quality measurement: time to get serious." *Journal of the American Pharmacists Association* 46, no. 6 (2006): 668-679.

[69]Donabedian, Avedis. "The quality of care: How can it be assessed?" *Journal of American Medical Association* 60, no. 12 (1988): 1743-1748.

[70]Donabedian, A, "The quality of care: How can it be assessed?" *Journal of American Medical Association* 60, no. 12 (1988): 1743-1748.

dispensing equipment. It also includes the qualities of human resource, their qualification, knowledge and experiences[71].

1.1.2. Process

Process includes all actions to deliver health service. In the context of drug sales, the process refers to two types of activities going on in the pharmacies. Firstly, the dispensing process and then all the services other than dispensing being carried out at pharmacies. The services other than dispensing include procurement of drugs, record keeping, maintaining storage conditions etc.

The term dispensing includes all the activities which are carried out from receiving an order for drugs to the issuance of drugs with sufficient counseling[72]. Dispensing includes the preparation and transfer of a medication for a client, taking steps to ensure the therapeutic suitability of the medication for its intended use, and taking steps to ensure its proper use by issuing medicine with clear instructions to its users[73].

1.1.3. Outcomes

Finally, outcomes are the effects of service on patients and populations[74]. These are the most important indicators of quality focusing on the primary goal of any health service.

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[71]Donabedian, A, "The quality of care: How can it be assessed?" Journal of American Medical Association 60, no. 12 (1988): 1743-1748.

[72]BIBLIOGRAPHY \l 1033 Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012.p. 30.2

[73]Donabedian, A, "The quality of care: How can it be assessed?" Journal of American Medical Association 60, no. 12 (1988): 1743-1748.

[74]Donabedian, Avedis. "The quality of care: How can it be assessed?" *Journal of American Medical Association* 60, no. 12 (1988): 1743-1748.

In the context of quality of drugs sales, outcomes can be the patient knowledge about medication use and compliance.

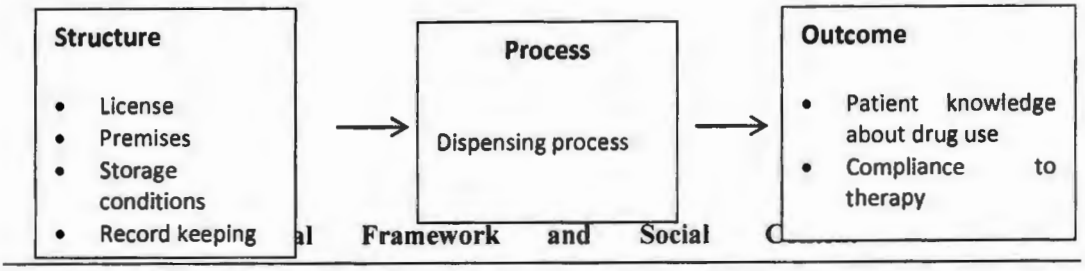

Figure I: Conceptual Framework for Drugs Sales

The standards and legislations are expected to cover all these aspects when dealing with the sales of drugs in any country[75].

[75]Donabedian, A, "The quality of care: How can it be assessed?" Journal of American Medical Association 60, no. 12 (1988): 1743-1748.

CHAPTER II

Drug Sales Regulation In Pakistan

2. Legal Regime for Sale of Drugs

In Pakistan, drugs are regulated under the provisions of the Drugs Act, 1976 (XXXI of 1976) and allied rules in Pakistan. Recently, in the post devolution scenario the Drug Regulatory Authority of Pakistan (DRAP) was established under the Drug Regulatory Authority of Pakistan Act, 2012 (Act No. XXI of 2012). It was established to coordinate and harmonize the inter-provincial activities related to drugs and therapeutic goods. There are two more legislative documents which supplement the Drugs Act, 1976 namely, the Pharmacy Act, 1967, and the Dangerous Drugs Act, 1987.

2.1. The Drugs Act, 1976

The Drugs Act, 1976 is an act to regulate all the activities related to drugs in the country. Such activities include import, export, trade, manufacture, distribution and sale of drugs. The Act clearly dictates that role of Federal government to regulate the imports, exports and manufacturing of drugs. While the drugs distribution and sales is provincial responsibility. This act specifies the prohibitions, offences, penalties and procedures in addition to the definitions and administration clauses.

The Federal Government is responsible for regulation of imports, exports, registration of drugs and licensing the pharmaceutical companies to manufacture drugs[76]. Drug pricing and advertisement also comes under the Federal Government control. Quality is assured under the provisions of the DRAP Act, 2012, the Drugs Act, 1976 and the rules made there under.

The Provincial Governments are required to regulate the sale of drugs and for that purpose can issue instructions to the dealers of drugs like importers, distributors, manufacturers[77]. Provincial Governments use the drug inspectors, government analysts and the provincial quality control board to regulate sales of drugs.

2.2. The Pharmacy Act, 1967

The Pharmacy Act, 1967 is an act to regulate the practice of pharmacy in Pakistan using Pharmacy Councils.[78] It issues the regulations for pharmacy institutions, pharmacy curriculum, registration of pharmacists and other qualified drug sellers. Under the clauses of this act, two types of pharmacy councils exist in Pakistan, the Central Pharmacy

[76]BIBLIOGRAPHY \l 1033 Section 4 (1) the Drugs Act, 1976.
"The Federal Government shall regulate the import and export of drugs in the prescribed manner and for that purpose may make such orders and issue such directions to the importers and exporters as it may deem fit."
Also the section 5(1) of the Drugs Act, 1976
"The grant of licenses to manufacture drugs shall be regulated in accordance with such conditions and procedure as may be prescribed, by a Central Licensing Board to be set up by the Federal Government and consisting of such representatives of the Federal Government and the Provincial Governments as may be prescribed".
Also the section 7(I) of the Drugs Act, 1976
"The Federal Government shall cause all drugs to be registered in-accordance with such conditions and procedure as may be prescribed and for that purpose set up a Registration Board, consisting of such number of persons, possessing such qualifications, as may be prescribed".
[77]BIBLIOGRAPHY \l 1033 Section 6, the Drugs Act, 1976
"the Provincial Governments shall regulate the sale of drugs in the prescribed manner and may for that purpose make such orders, and issue such directions to the importers, manufacturers, stockists, retailers or other dealers of drugs, as they may deem fit".
[78]The Pharmacy Act, 1967 (XI of 1967) As ammended upto 8th February 1973.

Council, known as the Pharmacy Council of Pakistan and the Provincial Pharmacy Councils.

The Central Council is mainly concerned with regulation of the pharmacy educational institutes and the curriculum.[79] While the Provincial Councils deal with the registration of pharmacists and other qualified apprentices in pharmacy profession.[80] No person is allowed to practice as pharmacist in Pakistan if s/he is not registered by the concerned provincial pharmacy council as pharmacist.

Three types of qualifications are recognized by the provincial pharmacy councils to register persons qualified in pharmacy profession. For the purpose of registration, these councils prepare and maintain registers namely, register A, register B and register C.[81] All pharmacists, having a degree in pharmacy are registered in the register A[82] while the diploma holders in pharmacy are registered in register B[83].

The apprentices in pharmacy who have passed the examination held by provincial councils are registered in register C.[84]

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[79]Section 19 (1), the Pharmacy Act, 1967 "Any institution or authority which conducts a course of study in pharmacy may apply to the Central Council for approval of such course of study for the purpose of admission to an approved examination."

[80]ibid

[81]ibid

[82]section 25 (1) (a) of the Pharmacy Act, 1967 "persons who hold a degree in pharmacy conferred by a University or an institution affiliated thereto, where the degree is recognized by the Central Council."

[83]Section 25 (1)(b) of the Pharmacy Act, 1967 "persons who hold a diploma in pharmacy granted by any institution recognized by the Central Council."
Also the Section 25 (1)(c) "persons who pass the examination in pharmacy held by a Provincial Council."

[84]Section 24 (1)(c) of the Pharmacy Act, 1967 "Register C - in which shall be registered the apprentices in pharmacy"

Persons who are dispenser in hospitals, are also considered as apprentice in pharmacy if certified by government hospitals.[85] These qualified persons are then allowed to practice in pharmacies or medical stores in under the provisions of the Drugs Sales Rules of respective provinces. This study is mainly aimed at the drugs sale regulations. Our main focus will be on the Punjab drugs sales rules, 2007.

2.3. The Punjab Drug Rules, 2007

These rules were introduced in super-session of the Punjab Drugs Rules 1988 by exercising the powers under section 44 of the Drugs Act, 1976.[86] These rules provide the detailed specification for drug sales in the province of Punjab. Other provinces also have the similar rules enforced.

According to the Punjab Drugs Rules, 2007 the sale of drugs should be carried out under the licenses issued by the licensing authority established under these rules. This authority

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[85]Section 25 (2)(ii) of the Pharmacy Act, 1967 "The following persons shall, subject to the provisions of sub-section (3) be qualified to be registered as an apprentice in Pharmacy, namely: a person certified by a Government Hospital to be a qualified compounder and dispenser."

[86]Section 44 (1), the Drugs Act, 1976

"(1) The Provincial Government may by notification in the official Gazette, make rules in respect of the following matters, namely :--

(a) the establishment of laboratories for testing and analyzing drugs;

(b) the qualifications and the procedure, for exercise of powers and performance of functions of Provincial Inspectors;

(c) the forms of reports to be given by Government Analysts and the manner of application for test or analysis and the fees payable therefor;

(d) the conditions to regulate sale or storage or distribution of drugs or any specific drug or class of drugs;

(e) the offences against this Act or any rule in relation to which the stock of drugs shall be liable to confiscation and destruction under this Act;

(f) the forms of licenses for the sale or distribution of drugs or any specified drug or class of drugs, the authority empowered to issue the same, the form of applications for such licenses, the fees payable therefor and the condition subject to which such licenses may be issued;

(g) the procedure to be followed by the Provincial Quality Control Board; and any other matter which is to be or may be, prescribed by the Provincial Government."

is responsible for grant as well as renewal of the licenses for drug sales.[87] The sale of drugs is carried out a medical stores or pharmacies in the province. The Punjab drugs sale rules, 2007 explicitly provide the legal definitions of *medical stores*[88] and pharmacies[89].

The license to sale drugs essentially bears the name and registration number of the qualified person who will personally supervise the sale of drugs. This qualified person must be registered under the provisions of the Pharmacy Act, 1967 either in register A or B for *medical store* and in register A for the license for *pharmacy*.[90] These registers are maintained under the provincial pharmacy councils.

Conditions for issuance of licenses to sale drugs

The Rule 19 (2) of the Punjab Drugs Rules, 2007 states that the license cannot be issued without inspection report of the premises made by the Area Drugs Inspector. These conditions are concerned with the structure of premises, storage facilities and qualified personnel.

The premises is required to be clean, hygienic and in tidy condition; and have adequate facilities for storing drugs. Such facilities include protection from direct

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[87]Rule 14, the Punjab Drugs Rules, 2007
"The licensing authority may issue a license of a pharmacy or a license of a medical store"
[88]Rule 2(1)(h), the Punjab Drugs Rules, 2007
"*Medical store* means premises where drugs excluding the drugs specified in the Schedule G are stored, sold or offered for sale."
[89]Rule 2(1)(k), the Punjab Drugs Rules, 2007 "*Pharmacy* means premises where drugs are stored, sold, compounded, dispensed or prepared on prescription or distributed in case of authorized agent of manufacturer, indenter or importer."
[90]Rule 19 (1)(f), the Punjab Drugs Rules, 2007
"(1) The licensing authority shall not issue a license in Form 9 (pharmacy) and Form 10 (medical store) unless- (f) a person who is registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) has agreed to personally supervise the sale of drugs for license in Form 9 (pharmacy) and a person who is registered under section 24(1)(a) & (b) of the said Act has agreed to supervise sale of drugs for license in Form 10 (medical store)."

sunlight and dust and the refrigeration facility.[91] The minimum area and dimensions of the premises are also specified in the rules.[92] Additional requirements are specified if the pharmacy will carry out the extemporaneous preparation or compounding of drugs.[93]

Further conditions of the license are mentioned in the licenses issued for *pharmacy* in form 9 and for *medical store* in form 10.[94]

The rules require a display of the signboards outside the drug selling premises. The specifications for these boards such as their color, font style and size are stated in rule 20(a).

The legislation requires that the license and registration certificate (from pharmacy council) of the person personally supervising the sale of drugs should be displayed in a prominent place inside the medical store or pharmacy.[95]

Conditions for the license again emphasize the sale of drugs under the personal supervision of qualified person[96]. In case of *pharmacy*, the licensee should report

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[91]Rule 19 (1), the Punjab Drugs Rules, 2007
"The licensing authority shall not issue a license in Form 9 (pharmacy) and Form 10 (medical store) unless-
(a) the premises has proper and adequate facility for storage of drugs and for their protection from direct sunlight, dust or dirt, including refrigeration facility;
(b) the premises is clean, hygienic and in tidy condition."

[92]Rule 19 (1) (d) the Punjab Drugs Rules, 2007 "the covered area of the premises of a pharmacy is not be less than 140 square feet with minimum breadth of 8 feet in the front and height of 8 feet and in case of a medical store, 96 square feet with minimum breadth of 8 feet and height of 8 feet"

[93]Schedule F, the Punjab Drugs Rules, 2007

[94]Schedule A, the Punjab Drugs Rules. 2007

[95]Conditions for license, Form No. 9, Schedule A, the Punjab Drugs Rules, 2007
"This license and registration certificate (from pharmacy council) of the person(s) in charge, personally supervising the sale of drugs shall be displayed in a prominent place in part of the premises open to the public."

[96]The Rule 20 (1) (b) state that the person registered under section 24(1) of the Pharmacy Act, 1967 shall personally supervise the sale of drugs in medical stores while a person registered under section 24(1)(a) of the Pharmacy Act 1967 shall personally supervise the sale of drugs in pharmacies.

immediately to the Licensing Authority, any change in person who is personally supervising the sale of drugs.

Drug storage is given high importance with explicit notification to store drugs at the required storage conditions of temperature and humidity throughout the period during which drugs remain at that place.[97] Special storage guidelines are given for the substances specified in the Schedule E (poisons) and the Schedule B drugs.[98] They shall be stored in a place where customers don't have access. Special storage conditions are required for the substances (poisons) mentioned in the Schedule E. They should be stored in poison resistant containers, which are sufficiently stout to prevent leakage during handling and transport.[99] Such substances, shall be labeled with the word "Poison" at the time of dispensing or compounding.[100]

Record keeping, to track the supply of drugs, is another essential condition for the license to sell drugs.

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[97]Conditions for License, Form No. 9 and 10, Schedule A, the Punjab Drugs Rules, 2007
"No drug requiring special storage conditions of temperature and humidity shall be stored or sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it remained in possession of the licensee."
[98]Rule 20(11), the Punjab Drugs Rules, 2007
"A substance specified in the Schedule E and that fall under the list of poisons and the drug specified in the Schedule B shall be stored in:
(a) in a part of the promises to which customers do not have access; or
(b) in a locked almirah, cupboard or drawer, reserved solely for the storage of the substance or the drug."
[99]Rule 20 (12), the Punjab Drugs Rules, 2007
"A substance that falls under the list of poisons in the Schedule E shall be stored in a container, impervious to the poison, and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport."
[100]Rule 20 (13), the Punjab Drugs Rules, 2007 "A substance that fall in the list of poisons under the Schedule E when compounded and dispensed shall be labeled with the word "Poison"."

The licensees are required to preserve the sale records for at least three years after the sale.[101] Provisions are available to maintain records of sales and purchases at medical stores and pharmacies.[102] In case of purchase, the medical stores and pharmacies need to obtain a warranty from the supplier that drug is conforming to the provisions of the Drugs Act, 1976.[103] The Rule 20 (7) states that the invoice/warranty should bear the full name and address of the purchaser, the warrantor's signatures with name and the date.[104]

The legislation imparts control over the sale of drugs without prescriptions at community pharmacies. The Punjab Drug Rules, 2007 prohibit the sale of drugs specified in the Schedules B and D without the prescription of a registered medical practitioner.[105] Pharmacies are further required to maintain a record of drug sales, for controlled drugs (Schedules B and D) in a special register maintained for this purpose. The Rule 20 (1) (f) states the information to be recorded in register: date of sale, name of patient, prescriber,

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[101]Rule 20 (1) (c), the Punjab Drugs Rules, 2007
"the supply of a drug shall be recorded suitably and the records, the bills or the counterfoils shall be preserved for a period of at least three years from the date of the sale."
[102]Rule 20 (8), the Punjab Drugs Rules, 2007
"The manufacturer, importer or seller of a drug shall maintain record of purchase or sale of a drug and shall preserve the record for a at least three years containing the following particulars:
(a) the date of purchase or sale;
(b) the name and address of the concern from which the drug is purchased or the concern to whom the drug is sold;
(c) the name of the drug, its batch number, the date of its expiry and the quantity of the drug;
(d) the name of the manufacturer."
[103]Rule 20 (4), the Punjab Drugs Rules, 2007.
"A manufacturer, importer or the seller of a drug shall sell the drug only to a holder of a valid drug sale license or to a registered medical practitioner and shall issue an invoice and warranty at the time of sale of the drug."
[104]The Punjab Drugs Rules, 2007
[105]Rule 20 (1) (d), the Punjab Drugs Rules, 2007
"a drug specified in the Schedules B and D and a preparation containing such drug shall not be sold except on and in accordance with the prescription (original to be retained by the pharmacy or the medical store) of a registered medical practitioner; a prescription may be dispensed with in case of an emergency (recorded in writing in the register); and no such prescription shall be required for sale of the drug to a registered medical practitioner, a hospital dispensary or any other institution."

drug and manufacturer. The quantity sold along with the batch number and signature of the qualified person should also be recorded. In case of refill of prescription containing drugs in Schedule D, it is sufficient to enter the serial number, the date of sale; the quantity sold; and a reference to an entry in the register recording the sale of the drug on the previous occasion.[106]

The provincial licensing authority has the powers to cancel or suspend the license of a person to sale drugs if the above mentioned conditions are violated.[107]

2.4. Offences and Penalties in Drug Sales

A recent advance in the history of Pakistan is made where more strict penalties for offences under the Drugs Act, 1976 and allied rules are introduced. Penalties for offences under the act had been very mild until recently which has dwelled the malpractices. The Governor of the Punjab has promulgated the amendment[108] in the penalties prescribed by the Drugs Act, 1976 following the specification of country's constitution.[109] This step was taken to eradicate the menace of spurious drugs and other violations of the Drugs Act, 1976 in the country. The major offences and penalties related to sale of drugs are:

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[106]The Punjab Drugs Rules, 2007

[107]Rule 21, the Punjab Drug Rules, 2007

"The licensing authority may, on the report of an Inspector or the Provincial and the District Board, after giving the licensee an opportunity to show cause and by an order in writing stating the reasons, cancel a license issued under these rules or suspend it for such period as it deems fit, if in its opinion the licensee has failed to comply with any of the conditions of the license or with any of the provisions of the Act or these rules."

[108]The Punjab Drugs (Amendment) Ordinance, 2015

[109]Article 128 (1) the Constitution of Pakistan. "The Governor may, except when the Provincial Assembly is in session, if satisfied that circumstances exist which render it necessary to take immediate action, make and promulgate an Ordinance as the circumstances may require."

The Section 7 (a) of the Punjab Drugs (Amendment) Ordinance, 2015 specifies punishment from three to ten years, to a person sells a spurious or adulterated drug or an imported drug which is not registered under the Drugs Act, 1976 or with a Foreign Drug Authority, or transports or sells a temperature sensitive drug in conditions which are likely to cause the drug to lose its potency. This punishment includes a fine as well, extending from one to five million rupees.[110] The same Ordinance in Section 7(b) specifies punishment of imprisonment from one to seven years for selling imitation drugs and for providing false warranty[111] . This further includes fine of up to one million rupees.

Any person who obstructs or disobeys an inspector is punishable with up to one year imprisonment, and/or with maximum of ten thousand rupees fine.[112]

In case of any other violation of the Drugs Act, 1976 and the rules made there under, the person shall be punished with imprisonment and with fine.

[110]Punjab Drugs (Amendment) Ordinance 2015.

[111]Section 7 (b) of the Punjab Drugs (Amendment) Ordinance, 2015 the punishments for person who himself or any other person on his behalf sells any imitation product, or sell any drug under a name other than the registered name, or gives to the purchaser a false warranty and is not able to prove that, when he gave the warranty, he had a good and sufficient reason to believe that the drug does not in any way contravene the provisions of the section 23 of the Drugs Act, 1976, or use the warranty of one drug for another drug. Such person shall be punished with imprisonment for a term which may extend to seven years but which shall not be less than one year with fine which may extend to one million rupees

[112]Section 27 (3), the Drugs Act, 1976

"Whoever obstructs an Inspector in the exercise of any power conferred upon him by or under this Act, or disobeys the lawful authority of any Inspector, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees, or with both."

The imprisonment in this case will be for a maximum of five years while a fine up to 500,000 rupees.[113]The Federal and Provincial Government can also forfeit the stocks and other materials as per the directions of drug court.[114]

The Ordinance specified that no court other than the Drug Court shall try an offence punishable under the chapter IV of the Drugs Act, 1976.[115] Appeals can be made to the High Court against the final orders of the drug court within sixty days and such appeals shall be heard by the Bench of High Court consisting of at least two judges.[116]

[113]Section 7 (c), the Punjab Drugs (Amendment) Ordinance 2015, "subject to the provisions of subsection (1), subsection (2), and subsection (3), if a person himself or through any other person acting on his behalf contravenes any of the provisions of this Act or any rules, he shall be punished with imprisonment for a term which may extend to five years but which shall not be less than six months and with fine which may extend to five hundred thousand rupees"

[114]Section 29(1), the Drugs Act, 1976

"Where any person has been convicted under this Act, for contravening any such provisions of this Act or any rule as may be prescribed in this behalf, the Drug Court may order that the stock of drug or substance by means of or in relation to which the offence was committed or anything of a similar nature belonging to or in the possession of the accused or found with such drug or substance, and if such contravention is punishable under sub-section (1) of section 27, any implements used in manufacture or sale of such drug and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances, used in carrying such drug, be forfeited to the Federal Government or, as the case may be, the Provincial Government and, upon such order being made, such .drug, substance, implements, receptacles, packages or coverings, animals, vehicles, vessels or conveyance may be disposed of as that Government may direct."

[115]Section 8, the Punjab Drugs (Amendment) Ordinance, 2015

"In the said Act, in Section 30, for subsection (2), the following shall be substituted:

"(2) Notwithstanding anything contained in the Code of Criminal Procedure, 1898 (V of 1898):

(a) an offence punishable under this Chapter, other than an offence mentioned in subsection (1) or subsection (2) of section 27, shall be non-cognizable,

(b) an offence punishable under subsection (1) and subsection (2) of section 27 shall be cognizable and non-bail able; and

(c) no court other than the drug court shall try an offence punishable under this chapter."

[116]Section 10, the Punjab Drugs (Amendment) Ordinance, 2015

"In the said Act, after section 31, the following section 31A shall be inserted"

"31A. Appeal.-(1) The provincial Government or the person sentenced by a Drug Court may, within sixty days, file an appeal against a final order of the Drug Court to Lahore High Court and the appeal shall be heard by a Bench of that Court consisting of not less than two Judges."

CHAPTER III

Critical analysis of Pakistani legislation against GPP guidelines

3.1.Quality of Pharmacy Services

Community pharmacies are often a site of final encounter between patients and drugs under the scrutiny of health care providers.[117] The quality of services at these outlets ultimately translates into health outcomes among patients.[118] To ensure the service quality at pharmacies, it is important to understand the meaning of quality. A general definition of quality is "meeting specific standards or specifications".[119] Without standards we have no way of assessing it. Merriam-Webster Dictionary[120] provides several key concepts for the definition of quality. Firstly, it states that quality is degree of excellence. Secondly, it suggests that it is something minimum with which a community may be reasonably content. Thirdly, quality serves as a basis for comparison and is recognized as a standard model for imitation. In healthcare setting a simple definition of quality is standards which are "a benchmark of achievement, based on a desired level of

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[117]BIBLIOGRAPHY \l 1033 Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012.p. 30.2.

[118]Hussian, A and Ibrahim, MIM, "Knowledge Level of Patrons Attending Community Pharmacies in Pakistan: Is It a Threat to Rational Use of Drugs," *HealthMed* 5, No. 4 (2011): 819-825.

[119]HYPERLINK "http://dictionary.cambridge.org/dictionary/english/quality" _ (Last accessed on August 12, 2015)

[120]HYPERLINK "http://www.merriam-webster.com/dictionary/quality" (Last accessed on November 14, 2015)

excellence".[121] But what is this benchmark in the context of pharmacy services? All countries have some sort of legislation specifying some standards to be practiced at pharmacies. However, the problems of counterfeit drugs, poor dispensing practices and irrational use of drugs prevail commonly in developing countries.[122] In contrast the service quality is much better in developed world with availability of high quality drugs, good dispensing practices and rational drug use.[123] One of the reasons for this difference of practice between developed and developing world is the difference in their standards and benchmarks of excellence for pharmacy services. However considering health as a human right, everyone has an equal right to best quality services irrespective of one's place of residence.[124]

Two international organizations namely the World Health Organization (WHO) and International Pharmaceutical Federation (FIP) have played major role in building a minimum set of international standards for pharmacy services to be practiced in all countries. These standards are named as Good Pharmacy Practices (GPP) in Community

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[121]Heidemann, E. The contemporary use of standards in health care. World Health Organization. WHO, Geneva (1993), p, 6. Available at HYPERLINK "http://apps.who.int/iris/bitstream/10665/59466/1/WHO_SHS_DHS_93.2.pdf"(last accessed on November 5, 2015).

[122]le Grand, A, et. al. "Intervention research in rational use of drugs: a review. *Health Policy and Planning* 14. No. 2 (1999): 89-102. Available at HYPERLINK "http://archives.who.int/prduc2004/Resource_Mats/intervention%20research%20in%20rational%20use%20of%20drugs.pdf" _ (last accessed on September 22, 2015).

[123]WHO. "Effective drug regulation: A multi country study". Available at HYPERLINK "http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf" (last accessed on September 22, 2015)

[124]The WHO Fact Sheet No. 31. *The Right to Health.* available at HYPERLINK "http://www.who.int/hhr/activities/Right_to_Health_factsheet31.pdf?ua=1" (last accessed on November 3, 2015).

and Hospital Pharmacy Settings.[125] FIP urges governments to revise and implement right standards, according to the guidelines given in the Good Pharmacy Practice (GPP).[126]

The basic aim of this thesis to assess if the drug sales legislation in Pakistan is complying with the good pharmacy practice (GPP) standards as specified by the FIP. This chapter is concerned with the comparison of Pakistani legal framework dealing with pharmacy practice against the standards set by the FIP in GPP. This comparison will go a step beyond and compare the similar legislation in UK against GPP and Pakistani regulations. Towards the end of the chapter, journey of Pakistan against step-wise implementation of GPP in developing countries will be explored.

3.2International Standards for Pharmacy Services: Good Pharmacy Practices (GPP)

All pharmacies are required to ensure that they are providing good quality services to all patients.[127] GPP is a roadmap to meet this target. The phrase GPP is defined as "the practice of pharmacy that responds the needs of people (using pharmacy services) by providing optimal, evidence based care".[128] The GPP guidelines can be used by

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[125]BIBLIOGRAPHY \l 1033 FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011.

[126]le Grand, A, et. al. "Intervention research in rational use of drugs: a review. *Health Policy and Planning* 14. No. 2 (1999): 89-102. Available at HYPERLINK "http://archives.who.int/prduc2004/Resource_Mats/intervention%20research%20in%20rational%20use%20of%20drugs.pdf" (last accessed on September 22, 2015).

[127]BIBLIOGRAPHY \l 1033 WHO. *Good pharmacy practice in community and hospital pharmacy settings.* Geneva: WHO, 1996. Available at http://apps.who.int/medicinedocs/documents/s21088en/s21088en.pdf (last accessed on 09 September 2015)

[128]Official website of FIP, HYPERLINK "http://www.fip.org/good_pharmacy_practice" (last accessed on November 12, 2015).

pharmaceutical organizations and governments, to set up national standards of pharmacy practice.[129]

It is important to understand and comprehend the core activities being carried out at pharmacies before stating the standards for such activities. The GPP first underscore the main activities expected from any pharmacy as the four main roles. Then it establishes the service standards for these roles/activities. These roles[130], as defined by FIP are:

1. Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products.
2. Provide effective medication therapy management[131].
3. Maintain and improve professional performance.
4. Contribute to improve effectiveness of the health-care system and public health.

The standards for these activities should be adapted according to the local needs.

3.3Critical Analysis

3.3.1.Basic pharmacy practice philosophy

Pharmacy practice varies across the world. However, almost all countries agree that the sale of drugs is different from the sales of other consumer goods. Hence have established

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[129]BIBLIOGRAPHY \l 1033 FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011.

[130]le Grand, A, et. al. "Intervention research in rational use of drugs: a review. *Health Policy and Planning* 14. No. 2 (1999): 89-102. Available at HYPERLINK "http://archives.who.int/prduc2004/Resource_Mats/intervention%20research%20in%20rational%20use%20of%20drugs.pdf" (last accessed on September 22, 2015).

[131]Medication therapy management is a service that optimizes therapeutic outcomes for individual patients. Such service is independent of, but can occur in conjunction with, the provision of a medication product.

quality standards for providing services in pharmacies.[132] The GPP states some basic philosophies regarding pharmacy practice which set the basis of all quality standards for pharmacy services.[133] These basic provisions are: defining the core pharmacy activity in the country, what to expect from pharmacies, what services can be provided in pharmacies, what are the legal obligations and who is responsible. These indicators set the basis of all practice standards. All countries need to be very clear on vision of pharmacy practice at national level.[134]

The first section of this chapter assesses if the legislation in Pakistan is providing information on these basic philosophies. Example of the UK is incorporated to establish a practical example (Table 1).

Table 1: Basic pharmacy practice philosophy, comparison of Pakistani and UK's legislation with GPP guidelines

Sr. No	GPP	Pakistan	UK
1	**Main pharmacy activity**		
	GPP states the main pharmacy activity as "the supply of medicines and other health care products of assured quality, appropriate information and advice for the patients, and monitoring the effects of use".[135]	Drug sales[136]	Dispensing medicines and appliances, repeat dispensing, clinical governance, public health promotion, disposal of unwanted medicines, signposting and support for self care.[137]

[132] Westerlund, T and Bjork, T. "Pharmaceutical Care in Community Pharmacies: Practice and Research in Sweden," *The Annals of Pharmacotherapy*, 40,no. 6 (2006): 1162-1169.

[133] BIBLIOGRAPHY \l 1033 FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011.

[134] FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011

[135] FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011

2	**Pharmacy Services**		
	1. Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products. 2. Provide effective medication therapy management. 3. Maintain and improve professional performance. 4. Contribute to improve effectiveness of the health-care system and public health.[138]	An extensive definition of pharmacy services is provided in the DRAP Act, 2012[139]	Three different service types are available at pharmacies: the essential services[140] to be provided by all pharmacies. Others are advanced services[141] and locally commissioned services[142]

[136] Rule 2 (1)(h), the Punjab Drug Rules, 2007 "medical store" means premises where drugs excluding the drugs specified in the Schedule G are stored, sold or offered for sale;
Also see the Rule 2 (1)(k)"pharmacy" means premises where drugs are stored, sold, compounded, dispensed or prepared on prescription or distributed in case of authorized agent of manufacturer, indenter or importer."

[137] Official website of the Pharmaceutical Services Negotiating Committee, UK. HYPERLINK "http://psnc.org.uk/contract-it/the-pharmacy-contract/" http://psnc.org.uk/contract-it/the-pharmacy-contract/ (last accessed on 12 September 2015) "All pharmacy contractors are obliged to provide essential services as part of the NHS Community Pharmacy Contractual Framework . These services include: dispensing medicines and appliances, repeat dispensing, clinical governance, public health promotion, disposal of unwanted medicines, signposting and support for self care."

[138] FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011

[139] Section 2 (xxvi), the DRAP Act, 2012
"pharmacy services are the services rendered by a pharmacist in pharmaceutical care, selection, posology, counseling, dispensing, use, administration, prescription monitoring, pharmacoepidemiology, therapeutic goods information and poison control, pharmacovigillance, pharmacoeconomics, storage, sales, procurement, forecasting, supply chain management, distribution, drug utilization evaluation, drug utilization review, formulary based drug utilization and managing therapeutic goods at all levels including pharmacy, clinic, medical store, hospital or medical institution."

[140] Official website of the Pharmaceutical Services Negotiating Committee, UK. HYPERLINK "http://psnc.org.uk/services-commissioning/essential-services/" http://psnc.org.uk/services-commissioning/essential-services/ (last accessed on 12 September 2015)
"Essential services and clinical governance: These are provided by all pharmacies and include dispensing of drugs and appliances, repeat dispensing, clinical governance, promotion of healthy lifestyle, disposal of unwanted medicines, signposting, and support for self care."

[141] Official website of the Pharmaceutical Services Negotiating Committee, UK. HYPERLINK "http://psnc.org.uk/services-commissioning/advanced-services/" http://psnc.org.uk/services-commissioning/advanced-services/ (last accessed on 09 August, 2015)
" HYPERLINK "http://www.psnc.org.uk/services-commissioning/advanced-services/" \o "Advanced Services" Advanced services can be provided by all contractors once accreditation requirements have been met. These include flu vaccination, medicine use review, appliances use review, new medicine service, and stoma appliance customization"

Sr. No	GPP Guidelines	Pakistan	UK
3	**Pharmacist obligation**		
	All pharmacists are obliged to ensure that they are providing services of appropriate quality to all patients[143]	"the pharmacist shall comply with the provision of the Drugs Act, 1976 and rules framed there under" [144]	To ensure that medicines are supplied correctly and that patients know how to use them and are aware of side effects. To provide advice and treatments for minor ailments.[145]
4	**Expectations from pharmacy**		
	The first steps in strategic planning for GPP usually involve determining the roles of pharmacists that are desired by patients, physicians, policy makers, insurers, payers, and the other health care practitioners.[146]	No such information available	Pharmacist to spend time with patient talking about medicines use. This would include how to take them, the side effects and about the outcomes. Pharmacist to have expertise on disease conditions to know how to help patients. Advocate for medicine safety issues.[147]

The legal frameworks dealing with drugs in Pakistan use a discourse which portrays the main pharmacy activity as drug sales just like sale of other consumer goods. If a close attention is paid to the definitions given by GPP and UK legislative bodies, pharmacy activity is a lot more than the mere sales of drugs. It is a specialized service which

[142]Official website of the Pharmaceutical Services Negotiating Committee, UK. HYPERLINK "http://psnc.org.uk/services-commissioning/locally-commissioned-services/" http://psnc.org.uk/services-commissioning/locally-commissioned-services/ (last accessed on 09 August, 2015)
"Locally commissioned services are commissioned by Local Authorities in UK, in response to the needs of the local population"

[143]FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011

[144]Form 8(A) and 8(B) , *The Punjab Drug Rules, 2007.*

[145]Official website of the Pharmaceutical Services Negotiating Committee, UK. HYPERLINK "http://psnc.org.uk/" http://psnc.org.uk/ (last accessed on 12 September 2015)

[146]FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011

[147]What should you expect from your community pharmacist? Available at HYPERLINK "https://www.rpharms.com/news-story-downloads/consultation---medicines-charter-for-patients.pdf" (last accessed on November 23, 2015)

involves dispensing[148] drugs and wellbeing of public is at the core. It is interesting to note that the DRAP Act, 2012 provides a detailed and exhaustive definition of pharmacy services despite no reference of it in any clause or the rules made there under.

GPP states that one of the first steps in establishing the GPP in any country is to be clear what to expect from pharmacies and pharmacist working in community pharmacies. Such expectations should be explicit and incorporate opinions from all relevant stakeholders, most importantly the public. However, there is no such information available in Pakistan.

3.3.2.Structural indicators of pharmacy practice

In the context of drug sales, structure[149] refers to the main physical and human resource inputs to provide pharmacy services in any country. For the purpose of this research, we included the license to practice, as well, in the structural components. If anything goes wrong in the structural inputs, the pharmacy processes will be of low quality. The structural standards are further divided into indicators of licensing/legal regime, premises, personnel, storage and dispensing equipment.

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[148]Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012
"*Dispensing* includes all the activities which are carried out from receiving an order for drugs to the issuance of drugs with sufficient counseling. It essentially includes six activities: receiving and validating the request for medicines, understanding and interpreting the request, preparation of the medication order according to patients' needs, labeling of items for individual patients, recording the action and finally issuing the medicines to patients or intermediary with clear instructions and advice."

[149]"Structure includes all the factors that affect the context in which care is delivered. This includes the physical facility, equipment, and human resources, as well as organizational characteristics such as staff training and payment methods."
Donabedian, A, "The quality of care: How can it be assessed?" *Journal of American Medical Association* 60, no. 12 (1988): 1743-1748.

Legal Regime

Every country should establish a legal framework which defines the scope of pharmacy practice as well as who can or cannot practice pharmacy.[150] The section below provides a detailed assessment of legislation in the UK and Pakistan against the standards set by the GPP (Table 2).

Table 2: Legal framework indicators, comparison of Pakistani and UK's legislation with GPP guidelines

Sr. No	Structural Indicators	GPP	Pakistan	UK
1	National governing body	Every country should establish a legal framework which defines the scope of pharmacy practice as well as who can practice.[151]	Provincial government[152]	General pharmaceutical council[153], NHS
2	Laws and regulation to monitor pharmacy practice		The Drug Act, 1976 & the allied Drug Sale Rules and the Pharmacy Act, 1967	The Medicines Act 1968; the Human Medicines Regulations 2012 and the Pharmacy Order 2010
3	License to practice		Essential	Essential
4	Accountability	Pharmacist in charge[154]	Not clear (may be the proprietor or the	The responsible pharmacist and

[150]BIBLIOGRAPHY \l 1033 FIP. *Good Pharmacy Practice (GPP) in developing countries: Recommendations for step-wise implementation.* The Hague, Netherlands: FIP, 1998.

[151]BIBLIOGRAPHY \l 1033 FIP. *Good Pharmacy Practice (GPP) in developing countries: Recommendations for step-wise implementation.* The Hague, Netherlands: FIP, 1998.

[152]Section 6, the Drugs Act, 1976.

"the Provincial Governments shall regulate the sale of drugs in the prescribed manner and may for that purpose make such orders, and issue such directions to the importers, manufacturers, stockiest, retailers or other dealers of drugs"

[153]HYPERLINK "https://www.pharmacyregulation.org/about-us" (last accessed on 09 August 2015)

"General pharmaceutical council is an independent regulator of pharmacy premises, pharmacy services, pharmacists and pharmacy technicians in the Great Britain. Its job is to protect, promote and maintain the health, safety and wellbeing of public by upholding standards and public trust in pharmacies."

[154]BIBLIOGRAPHY \l 1033 FIP. *Good Pharmacy Practice (GPP) in developing countries: Recommendations for step-wise implementation.* The Hague, Netherlands: FIP, 1998.

			qualified person or both)	superintendent pharmacist[155]

As per GPP requirements, the government of Pakistan has made laws and rules to regulate the practice of community pharmacies in the country. However, it is worth exploring if these laws are comprehensive.

Indicators for the quality of premises

The design of pharmacy premises can contribute to quality of drugs as well as to the quality of dispensing processes. The specific indicators related to premises are discussed in (Table 3).

[155]HYPERLINK"http://www.pharmacyregulation.org/sites/default/files/Inspector%20Sep12.pdf" (last accessed on 09 August 2015)
"Every registered pharmacy premises is required to have a responsible pharmacist appointed during the pharmacy's business hours. The owner and/or superintendent pharmacist has an obligation to be satisfied that the person they appoint as a responsible pharmacist is competent to take on the role. The responsible pharmacist is responsible for the safe and effective running of the registered pharmacy."

Table 3: Premises indicators, comparison of Pakistani and UK's legislation with GPP guidelines

Sr. No	GPP	Pakistan	UK
1	Pharmacy premises should be appropriately designed to allow ease of operations. They must meet safe and clean.[156]	Details are provided in the Punjab Drug Rules, 2007.[157]	Details are provided different documents[158]
2	Every pharmacy should have a suitable place for discussing confidential information with the customers and patients.	Not required	It is essential that patients can receive advice without being overtly overheard[159]

[156]BIBLIOGRAPHY \l 1033 FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011.

[157]Rule 19 and 20, *The Punjab Drug Rules, 2007.*

The premises is required to be clean, hygienic and in tidy condition; and have adequate facility for storage of drugs including their protection from direct sunlight, dust or dirt with refrigeration facility. The covered area of the premises of a medical store should not be less than 96 square feet with minimum breadth of 8 feet and height of 8 feet and in case of a pharmacy; it should not be less than 140 square feet with minimum breadth of 8 feet in the front and height of 8 feet. Additional requirements are specified in Schedule F of the said Rules, for pharmacies carrying out the extemporaneous preparation or compounding of drugs.

[158]HYPERLINK "https://www.pharmacyregulation.org/pharmacystandardsguide/managing-pharmacy-premises-standards" _(last accessed August 23, 2015)

Premises are safe, clean, properly maintained and suitable for the pharmacy services provided and maintained to a level of hygiene appropriate to the pharmacy services provided.

Further detailed specifications for premises are available in these documents:

Design for patient safety: A guide to the design of the dispensing environment (NHS, 2007) available at HYPERLINK "file:///C:/Users/PC/Downloads/0586a_Dispensing%20environment.pdf (last accessed August 23, 2015), Standards for registered pharmacies (General Pharmaceutical Council, 2012) available at HYPERLINK "http://www.pharmacyregulation.org/sites/default/files/Standards%20for%20registered%20pharmacies%20September%202012.pdf" (last accessed August 23, 2015), Inspector's checklist for monitoring and inspection visits (General Pharmaceutical Council, 2012) available at HYPERLINK "http://www.pharmacyregulation.org/sites/default/files/Inspector%20checklist%20website%20version%20Sep12.pdf" (last accessed August 23, 2015).

[159] NHS (2007) Design for patient safety: A guide to the design of the dispensing environment. Edition 1. HYPERLINK "file:///C:/Users/PC/Downloads/0586a_Dispensing%20environment.pdf" (last accessed August 25, 2015)

Pakistani legislation provides detailed specifications for the design of pharmacy outlets. There are provisions for the protection of stocks from direct sunlight, dust, unauthorized access, placement of drugs behind the counter away from general public. The physical dimensions specified in the Drug Rules, 2007 do not allow overcrowding in the outlets. However, the regulations ignore the necessity of a confidential area for patient counseling. As the structural specifications are completely ignoring the patient advice and counseling function at pharmacies, this may be the reason that this function is not carried out professionally during dispensing drugs in Pakistan.

Indicators for the personnel

GPP stress the need of a national framework that characterizes the personnel needed to provide GPP. It requires clear guidelines to ensure competence of pharmacy staff. Minimum national standards should be established for continuing professional development of staff to improve their clinical knowledge, skills and performance.[160] The (Table 4) gives a situation analysis of indicators related to pharmacy personnel in Pakistan against the GPP guidelines. The example of UK is also quoted.

[160] *The Punjab Drug Rules, 2007*

Table 4: Personnel indicators, comparison of Pakistani and UK's legislation with GPP guidelines

Sr. No	Structural Indicators	GPP	Pakistan	UK
1	Personnel	Pharmacist is the at the core of GPP, other qualified personnel can assist the pharmacist[161]	The pharmacists, qualified dispenser or apprentices in pharmacy shall personally supervise the sale of drugs in *medical stores.* Only pharmacist is allowed to supervise sales in *pharmacies*[162]	Pharmacist, pharmacy technician and pharmacy assistant[163]
2	Continuing education	Pharmacists should perceive continuing education as being lifelong and be able to demonstrate evidence of continuing education[164]	Not a requirement	The general pharmaceutical council has set standards for the continuing professional development for pharmacy staff[165]

[161]BIBLIOGRAPHY \l 1033 FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011.

[162]Rule 20 (1) (b), the Punjab Drug Rules, 2007

"a person who is registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) shall personally supervise the sale of drugs under license in Form 9 (pharmacy) and a person who is registered under section 24(1) of the said Act shall personally supervise sale of drugs under license in Form 10 (medical store)."s

[163]NHS website HYPERLINK "http://www.nhscareers.nhs.uk/explore-by-career/pharmacy/" _, (last accessed on 12 September, 2015).

Appropriate definitions, qualifications and detailed roles and responsibilities for all tiers of staff working at pharmacies are also available

[164]BIBLIOGRAPHY \l 1033 FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011.

[165]General Pharmaceutical Council. Standards for continuing professional development, General Pharmaceutical Council, 2010. Available at HYPERLINK "https://www.pharmacyregulation.org/sites/default/files/Standards%20for%20continuing%20professional%20development%20s.pdf" (last accessed on October 3, 2015).

It is important to note that the drug sales should be carried out by the trained and qualified personnel as per GPP specifications. This involves a check on the competence and exercise of the powers of the qualified persons. The inspection system in UK is designed to assess the use of competence of the pharmacist and other personnel working in pharmacies. However, there is no such check or monitoring in Pakistan. Many researchers have just assessed if the pharmacist/qualified person was present at the pharmacy or not. There is a big question mark on their roles and practice when they are available and present in the pharmacy premises.

Indicators for the storage

All drugs should be stored in pharmacies in a way that retain their quality and efficacy. All pharmacy personnel should receive proper training in relation to good storage practices.[166] Storage areas should be of sufficient capacity to allow the orderly storage and handling of drugs. Premises should be designed or adapted to ensure good storage conditions.[167] In particular, it should be clean and dry and maintained within acceptable temperature limits.[168] The storage protocols of Pakistani legislation are compared against GPP guidelines and legislations in UK in this section

[166] WHO. "Guide to Good Storage Practices for Pharmaceuticals." Geneva, 2003. Available at HYPERLINK "http://apps.who.int/prequal/info_general/documents/TRS908/WHO_TRS_908-Annex9.pdf" __ (last accessed on November 23, 2015).

[167] WHO. "Guide to Good Storage Practices for Pharmaceuticals." Geneva, 2003. Available at HYPERLINK "http://apps.who.int/prequal/info_general/documents/TRS908/WHO_TRS_908-Annex9.pdf" __ (last accessed on November 23, 2015).

[168] FIP. *Good Pharmacy Practice (GPP) in developing countries: Recommendations for step-wise implementation.* The Hague, Netherlands: FIP, 1998.

Table 5 and 6: Storage indicators, comparison of Pakistani and UK's legislation with GPP guidelines

Sr. No	Structural Indicators	GPP	Pakistan	UK
1	Temperature, humidity and light	GPP demands that pharmacists should assure provision of proper storage conditions for all medicines, especially for controlled substances.[169]	Specifications are available[170]	Detailed specifications are available[171]
2	Safety			

Sr. No	GPP	Pakistan	UK
1	National standards are needed for equipments required for dispensing, assembly of prescribed items and extemporaneous preparations[172]	A detailed list of equipment and apparatus is provided for only those pharmacies carrying out the extemporaneous dispensing in the schedule F of the Punjab Drug Rules, 2007.[173]	The availability of safe and suitable equipment and facilities is fundamental to the provision of pharmacy services. Such equipments should be readily available, obtained from a reputable source, safe to use and fit for purpose, stored securely, safeguarded from unauthorized access and

[169]FIP. *Good Pharmacy Practice (GPP) in developing countries: Recommendations for step-wise implementation.* The Hague, Netherlands: FIP, 1998.

[170]Government of Punjab. *The Punjab Drug Rules, 2007.* Government of Punjab, Pakistan, 2007.

Rule 19(1)(a) the premises has proper and adequate facility for storage of drugs and for their protection from direct sunlight, dust or dirt, including refrigeration facility.

Rule (20) (11) A substance specified in the Schedule E and that fall under the list of poisons and the drug specified in the Schedule B shall be stored in: (a) in a part of the promises to which customers do not have access; or (b) in a locked almirah, cupboard or drawer, reserved solely for the storage of the substance or the drug..

[171]HYPERLINK"http://www.pharmacyregulation.org/sites/default/files/Sep12.pdf" (last accessed on October 13, 2015).

Inspection team checks if the medicines are stored at appropriate temperature and humidity levels, in their original boxes, fully labeled, no loose blisters, mixed batches and in organized manner; also if the dispensing containers are stored properly.

Further details on how to stock drugs in racks, drawers, cupboards and refrigerator are detailed in the *Design for patient safety: A guide to the design of the dispensing environment* (NHS, 2007) first edition. National Patient Safety Agency, 4-6 Maple Street, London.

[172]FIP. *Good Pharmacy Practice (GPP) in developing countries: Recommendations for step-wise implementation.* The Hague, Netherlands: FIP, 1998.

[173]Schedule F, the Punjab Drugs Rules, 2007

illustrates the dispensing protocols specified in Pakistani legislation against the GPP guidelines and practices in UK.

Table 7: Dispensing protocols, comparison of Pakistani and UK's legislation with GPP guidelines

Sr. No	Dispensing protocols	GPP	Pakistan	UK
1.	Definition of dispensing	No explicit definition[176]	No definition	"The supply of medicines and appliances ordered on NHS prescriptions, together with information and advice, to enable safe and effective use by patients and cares, and maintenance of appropriate records."[177]
2.	SOPs for dispensing process	GPP demand national governments to establish minimum standards for dispensing activities.[178]	Not a legal requirement	Pharmacies must establish SOPs for pharmacy practice, they will be monitored by the inspection teams[179]
4.	Authorized	Pharmacist	Under the personal	Responsible Pharmacist

[176]BIBLIOGRAPHY \l 1033 Management Sciences for Health. *MDS-3 Managing Access to Medicines and Health Technologies.* Arlington, VA: Management Sciences for Health, 2012. Available at HYPERLINK "http://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf", last accessed Sep 3rd, 2015.
The MSH and WHO agrees on a general definition of dispensing as "all the activities being carried out from receiving an order for drugs to the issuance of drugs with sufficient counseling. It essentially includes six activities: receiving and validating the request for medicines, understanding and interpreting the request, preparation of the medication order according to patients' needs, labeling of items for individual patients, recording the action and finally issuing the medicines to patients or intermediary with clear instructions and advice".

[177]HYPERLINK"http://psnc.org.uk/wpcontent/uploads/2013/07/service20spec20es1202_.pdf" ___ (last accessed on August 16, 2015).

[178]FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011

[179] HYPERLINK"http://psnc.org.uk/wpcontent/uploads/2013/07/service20spec20es12oct2004_.pdf" (last accessed on August 16, 2015).

	person to dispense medication		supervision of the qualified person	should personally supervise dispensing and carryout patient counseling[180]
Sr. No	**Dispensing protocols**	**GPP**	**Pakistan**	**UK**
5.	Dispensing without prescription	There is need to devise standards for both prescription and non prescription items[181]	No standards or stepwise protocols	Standard protocols are available and authorized personnel are trained to use them[182]
6	Steps in dispensing	Detailed steps given and mentioned in table below	Not available	Detailed list of steps is provided to carryout dispensing at pharmacies[183]

The legislative documents in Pakistan lack the definition of the core pharmacy activity i.e. dispensing. The term *sale of medicines* is also not elaborated in the Drug Act, 1976 and the allied rules. This lack of details has led to unavailability of the steps, SOPs and

[180]The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 available at HYPERLINK "http://www.legislation.gov.uk/uksi/2008/2789/pdfs/uksi_20082789_en.pdf" (last accessed 02 October 2015)
The responsible pharmacist cannot be absent from the premises for more than two hours during the working hours in a day. S/he has to make arrangements according to rules in case of absence.
[181]FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011
[182]HYPERLINK"http://psnc.org.uk/wpcontent/uploads/2013/07/service20spec20es1oct2004_.pdf (last accessed on August 16, 2015).
[183]HYPERLINK "http://psnc.org.uk/funding-and-statistics/funding-distribution/essential-service-payments/practice-payment-and-dispensing-staff-levels/"(last accessed on 02 October 2015)
Dispensing process include: the taking in and issuing of prescriptions; dispensing prescriptions; clinical assessment of prescriptions and accuracy check of dispensed items; stock ordering and putting stock away; preparation and assembly of medicinal products; resolving queries related to prescriptions; counseling patients on their prescriptions, and carrying out the administration necessary for the payment of prescriptions (e.g. endorsing and filing prescriptions)

protocols for dispensing activity in the country. The practical situation is depicted in (Table 8).

Table 8: Dispensing process, comparison of Pakistani and UK's legislation with GPP guidelines

Sr. No	Essential elements of dispensing as per GPP	Standards needed for[184]	Pakistan	UK
1	Reception of the prescription and confirmation of the integrity of communication	Facilities	Not available	Detailed SOPs are required at every pharmacy[185]
		Procedures		
		Personnel		
2	Assessment of the prescription by the pharmacist for its therapeutic aspects, appropriateness for the individual, its social, legal and economic aspects.	Information sources	Not available	The pharmacy perform appropriate legal, clinical & accuracy check in line with clinical governance requirements, competence of pharmacy staff is assessed as part of inspection[186]
		competence of pharmacist		
		Medication records		

[184] WHO. Good Pharmacy Practice (GPP) in community and hospital setting. Available at HYPERLINK "http://apps.who.int/medicinedocs/en/d/Js21088en/" (last accessed on November 22, 2015)

[185] WHO. Good Pharmacy Practice (GPP) in community and hospital setting. Available at HYPERLINK "http://apps.who.int/medicinedocs/en/d/Js21088en/"(last accessed on November 22, 2015)

[186] HYPERLINK "http://psnc.org.uk/wpcontent/uploads/2013/07/service20spec20es12020 dispensing20_v1201020oct2004_.pdf" (last accessed on August 16, 2015).

3	Assembly of prescribed items	Sources of supply of medicines, Personnel involved, Equipment required, Facilities & workplace required, Quality assurance of extemporaneous preparations, waste disposal	Not available	Detailed SOPs and self inspection and quality assurance mechanisms need to be there with every pharmacy.[187]
		Disposal of unused pharmaceutical products	Legal requirement	Protocols available[188]
Sr. No	**Essential elements of dispensing as per GPP**	**Standards needed for[189]**	**Pakistan**	**UK**
4	Advice to ensure that the patient or carer receives and understands sufficient information to derive maximum benefits from the treatment	Facilities for confidential conversation	Not available	Essential requirement[190]
		Information sources	Not available	Not available
		Procedures to be followed and appropriate documentation of such procedures	Not available	Protocols available[191]
5	Following up the effect of prescribed items		No protocols available	Pharmacy specific protocols must exist. Presence of such protocols will be checked during inspections

[187]WHO. Good Pharmacy Practice (GPP) in community and hospital setting. Available at HYPERLINK "http://apps.who.int/medicinedocs/en/d/Js21088en/" (last accessed on November 22, 2015)

[188] WHO. Good Pharmacy Practice (GPP) in community and hospital setting. Available at HYPERLINK "http://apps.who.int/medicinedocs/en/d/Js21088en/"(last accessed on November 22, 2015)

[189] World Health Organization. Good Pharmacy Practice (GPP) in community and hospital setting. Geneva, 1996.

[190]NHS. Design for patient safety: A guide to the design of the dispensing environment. 2007, Edition 1. HYPERLINK "http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=59830" (last accessed on 13 September 2015)

[191]NHS. Design for patient safety: A guide to the design of the dispensing environment. 2007, Edition 1. HYPERLINK "http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=59830" (last accessed on 13 September 2015)

6	Self care (treating symptoms) Standards are needed for: Qualification of personnel to be involved, How proper assessment of need is to be made: assessing symptoms, duration of symptoms, other medical problems and medication history, Efficacy and safety of products recommended, Referral criteria and how to follow up	No protocols available	Pharmacy medicines[192] should be dispensed under the supervision of pharmacist.
			Practice SOPs should be available. They will be monitored as part of inspection visits.[193]

The legislation in Pakistan is completely silent regarding the provisions of dispensing process. No national or provincial protocols are available. None of the pharmacies in country has reported to have established such protocols for personal use even. This is an alarming and an eye opening finding that the legislation is ignoring the core pharmacy activity of dispensing medicines. If dispensing is not carried out properly, the drugs will not be used in appropriate way leading to a question mark on rational use of medicine. There is a lack of guidelines to dispense or refer in the cases where people present with symptoms to a pharmacy and expect treatment.

[192]HYPERLINK "http://www.nhs.uk/conditions/Medicinesinfo/pages/introduction.aspx", (last accessed on 13 September 2015)
There are three types of medicines in UK: prescription medicines, pharmacy medicines and general sales list medicines. Prescription medicines need a prescription by GP or any other authorized professional. Pharmacy medicines are available at pharmacies without prescription but under direct supervision of pharmacist. Pharmacist will assess medication suitability for a particular person and his/her disease state before dispensing it. the general sales list medicines can be bought from pharmacies, supermarkets or other stores without supervision of pharmacist.

[193]General Pharmaceutical Council. "Inspectors' checklist: monitoring and inspection visits." (2012) Available at HYPERLINK "http://www.pharmacyregulation.org/sites/default/files/Inspector%20checklist%20website%20version%20Sep12.pdf" (last accessed on November 02, 2015)

3.3.4.Protocols for processes other than Dispensing

The procurement process: GPP require that the procurement process should be transparent, professional. It must be supported by strong quality assurance principles to assure that counterfeit medicines are not allowed into the system. Furthermore, the procurement needs to be supported by a reliable information system which provides accurate, timely and accessible information.[194]

The Punjab Drug Rules, 2007 fully meet these procurement protocols by providing the explicit standards for procurement of drugs. It is mandatory for medical stores and pharmacies in Pakistan to take a written warranty from the distributor or whole sale representative, or any other person selling drugs to these outlets.[195] The invoice and warranty should contain the full name and address of the purchaser and be signed by the warrantor clearly indicating his name and should be dated.[196] Such warranty should be obtained when ever drugs are purchased by the drug sellers.

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[194]FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011

[195]Rule 20 (4), the Punjab Drugs Rules, 2007. "A manufacturer, importer or the seller of a drug shall sell the drug only to a holder of a valid drug sale license or to a registered medical practitioner and shall issue an invoice and warranty at the time of sale of the drug."

[196]Rule 20 (7), the Punjab Drugs Rules, 2007. "The invoice and warranty shall bear the full name and address of the purchaser and shall be signed by the warrantor clearly indicating his name and shall be dated."

Legislation demands the preservation of the records, the bills or the counterfoils for a period of at least three years from the date of the sale.[197]

FIP also demands in GPP that pharmacists should establish contingency plans for shortages of medicines and for purchases in emergencies.[198] There is no such clause in Pakistan.

Disposing off the medicines: According to the protocols set in GPP, pharmacists are required to establish a safe way of medicines waste disposal at pharmacies. This is aimed to encourage patients and public to return their expired or unwanted medicines. Otherwise, appropriate information should be provided to patients on safely disposing expired and unwanted medicines.

Such service is considered mandatory in UK and is listed in the essential services provided by the pharmacies.[199] However, Pakistani pharmacies or medical stores have no such obligation by law. Further, no pharmacy is carrying out such services even voluntarily in the country.

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[197]Rule 20 (8), the Punjab Drugs Rules, 2007. "The manufacturer, importer or seller of a drug shall maintain
record of purchase or sale of a drug and shall preserve the record for a at least three years containing the following particulars:
(a) the date of purchase or sale;
(b) the name and address of the concern from which the drug
is purchased or the concern to whom the drug is sold;
(c) the name of the drug, its batch number, the date of its
expiry and the quantity of the drug;
(d) the name of the manufacturer"

[198]BIBLIOGRAPHY \l 1033 FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011.

[199]HYPERLINK"http://psnc.org.uk/wpcontent/uploads/2013/07/service20spec20eoct2004_.pdf" (last accessed on August 16, 2015).

Removal of outdated stocks: Pharmacists are obliged to carryout regular inspections in their pharmacies under the provisions of GPP, to separate the out dated and expired items. There is need for proper procedures to dispose of such items. [200] There are no such explicit provisions in Pakistan.

Product recalls: Pharmacists should establish an effective distribution system which includes a written procedure, to recall promptly and effectively medical products known or suspected to be defective or spurious/falsely-labeled/falsified/counterfeit, with a designated person(s) responsible for recalls.[201] No such services are available in Pakistan.

Medication therapy management: Pharmacists should ensure that health management, disease prevention and healthy lifestyle behavior are incorporated into the patient assessment and care process according to the GPP protocols.[202] There is no such legal obligation in Pakistan. However, UK laws require availability of such specialized services. NHS has recently introduced the New Medicine Service (NMS)[203] that is free of charge to help people who have problem with the use of medicines and to get best out of it. This service is offered to people who are newly diagnosed with asthma, chronic obstructive pulmonary disease, diabetes, hypertension, or who have been prescribed medicine to thin blood.

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[200]BIBLIOGRAPHY \l 1033 FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011.

[201]BIBLIOGRAPHY \l 1033 FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011.

[202]HYPERLINK"http://psnc.org.uk/wpcontent/uploads/2013/07/service20spec20es12oct2004_.pdf" (last accessed on August 16, 2015).

[203]HYPERLINK "http://psnc.org.uk/services-commissioning/advanced-services/nms/" (last accessed on November 20, 2015)

Preventive care activities and services: The GPP protocols state that there is need of national standards on provision of health promotion and preventive care services, including point-of-care testing for high risk people in pharmacies. Pharmacists should engage in preventive care activities in areas such as smoking cessation, infectious and sexually transmitted diseases.[204]

In UK many pharmacies are providing smoking cessation services by law. Health promotion services are mandatory in UK under the standards for registered pharmacy. However, there is no such legislation or standards in Pakistan. In UK, some pharmacies are providing the blood pressure, cholesterol and blood glucose testing services. Chlamydia and allergy screening is also being done at some pharmacies in UK.[205]

3.4.Step-wise implementation of GPP in Pakistan

It is recognized at international level that all countries cannot achieve GPP at once. Hence, a stepwise implementation guide is developed for developing countries. Table 9 presents Pakistan's journey towards the step-wise implementation of GPP.

Table 9. Step-wise implementation of GPP in Pakistan

Sr. No	Steps-wise implementation guide[206]	Position of Pakistan
1	**Personnel**	

[204]BIBLIOGRAPHY \l 1033 FIP/WHO. *Joint FIP/WHO Guidelines on Good Pharmacy Practice: Standards for Quality of Pharmacy Services. WHO Technical Report Series, No. 961, 2011, Annex 8.* The Hague, The Netherlands: FIP, 2011.

[205]HYPERLINK "http://psnc.org.uk/services-commissioning/advanced-services/ (last accessed on October 30, 2015)

[206]FIP. *Good Pharmacy Practice (GPP) in developing countries: Recommendations for step-wise implementation.* The Hague, Netherlands: FIP, 1998

Sr. No	Steps-wise implementation guide[206]	Position of Pakistan
	Ultimate aim is to establish direct access to a pharmacist at all pharmacies, if not possible then other trained pharmacy staff must be available	Very limited access to pharmacists is available. Need to focus on support staff training
2	**Training of pharmacy personnel**	
	1: Train local community health care workers with appropriate pharmaceutical input 2: Train workers to a higher level with appropriate pharmaceutical input 3: Train pharmacy technicians 4: Educate pharmacists to graduate level or provide access to education elsewhere 5: Provide access to continuing education and continuing professional development for pharmacists and pharmacy technicians	Steps 3 and 4 are in place but with limited scope. Need to further work on it as well as on step 5
3	**Standards for premises**	
	The ultimate aim is to have a clearly defined, self-contained area or facility i.e. community pharmacy or pharmacy department in hospital	Pakistan is already at highest step
4	**Standards for dispensing**	
A	**Patient information**	
	Step 1 Instructions are verbal Step 2 Instructions are verbal + hand-written and affixed to the container Step 3 Instructions are verbal + printed/typed and affixed to the container Step 4 In addition to step 3, verbal counseling is given to the patient Step 5 In addition to step 4, supplementary written information is given Step 6 GPP is observed	No legal steps taken so far

Sr. No	Steps-wise implementation guide[206]	Position of Pakistan
B	**Containers**	
	Tablets/capsules should be dispensed in:[207] Step 1 An air-tight plastic wallet (this is considered to be the minimum requirement) Step 2 An airtight, rigid container Step 3 An airtight, rigid container with a child resistant closure Step 4 The manufacturer's original pack Liquid preparations should be dispensed in "pharmaceutical" bottles so as to distinguish them from non-pharmaceutical preparations	Pakistan has already taken all steps However, there are violations in some cases
C	**Dispensing labels**	No steps taken so far
D	**Patient records**	
	Step 1 A record of all medicines supplied should be kept detailing name of patient, name & strength of medicine, dosage, quantity supplied, date of dispensing Step 2 Individual patient medicine records should be maintained in a system, manual or computerized, which allows for easy retrieval of patient information	Provision for step 1 is available in the Punjab Drug Rules, 2007. But not implemented. No step taken so far for the step 2
E	**Health information, patient counseling & pharmaceutical care**	
	Step 1 Provide health promotion literature and support materials on general health Step 2 Provide or identify an area suitable for the delivery of basic information, counseling and pharmaceutical care Step 3 Provide a separate, confidential room or facility for the above activities	No steps taken so far
F	**Self care protocols**	
	Where pharmacies are involved in self medication and response to symptoms, protocols should be devised to ensure that the advice is accurate and appropriate	No steps taken so far

[207]FIP. *Good Pharmacy Practice (GPP) in developing countries: Recommendations for step-wise implementation.* The Hague, Netherlands: FIP, 1998

CHAPTER IV

Critical Analysis of Cases Prosecuted for violation of Pharmacy Practice Standards

4.1Rationale

Any negligence in pharmacy practice or malpractice can have life threatening consequences. A clear example of this is the Fake Drug Crisis in Pakistan in 2012, where over 100 individuals died due to using adulterated and substandard antihypertensive drugs in Lahore, Pakistan.[208] This crisis is just an example from a pool of many. The major contributors to such crises are poor law enforcement, lenient penalties and delayed justice. The purpose of this chapter is to critically assess the practice of penalties for violation of the Drugs Act, 1976 in Pakistan. To meet this purpose, we reviewed the judgment/charge sheets of 17 randomly selected cases from the Drug Court, Rawalpindi. Before presenting the analysis, a brief summary of the offences and penalties under the Drugs Act, 1976 is provided to contextualize the analysis.

4.2.Penalty

A penalty is defined as a punishment for violating a law or agreement.[209] Such punishment can be in the form of removal/denial of something desirable, fine, forfeiture

[208]HYPERLINK "http://www.thenews.com.pk/article-32278-69-die-from-substandard-medicine-" About 100 people have died from spurious antihypertensives in Lahore . Thenews.com.pk. 2012-01-24. Retrieved on November 25, 2015.

[209]HYPERLINK "http://www.investorwords.com/3648/penalty.html" (last visited28 sep 2015

or imprisonment or any combination of these.[210] Penalties serve a fourfold purpose of retribution, deterrence, rehabilitation, and incapacitation.[211] Retribution simply refers to a punishment inflicted upon someone as a result of his wrong or criminal act.[212] This punishment is not a personal revenge but refers to the retributive justice. The concept of deterrence implies that punishments imposed on offenders will "deter" or prevent them from committing further crimes. Moreover, the fear of punishment will prevent others from committing similar crimes.[213]

4.3.Penalties under the Drugs Act, 1976

Chapter IV of the Drugs Act, 1976 gives details of the offences, penalties and procedures to deal with. The offences under the said Act can be categorized into four groups, which are described under the sub-sections 1 to 4 of the Section 27. These categories of possible violations are used to determine appropriate penalties.

The Section 27 of the Drugs Act, 1976 provides the details of penalties for offenses under this Act. Its subsection (1) states the most serious type of offenses which are export, import, manufacture or sale of spurious or adulterated drugs; import and sale of imported drugs which are not registered. Another new addition in these offences is the manufacture, transport and sale of temperature sensitive drugs in conditions which can harm the drug's potency.[214] The second types of offenses are categorized in the Section

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[210]HYPERLINK http://thelawdictionary.org/penalty/last(last visited 28 sep 2015)
[211]HYPERLINK "https://en.wikipedia.org/wiki/Punishment" (last visited 28 sep 2015)
[212]HYPERLINK "http://www.merriam-webster.com/dictionary/retribution"(last visited 28 sep 2015)
[213]HYPERLINK "http://voices.yahoo.com/evolution-deterrence-crime-theory-37965.html?cat=37" (last visited 29 sep 2015)
[214]Section 7(a) of the Punjab Drugs (Amendment) Ordinance 2015:

27(2) of the Drugs Act, 1976. These include import, manufacture and sale of imitation products; import, manufacture or sell drugs under a name other than the registered name, and providing false warranties.[215] The offenses under sub-sections (1) and (2) of the Drugs Act, 1976 are cognizable and non-bailable.[216] The third category of offence includes obstructing Inspector in exercise of his powers or disobeying the lawful authority of Inspector.[217]

While all other violation of the Drugs Act, 1976 and the rules made there under are grouped into fourth category.[218] However, the legislation in Pakistan does not formally

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For subsection (1) of the section 27 of the Drugs Act, following should be substituted:
"(1) If a person himself or through any other person acting on his behalf:
(a) exports, imports, manufactures or sells any spurious or adulterated drug,
(b) manufactures for sale any drug without license;
(c) manufactures, transports or sells a temperature sensitive drug in conditions which are likely to cause the drug to lose its potency; or
(d) imports or sells an imported drug not registered under this Act or by a Foreign Drug Authority;"

[215]Section 7 (b) of the Punjab Drugs (Amendment) Ordinance, 2015
For subsection (2), the following shall be substituted"
"(2) If a person himself or by any other person on his behalf:
(a) imports, manufactures or sells any imitation product; or
(b) gives to the purchaser a false warranty in respect of any drug sold by him that the drug does not in any way contravene the provisions of section 23 and is not able to prove that, when he gave the warranty, he had good and sufficient reason to believe the same to be true; or
(c) applies or permits to be applied to any drug sold, or stocked or exhibited for sale, by him, whether on the container, a warranty given in respect of any other drug, or
(d) imports, manufactures for sale or sells any drug under a name other than the registered name;"

[216]Section 8 (b), the Punjab Drugs (Amendment) Ordinance, 2015
"an offence punishable under subsection (1) and subsection (2) of Section 27 shall be cognizable and non-bail able."

[217]Section 27 (3) of the Drugs Act, 1976
"Whoever obstructs an Inspector in the exercise of any power conferred upon him by or under this Act, or disobeys the lawful authority of any Inspector, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees, or with both."

[218]Section 7 (c) of the Punjab Drugs (Amendment) Ordinance, 2015
"for subsection (4) following shall be substituted:
"(4) Subject to the provisions of sub-section (1), sub-section (2) and sub-section (3), if a person himself or through another person acting on his behalf contravenes any of the provisions of this Act or any rule shall be punished with imprisonment for a term which may extend to five years, but which shall not be less than six months and with fine which may extend to fife hundred thousand rupees."

categorize and label offences into different categories depending on the severity unlike the pharmacy regulations in California.[219]

Until recently, the penalties for these offenses have been quite lenient. The Punjab Drugs (Amendment) Ordinance, 2015 introduced stricter penalties in August, 2015. The penalties before the Amendment Ordinance are detailed in Table 10 while after amendment penalties are listed in Table 11.

The main purpose of this chapter is to assess the judgments made by the Drug Courts, if they are complying with the recommended penalties and if the penalties are applied in lenient manner. A lenient manner can contribute negatively towards the deterrence objective of penalties. A detail of recommended penalties both before and after the Punjab Drugs (Amendment) Ordinance is provided here because some judgments (under analysis) were made before August 2015 and hence would need to comply with earlier penalties.

Table 10: Penalties for offenses under the Drugs Act, 1976*

Sr. No.	Offense	Penalty			Reference
		Imprisonment	And/or	Fine	
If a person who himself or through any other person acting on his behalf manufacture, import, export, or sells					
1	Spurious drugs	3 – 10 years	And	Up to 100,000 rupees	Section 27 (1)
2	Unregistered drugs	3 – 10 years	And	Up to 100,000 rupees	Section 27 (1)
3	A drug with which any substance has been mixed so as to reduce its quality	Up to 7 years	And/or	Up to 100,000 rupees	Section 27 (2)

[219]California State Board of Pharmacy (2007). A Manual of Disciplinary Guidelines and Model Disciplinary Orders. Available at HYPERLINK "http://www.pharmacy.ca.gov/laws_regs/1760_guidelines.pdf" (last accessed on November 23, 2015)

If a person who himself or through any other person acting on his behalf manufacture, import or sells					
4	Counterfeit drugs	Up to 7 years	And/or	Up to 100,000 rupees	Section 27 (2)
5	Any drug under a name other than the registered name	Up to 7 years	And/or	Up to 100,000 rupees	Section 27 (2)
If a person himself or through any other person acting on his behalf					
6	Gives to the purchaser a false warranty in respect of any drug sold	Up to 7 years	And/or	Up to 100,000 rupees	Section 27 (2)
7	Applies warranty of one drug to other drugs	Up to 7 years	And/or	Up to 100,000 rupees	Section 27 (2)
8	Manufacture for sale a drug without license	3 – 10 years	And	Up to 100,000 rupees	Section 27 (1)
9	Imports an imported drug without License	3 – 10 years	And	Up to 100,000 rupees	Section 27 (1)
10	Obstructs an Inspector or disobeys the lawful authority of any Inspector	Up to one year	And/or	Up to 10,000 rupees	Section 27 (3)
11	Contravenes any of the provisions of the Act or any rule	Up to 5 years	And/or	Up to 50,000 rupees	Section 27 (4)

* Before the Punjab Drugs (Amendment) Ordinance 2015

It is allowed for the court to award a sentence of imprisonment less than the recommended minimum limit of 3 years under special reasons under Section 27 (1).[220]

[220]Last para of Section 27 (1), the Drugs Act, 1976
"Provided that the Drug Court may, for any special reasons to be recorded, award a sentence of imprisonment for a term of less than three years."

Table 11: Penalties for offenses under the Drugs Act, 1976*

Sr. No.	Offense	Penalty			Reference
		Imprisonment	And/or	Fine	
If a person who himself or through any other person acting on his behalf manufacture, import, export, or sells					
1	Spurious drugs	5 – 10 years	And	1 million – 5 million rupees	Section 27 (1)
2	Adulterated drugs	3- 10 years	And	1 million – 5 million rupees	Section 27 (1)
If a person who himself or through any other person acting on his behalf manufacture, import or sells					
3	Imitation product	1-7 years	and	Up to 1million rupees	Section 27 (2)
4	Any drug under a name other than the registered name	1-7 years	and	Up to 1million rupees	Section 27 (2)
If a person himself or through any other person acting on his behalf					
5	Gives to the purchaser a false warranty in respect of any drug sold	1-7 years	and	Up to 1million rupees	Section 27 (2)
6	Applies warranty of one drug to other drugs	1-7 years	and	Up to 1million rupees	Section 27 (2)
7	Manufacture for sale a drug without license	3- 10 years	And	1 million – 5 million rupees	Section 27 (1)
8	Imports or sells an imported drug not registered under the Drugs Act, 1976 or by a Foreign Drug Authority	3-10 years	And	1 million – 5 million rupees	Section 27 (1)
9	Manufacture, transport, or sell temperature sensitive drugs in conditions which are likely to cause harm to drug's potency	3-10 years	And	1 million – 5 million rupees	Section 27 (1)
10	Obstructs an Inspector or disobeys the lawful authority of any Inspector	Up to one year	And/or	Up to 10,000 rupees	Section 27 (3)
11	Contravenes any of the provisions of the Act or any rule	6 months to 5 years	and	Up to 500,000 rupees	Section 27 (4)

* After the Punjab Drugs (Amendment) Ordinance 2015

The federal and provincial government can also forfeit the stocks and other materials as per the directions of drug court.[221] The licensing authorities under the Drugs Act, 1976, also have the powers to cancel or suspend the license to import, export, manufacture or sell drugs if the practice of licensees is considered to be a danger to public health.[222]

Penalty for subsequent offence

Generally the penalties for subsequent offenses are stricter as compared to first time conviction. It is interesting to note that the Punjab Drugs (Amendment) Ordinance, 2015 has specified amendments in the Section 27 of the Drugs Act, 1976 while ignored the strictness of penalties for subsequent offenses prescribed in Section 28.

Table 12: Penalties for subsequent offenses under the Drugs Act, 1976

Sr. No.	Offense	Penalty			Reference
		Imprisonment	And/or	Fine	
A person having been convicted of an offence under					
1	sub-section (1) of section 27 is convicted for a [subsequent offence] under that sub-section	5 years – imprisonment for life	and	Up to 200,000 rupees	Section 28 (1)

[221]Section 29(1), the Drugs Act, 1976
"Where any person has been convicted under this Act, for contravening any such provisions of this Act or any rule as may be prescribed in this behalf, the Drug Court may order that the stock of drug or substance by means of or in relation to which the offence was committed or anything of a similar nature belonging to or in the possession of the accused or found with such drug or substance, and if such contravention is punishable under sub-section (1) of section 27, any implements used in manufacture or sale of such drug and any receptacles, packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances, used in carrying such drug, be forfeited to the Federal Government or, as the case may be, the Provincial Government and, upon such order being made, such .drug, substance, implements, receptacles, packages or coverings, animals, vehicles, vessels or conveyance may be disposed of as that Government may direct."

[222]Section 41, the Drugs Act, 1976
"Where any person has been found to have contravened any of the provisions of this Act, or the rules in respect of any drug and the contravention is of such a nature that the import, export, manufacture or sale of any drug by such person is, in the opinion of the licensing authority or the Central Licensing Board, likely to endanger public health, that authority may, after giving such person an opportunity of being heard, cancel the license to import, export, manufacture or sell drugs issued to such person or suspend such license for a specified period."

2	sub-section (2) of section 27 is [convicted for a subsequent offence] under that sub-section	2 years- 10 years	And/or	Up to 200,000 rupees	Section 28 (2)
3	sub-section (4) of section 27 is convicted for a [subsequent offence] under that sub-section	Up to 7 years	And/or	Up to 100,000 rupees	Section 28 (3)

4.4.Critical Analysis of the Court Judgments

A total of 13 judgments/charge sheets were analyzed for the purpose of this thesis. All of the cases were dealt in the Drug Court, Rawalpindi. Out of these 13 cases, offenses were proved and penalties were awarded in 10 cases. However, the accused were acquitted due to legal flaws in the complaints for remaining three cases. For the purpose of this analysis, the cases were divided into two groups. In the first group all those 10 cases were included where the offense had been proved and penalties imposed while the second group included remaining three cases. Analysis of each group is presented here separately.

Analysis of Sanctions

A total of 10 cases fall in this category. All judgments were made before the Punjab Drugs (Amendment) Ordinance, 2015, except one. Hence, 9 assessments were made against the penalties recommended before the amendment.

All the 10 cases were penalized under Section 27 (4) while three cases were penalized under Section 27 (1) of the Drugs Act, 1976 as well. The major offenses were sale of drugs without warranty, expired drugs, sale without drug sale license, sale without the supervision of qualified person, misbranded drugs, failure to maintain the cold chain,

absence of drug sale purchase records, unregistered drugs, and illegal advertisement of offer of treatment for different disease.

Table 13: Lahore High Court Judgments

Sr.No	Accused	Offences U/S and in words		Punishable U/S	penalty	Date
1[223]	Owner of Drug manufacturing factory	24 different drugs substandard	23(1)(i	27	Imprisonment five years Fine 1 million rupees Refusal of bail	14,jan 2012
		Manufacturing and packing substandard drugs	23			
2[224]	Sajid clinic and Bismillah Zacha Bacha Center	4 spurious and six misbranded and unregistered drugs 23(1)(a)(vii)		27(1)	Fine 2 lac rupees Grant of bail on furnishing of security	3,Nov 2011
3[225]	Owner of medical store	Unregistered Drugs, medicine kept at high temperature, expired medicines, misbranded medicine, medicine without warrenty,non availability of sale purchase record of drugs and absence of qualified person, 23(1)(a)(iii)(vi)(vii)(x),23(1)(k)		27(4)(1)	Fine 10,000 rupees each Further fine of five thousand each in case of default and six months simple imprisonment in case of default	20,june 2012

[223] 2012YLR1143Javed Robert and others vs the State
[224] 2013MLD142Miran bakhshand six others vs Ali Muhammad
[225] 2012 PCR.LJ1473 Shahid Siddique and others vs the State

Comments

All of the above mentioned cases were firstly prosecuted in Drug Court of Rawalpindi and when the Drug Court penalized the accuses then the aggrieved party approach to the Lahore High Court in appeal. In appeals the Lahore High Court once again establish their penalty .The attitude of Lahore High Court is sticker than Drug Courts of Lower level.one another thing is important that always accuse go into appeal the practice is that public prosecutor or Drug Inspector never go to in appeal at high court.

Table 14: Drug Court Rawalpindi Judgments

Sr. No.	Accused	Offenses U/S and in words		Punishable U/S	Penalty	Date
1[226]	Proprietor of Medical Store	15 different drugs without warranty	23 (1) (i)	27 (4)	• Imprisonment till the rising of court • Fine: Rs. 35000 or in default he shall further undergo two months S.I. • The case property be confiscated in favor of the state and be dealt according to rules.	Sep, 2015
		No valid Drug Sale License	23 (1) (c)			
2[227]	Proprietor of Diagnostic Centre	Illegal advertisement of offer of treatment of different diseases	24	27 (4)	• Imprisonment till the rising of court • Fine: Rs. 40000 or in default he shall further undergo four months S.I. • The case property be confiscated in favor of the state and be dealt according to rules.	July, 2015

[226] Case No. Judl/3319/DC/Rwp/15
[227] Case No. Judl/3142/DC/Rwp/14

Sr. No.	Accused	Offenses U/S and in words		Punishable U/S	Penalty	Date
3[228]	Proprietor of Medical Store	11 different drugs: Unwarranted	23 (1) (i)	27 (4)	• Imprisonment till the rising of court • Fine: Rs. 40000 or in default he shall further undergo two months S.I. • The case property be confiscated in favor of the state and be dealt according to rules.	March, 2015
		11 different drugs: Expired	23 (1) (a) (vi)			
		Sale of drugs without qualified person	23 (1) (a) (x)			
		Record of controlled drugs not maintained	23 (1) (c)			
		AC was not installed	23 (1) (c)			
	Qualified Person of Medical Store	Failure to supervise sale of drugs	23 (1) (a) (x)	27 (4)	• Imprisonment till the rising of court • Fine: Rs. 20000 or in default he shall further undergo two months S.I.	
Sr. No.	**Accused**	**Offenses U/S and in words**		**Punishable U/S**	**Penalty**	**Date**
4[229]	Proprietor of Medical Store	6 different unregistered drugs	23 (1) (a) (vii)	27 (1)	• R.I for 25 days • Fine: Rs. 40,000 or in default he shall further undergo four months S.I.	Oct, 2014
		Expired drugs	23 (1) (a) (vi)	27(4)	• Imprisonment till the rising of court • Fine: Rs. 20000 or in default he	
		Without warranty	23 (1) (i)			

[228] Case No. Judl/3266/DC/Rwp/15
[229] Case No. Judl/3075/DC/Rwp/14

		No Valid Drug Sale License	23 (1) (c)		shall further undergo two months S.I. • The case property be confiscated in favor of the state and be dealt according to rules. • Both sentences of imprisonment will run concurrently	
5 [230]	Proprietor of Medical Store	Expired drugs	23 (1) (a) (vi)	27(4)	• Imprisonment till the rising of court • Fine: Rs. 35000 or in default he shall further undergo two months S.I. • The case property be confiscated in favor of the state and be dealt according to rules.	April, 2015
		Without warranty drugs	23 (1) (i)			
		Drug sale without qualified person	23 (1) (a) (x)			
		Sale purchase record was not maintained	23 (1) (c)			
	Qualified Person of Medical Store	Failure to supervise sale of drugs	23 (1) (a) (x)	27(4)	• Imprisonment till the rising of court • Fine: Rs. 20000 or in default he shall further undergo two months S.I.	
Sr. No.	**Accused**	**Offenses U/S and in words**		**Punishable U/S**	**Penalty**	**Date**
6 [231]	Proprietor Of Clinic	Without warranty drugs	23 (1) (i)	27(4)	• Imprisonment till the rising of court • Fine: Rs. 20000 or in default he shall further undergo two months S.I. • The case property be confiscated in favor of the state and be dealt according to rules.	May, 2014
		Drug sale without License	23 (1) (c)			
7 [232]	Proprietor of	Without warranty drugs	23 (1) (i)	27 (4)	• Imprisonment till the rising of	March,

[230] Case No. Judl/3274/DC/Rwp/15
[231] Judicial No. 3037 DC/RWP/2014
[232] Case No. Judl/3259/DC/Rwp/14

	Pharmacy	Drug sale without License	23 (1) (c)		court • Fine: Rs. 35000 or in default he shall further undergo two months S.I. • The case property be confiscated in favor of the state and be dealt according to rules.	2015
	Person Present	Without warranty drugs	23 (1) (i)	27 (4)	• Imprisonment till the rising of court • Fine: Rs. 15000 or in default he shall further undergo two months S.I.	
Sr. No.	**Accused**	**Offenses U/S and in words**		**Punishable U/S**	**Penalty**	**Date**
8 [233]	Proprietor of Medical Store	8 unregistered drugs	23 (1) (a) (vii)	27 (1)	• Imprisonment till the rising of court • Fine: Rs. 40,000 or in default he shall further undergo four months S.I.	July, 2015
		Without warranty drugs	23 (1) (i)	27 (4)	• Imprisonment till the rising of court • Fine: Rs. 20,000 or in default he shall further undergo two months S.I. • The case property be kept intact and till the arrest of co-accused and produced in court.	
		Expired drugs	23 (1) (a) (vi)			
		Cold chain was not maintained	23 (1) (a) (x)			
	Person Present	8 unregistered drugs	23 (1) (a) (vii)	27 (1)	• Imprisonment till the rising of court • Fine: Rs. 25,000 or in default he shall further undergo four months S.I.	
		Without warranty drugs	23 (1) (i)	27 (4)	• Imprisonment till the rising of court • Fine: Rs. 10,000 or in default he	
		Expired drugs	23 (1) (a) (vi)			

[233] Case No. Judl/3154/DC/Rwp/14

		Cold chain was not maintained	23 (1) (a) (x)		shall further undergo two months S.I.	
Sr. No.	**Accused**	**Offenses U/S and in words**		**Punishable U/S**	**Penalty**	**Date**
9 [234]	Proprietor of Medical Store	Misbranded drugs	23 (1) (a) (iii)	27 (4)	• Imprisonment till the rising of court • Fine: Rs. 35,000 or in default he shall further undergo two months S.I. • The case property be kept intact and till the arrest of co-accused and produced in court.	Sep, 2015
		Expired drugs	23 (1) (a) (vi)			
		Sale of drugs without qualified person	23 (1) (c)			
10 [235]	Proprietor of Medical Store	Unregistered drugs	23 (1) (a) (vii)	27 (1)	• Imprisonment till the rising of court • Fine: Rs. 30,000 or in default he shall further undergo three months S.I. • The case property be kept intact and till the arrest of co-accused and produced in court.	Oct, 2013
		Sale of drugs without Drug Sale License	23 (1) (c)	27 (4)		
		Un warranted drugs	23(1) (i)			

All of the above mentioned cases were prosecuted by the Provincial Inspectors of Drugs after the approval of provincial quality control board. A total of 14 individuals were prosecuted in these 10 cases, decisions were taken against 12 while for remaining two the decisions were pending. Seven cases were from the medical store, one from pharmacy, one from a clinic and one from a diagnostic center. Proprietors of all 10 outlets were under prosecution while two qualified persons and two present persons at the time of raid were also prosecuted.

[234] Case No. Judl/3229/DC/Rwp/15
[235] Judicial No. 2892/DC-RWP/13

For all cases, the Drug Court had taken the lenient view while penalizing. The reasons reported were the voluntary confession by all accused, it's their first offence and the quantity of drugs violating the clauses of the Drugs Act, 1976 were small. All the convicted persons had requested the court to not be sent to jail and their requests were acceded to. All of the accused were discharged of their bail bonds and their surety was released after court hours after their deposit of fine on the same day.

Three cases (case no. 4, 8 & 10) were to be penalized under two sections at a time, Section 27 (1) and (4). However, only two had received penalties under the both said sections while one case (case no. 10) had received just one penalty without specifying the reason of this leniency.

All the three cases to be penalized under the Section 27 (1) were for the sale of unregistered drugs and judgments were made before the Punjab Drugs (Amendment) Ordinance, 2015. The recommended penalty was "imprisonment for a term which shall not be less than three years or more than ten years and with fine which may extend to one lakh rupees: Provided that the Drug Court may, for any special reasons to be recorded, award a sentence of imprisonment for a term of less than three years". However, the Drug Court decided to fine from Rs. 20,000 to a maximum of 40,000 rupees, and imprisonment till the rising of court only. One person was sentences with rigorous imprisonment for 25 days, however upon the request of accused to not send him to jail he was released after the court hours. This shows a quite lenient view of Drug Court, it may be justifiable upon the clauses of voluntary confession but it can harm the deterrence purpose of

penalties. If people know that they can get away with the paying a small amount of fine without going to jail, there is high probability of committing crime again and motivating others to go for crime. The monetary benefits of selling unregistered drugs are far more than the maximum fine imposed by the drug court in these cases.

Nine cases were penalized under Section 27 (4) before the Punjab Drugs (Amendment) Ordinance, 2015 while one after it. The recommended penalty for before introduction of amendments was "imprisonment for a term which may extend to five years, or with fine which may extend to fifty thousand rupees, or with both". However, the court has awarded all accused with an imprisonment penalty only till the rising of court and with fine which ranged from Rs. 10,000 to 40,000. Court had taken lenient view in some cases but had fined to the maximum limit allowed. Considering the nature of offences which are punishable under Section 27 (4), this penalty was quite low. However the penalty was made stricter after the introduction of the Punjab Drugs (Amendment) Ordinance, 2015. Now it is "imprisonment for a term which may extend to five years but which shall not be less than six months and with fine which may extend to five hundred thousand rupees". But the one case (case no. 1) for which judgment was made in September 2015, again the accused was sentenced with imprisonment till the rising of court only. The fine imposed was Rs. 35,000 which was quite lenient penalty. The point to ponder is that why the Drug Courts are not using imprisonment penalties effectively. If the law prescribes a punishment with imprisonment not less than six month then why court decides for a less stricter view.

The fines imposed for committing multiple offenses at a time were not different for lesser or more number of offenses. This could encourage people to violate multiple clauses of law at a time as it would not affect the severity of penalty. This could also result in under deterrence.[236] Fine imposed are very less. The monetary benefits of selling drugs without license, or selling misbranded, expired and unwarranted drugs and not installing AC or not maintaining the cold chain; are far more than the maximum fine imposed by the drug court in these cases. For example it is expensive to install the AC and maintain the room temperature during longer summer periods as compared to the maximum fine imposed by the court.

Another point noted was that the qualified persons were not awarded stricter penalties (case no. 3 & 5). They are the main individuals who have signed the license and promised to abide by the laws and regulations. Implications of stricter penalties on them and holding them accountable can be a useful tool to improve the pharmacy practice in country.

Court has not ordered in any case to recall the drugs already sold. The expired, unwarranted, and substandard drugs which are already sold can harm individuals' health. The Drug Law is silent about it in Pakistan. There was no compensation sanctions imposed.

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[236] 'under deterrence' implies that the expected fine is less than the harm caused.
Polinsky AM and Shavell S. (1983). The optimal use of fine and imprisonment. Journal of Public Economics 24 (1984) 89-99. Available atHYPERLINK"http://www.law.harvard.edu/faculty/shavell/pdf/24_J_Public_Econ_89.pdf" (last accessed on December 12, 2015).

Court has not ordered to destroy the stock of drugs which were kept in the stores without AC and where the cold chain was not maintained (case no. 3 & 8). Uncontrolled temperature can badly affect the quality of medicines. A positive step is taken in the Punjab Drugs (Amendment) Ordinance, 2015 to include this offence in to be sanctioned under the Section 27 (1) with the strictest penalties.

Under the clauses of the Drugs Act, 1976, the Drug Courts don't have the authority to suspend or revoke the drug sale license. Although the authority is given to the licensing authority under the Section 41 of the Drugs Act, 1976[237], it is not commonly exercised. The suspension and revocation of license to practice is the most common and effective penalty in pharmacy practice all over the world. It can well serve the deterrence, retribution and incapacitation objectives of imposing the penalties. Government of Pakistan should consider the case of giving this authority to the drug courts to make best use of its effectiveness.

Analysis of other Judgments

There were four cases where the accused were acquitted of the complaints because of the failure of the concerned authorities, who allowed the Drug Inspectors for prosecution, to conform to their codal formalities. Two cases were of spurious drugs recovered from medical stores (Case no. 1 & 3). One case (Case no. 2) was based on the offense of

[237]Section 41, the Drugs Act, 1976
"Cancellation or suspension of licenses: Where any person has been found to have contravened any of the provisions of this Act, or the rules in respect of any drug and the contravention is of such a nature that the import, export, manufacture or sale of any drug by such person is, in the opinion of the licensing authority or the Central Licensing Board, likely to endanger public health, that authority may, after giving such person an opportunity of being heard, cancel the license to import, export, manufacture or sell drugs issued to such person or suspend such license for a specified period."

unwarranted drugs and absence of a valid drug sale license at a clinic. case no 4 is based on supplying of spurious Drugs

Case summaries

Case I[238]: The Provincial Inspector of Drugs inspected a drug sale outlet recovered drug which he suspected as spurious. He collected the sample of drug and sent to the drug testing laboratory according to the legal procedures. The drug was later declared as spurious by the drug testing laboratory. The Drug Inspector referred the case to the Provincial Quality Control Board (PQCB) to lodge FIR against the accused. The PQCB allowed Drug Inspector for prosecution against the accused. However, the accused claimed that a fake case was launched against him. During the case proceedings in the Drug Court, it was proved that PQCB has not properly scrutinized the case and allowed the Drug Inspector to prosecute the accused in a stereotype manner. The drug inspector had installed a witness, protocols of test were not provided in the report of Government Analyst, specifications of drug were not available with Government Analyst to declare it as spurious, and sample was not sent to manufacturer of drug. Considering the legal flaws, the drug court acquitted the accused of the complaint.

Case II[239]: The complaint was filed by the Drug Inspector who had inspected the premises of the accused, a clinic. The accused could not provide the warranty for 23 different drugs and failed to produce the valid drug sale license. The drug inspector referred the case to the District Quality Control Board (DQCB) for permission to

[238] Case No. Judl/3157/DC/Rwp/14
[239] Case No. Judl/3071/DC/Rwp/14

prosecute the accused which was then granted. It was proved during the court proceedings that the DQCB has not fulfilled its legal formalities while dealing with the case. The proceedings of the DQCB were stereotype and were only done in papers without holding an actual meeting and without any scrutiny of the case. Thus the order of prosecution cannot sustain. The drug inspector did not collect evidence to connect the accused with the place of recovery. The show cause notice was sent to an address, the accused was not a resident of. There is no documentary proof that the DQCB had fulfilled its codal formalities. In nutshell the prosecution was not able to bring home the charge against the accused. He was therefore acquitted in this complaint.

Case III[240]: The case was initiated by a Federal Inspector of Drugs, who inspected an outlet and sent the sample of drug to the Central Drug Testing Laboratory which subsequently declared the drug as spurious. Then the Central Licensing Board decided to start prosecution after observing the formalities. However, it was proved that the proceedings had been conducted by unauthorized persons (in the Central Licensing Board) in violation of the law and rules in this case. There was no documentary proof for the delegation of powers under the Rule 8(7) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.[241] There were no minutes of the meetings when the case was preceded in the Board. Further, the mandatory provisions had been flagrantly violated; that neither the Drug Inspector nor the Board collected the Drug Sale License/Drug Manufacturing License for ascertaining the names of the proprietors, qualified persons

[240] Case No. 2434/DC/11

[241] Rule 8 (7), the Drugs (Licensing, Registering and Advertising) Rules, 1976
"The Central Licensing Board may authorize the Chairman or any of its members to perform any specific function of the Board for a specified period."

and other for fixing liability. Hence the court decided to acquit the accused of the imposed charges.

Case IV[242]: An appeal was filed in Supreme Court of Pakistan against Orders dated 6-6-2014 and 16-6-2014 passed by Islamabad High Court, violation of section 23 punishable under section 27 of Drug Act 1976, case was firstly filed in Islamabad High Court .the petitioner was involved in supplying spurious Drugs and some spurious Drugs were recovered from his Drug sale outlet in his absence. High Court of Islamabad did not grant bail to the petitioners but when appeal was filed in Supreme Court of Pakistan. the supreme court grant the bail to the petitioners on ground that spurious were recovered in the absence of petitioners and secondly the petitioners were not directly nominated in F.I R. so some of the legal flaws were present in the above mentioned case, therefore, accused were acquitted.

Analysis/Comments

Charge of spurious drug was proved in one case (case III). There was no doubt in the report of the Laboratory. But no sanctions were imposed to anybody. How it can be ignored that the drug was spurious. What about those people who have bought the spurious drugs?

[242] PLD2014Supreme Court 760 Alam Zeb and others vs The State

There must be some internal protocols for the Central Licensing Board, PQCB and DQCB to reflect on court's judgment about their documentary flaws while dealing with the cases. The aim of such protocols would be to not repeat the same mistakes in future.

There is a grave need to appoint a legal advisor with the Drug Inspectors at district level. Drug Inspectors are not trained in law and hence lack necessary skills to fight with other counselors. Moreover, the nature of their job does not allow them to spend a lot of time in preparing the case. They are already burdened with a large number of medical stores to inspect, deal with licensing issues for the drug sales and documentary obligations. It would be in the country's favor to appoint legal advisors for the drug inspectors

CHAPTER V

Conclusion and Recommendations

Conclusion

Drug sales are regulated by the Provincial Governments under the clauses of the Drugs Act, 1976 and the rules made there under. All provinces have the drug sales rules in practice like the Punjab Drug Rules, 2007 in Punjab. These rules specify all the conditions needed for the distribution, storage and sales of drugs. The drug pricing, registration and manufacture is under the Federal Government control and regulated by the DRAP Act, 2012, the Drugs Act, 1976 and allied rules.

The Drugs Act 1976 and the Punjab Drug Rules 2007 were critically analyzed and compared against the International Good Pharmacy Practices (GPP) guidelines using the Donabedian model of quality assessment.

Critical analysis of court judgments for 13 cases of drug sales is presented. In ten cases, the sanctions were imposed on the accused while in three cases they were acquitted of complaint due to legal flaws in the case. When sanctions were imposed, they were very lenient and were not serving the true objective of deterrence and retribution. The drug court had not made effective use of the imprisonment penalty. All accused offended multiple clauses of the Drugs Act, 1976. But more number of offenses was penalized in

the same rigor as lesser number of offenses. The drug courts had no authority to suspend or revoke the license to sale drugs, a very common penalty used all over the world. Almost 23 % of the accused were acquitted of the complaints due to legal flaws and failure to produce documentary evidence of the proceedings of the concerned authorities like Provincial Quality Control Board and District Quality Control Board. There is need for appointment of legal advisors at district level to facilitate the drug inspectors.

The legislation in Pakistan has been found to be insufficiently complying with the GPP protocols. The quality control of the dispensing process, the core activity in the pharmacies as per GPP, is completely missing in the legislation. Patient counseling is not mandatory in Pakistan and not even mentioned as a pharmacy function in the legislation. Drug sale rules are mainly concerned with the structural indicators but the clauses on the human resource are inadequate. The qualification, training and competence of dispensing staff are completely ignored. Storage conditions are vaguely specified considering the local context of temperature, humidity and shortage of electric supply in the country. Monitoring protocols are not established for drug inspectors in the legislation. Few clauses like record keeping for dispensed medicines, temperature maintenance in premises, personal supervision of drug sales by qualified persons though clearly stated in the rules, are poorly implemented. Such practices are a clear example of the idiom an elephant in the room. This is an alarming situation as the right and high quality drugs, if dispensed in wrong manner or without counseling can have profound adverse effects. Even if the laws are present for dispensing process like demarcation of drugs into

prescription only medicines or over the counter medicines, violations are observed in daily life. This shows poor enforcement of available laws.

The semantics of the drug rules portray that the pharmacies are business entities in the country and not much different from other businesses involving consumer goods. The phrase of 'drug sales' is used in the Drugs Act, 1976 and the Punjab Drug Rules, 2007. This *sale of drugs* is not further defined to demonstrate its importance in the public health and lives of people. No official information is available for the overall vision of pharmacy practice or drug sales in the country or what to expect from pharmacies. In contrast to GPP and the legislation in other developed countries like UK, the law has not yet defined the services or activities to be carried out at pharmacies in Pakistan. This lack of vision and proper characterization of pharmacy services or activity can be considered as the root cause of irrational practices at Pakistani pharmacies. The current laws relating to community pharmacies in Pakistan are inadequate to accommodate the vision of pharmaceutical care and rational drug use even in the long run.

Recommendations

The pharmacy professional associations in Pakistan need to work together with their governing bodies and other health-care associations to define the vision of pharmacy practice in the country. The vision is supposed to highlight the importance of pharmacy practice beyond just the sales of drugs. The long term mission of pharmacy practice should consider the provision of pharmaceutical care and achieving rational drug use in the country. A step wise approach needs to be laid out at national level. The government of Pakistan should take the responsibility to translate that vision and mission into policy

statements and legislations. Community pharmacies should be considered as part of health systems and their potential needs to be fully utilized in primary health care as well as in public health activities.

A professional definition of 'drug sales' should be incorporated in the laws that characterizes the core pharmacy activity. It will be more appropriate to replace this business oriented phrase with the one having professional orientation. There is a need to define the list of services that should be essentially available and can be expected from pharmacies in the country. The GPP states that one of the first steps in achieving good pharmacy practice is to know what services to expect from pharmacies. The UK model of service categorization in pharmacies is a good example for Pakistan. Such list can help pharmacy owners and drug sellers in focusing efforts and building their strengths. This can also limit expectations from people like getting drugs without prescription from pharmacies.

A detailed and itemized pharmacy inspection list should be available to all drug inspectors and pharmacy owners for assessing the structural and process indicators at pharmacies. Computerized system should be available to drug inspectors which can be used to upload the inspection reports of different pharmacies with biometric data of the proprietor, person present or qualified persons. Such systems should allow the prompts to drug inspectors to highlight pharmacies which need inspection or whose inspection reports were poor. This system can be used to communicate with government analysts, provincial quality control board and other relevant bodies. This system should have inbuilt all legal requirements for proceeding the case so that no requirement is ignored.

Drug inspectors should use smart and innovative techniques to monitor the storage conditions at pharmacies. Special thermometers with a function of recording history need to be installed at all the community pharmacies. Such thermometers must be inspected by drug inspectors to assess the storage conditions at the premises. Pharmacy inspection reports can be made public, to help people choosing the right pharmacy. This can build a healthy competition among pharmacy owners to maintain quality standards.

Availability of competent qualified staff is a major issue in community pharmacies in Pakistan. Legislation needs to be strictly enforced in this regard. Stricter penalties should be imposed on those qualified person who do not supervise the sale of drugs. They must be held accountable for all the offenses. Pharmacists should be offered reasonable incentives for working as community pharmacists. The legislation in Pakistan does not specify the qualification or training of other people working at the pharmacies in contrast to UK where a detailed profile of all pharmacy staff should be maintained with job descriptions and submitted to the law enforcement bodies. There should be minimum criteria of knowledge and competence for all people working at pharmacies. Protocols need to be established for continuing education of pharmacist and other pharmacy staff to meet the needs and challenges of the profession.

Dispensing activity should be defined legally as per GPP criteria. The definition must differentiate dispensing from mere sales of items. Clear steps need to be laid down with SOPs and expected quality standards. Flow charts and pictograms can be supplied to community pharmacies to assist implementing the standard procedures. Pharmacy

teaching institutes can be involved in training the drug sellers using the existing resources of the institutes.

Patient counseling should be mandatory, pictorial signs can be used to enhance the utilization of such services. Clear rules are needed to indicate who can counsel, what information is essential to communicate to drug users and which drug information sources can be used. The rules must also elaborate on the competence of the pharmacist or other pharmacy staff to perform such professional duties.

Community pharmacies are often the first point of contact between patient and health system. There is a grave need to develop national protocols for dealing with symptoms at community pharmacies and referral criteria. Such protocols must be part of the pharmacy curriculum both for pharmacists and the dispensers. A list of medicines must be specified which can be prescribed by the pharmacist and/or dispenser. Such rules need to be uniformly implemented in the country. Legislation should be strictly enforced in this regard. Sale of prescription drugs without prescription should be considered as a serious violation of laws and must be categorized separately as offence with strict penalty.

Drug inspectors must incorporate all these process indicators in their routine inspection protocols. The drug rules should be amended to include the details of these protocols.

Outcomes of pharmacy practice such as patients' knowledge about drug use, rational dispensing and patient compliance needs be monitored in the country. Such monitoring commitment must be made in the country's drug policy.

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