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The Role of Drug Regulatory Authority in Ethical Promotion of Pharmaceuticals in Pakistan: A Grounded Theory Study

Fazle Malik[1], Sadullah Shah[2]& S.M.Majid Shah[3]

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ABSTRACT

This paper elucidates on the current achievements of Drug Regulatory Authority of Pakistan (DRAP) in ethical promotion of medicines. The old orthodoxy of maximizing shareholders wealth has no significance in contemporary businesses where prominence is given to fair, transparent and ethical behaviors. Ethical and moral behaviors in product promotion are linchpins for pharmaceutical industry. Pharmaceuticals reduce illness of mankind and their appropriate promotion further boosts the wellbeing and reduces sufferings of patients. Nevertheless, Pharmaceutical marketing has an unswerving and unwavering impact on human lives, so this entails regularization and legalization of the discipline through an authentic statutory body. This study conducted open ended interviews from 12 respondents which consist of DRAP employees, sales managers from industry, and pharmacists. After analysis and findings of data, a theme explicitly emerged which shows that the current performance of DRAP is unjustifiable and not up to the mark in governing the sales and use of controlled drugs. The categories are poor enforcement, failure to implement Drug Act 1976 and lack of power to mitigate the malpractices of drugstores. Inescapably, the sales of drugs over-the-counter are common which leads to drug overuse and misuse and subsequently increase the chances of drug related side effects, particularly antibiotic resistance. This is an emerging global challenge for all stakeholders. The study suggests some recommendations for improving the current performance of DRAP within the existing resources.

INTRODUCTION

In today's competitive environment, business organizations use all available means to allure customers. The marketing function has assumed a critical role in delivering value to customers through informing them. Fierce competition can compel corporations to break ethical boundaries in various ways. Such companies bleed out and use their resources ruthlessly in competing with each other. Some organizations

[1] *Otsuka Pakistan Ltd (A Subsidiary of Otsuka Pharmaceutical Japan) (fazalmalikopl@gmail.com)*
[2] *PhD Scholar, Institute of Management Studies, University of Peshawar (saadx5@yahoo.com)*
[3] *Lecturer Management Quaid-e-Azam College of Commerce University of Peshawar (majidshah21@uop.edu)*

reduce their costs and adopt unethical marketing strategies to beat competition. For example, Nestle repeatedly advertised their unhealthy food to children to promote it, because children are much cognizant and prone to advertising. The discipline is blameworthy for the marketing of calorie-dense food with low nutrients to children and adults, ushering the epidemic of obesity. Nonetheless, it has the potential to create awareness regarding high nutritious foods with less concomitant health hazards. The tobacco industry attracts new smokers by creating an imaginary inspirational life in marketing campaigns. Similarly, in the marketing of alcohol, they create so much allure in the products that customers fall prey to it and enter into a vicious circle. Although, social marketing can be capitalized to create awareness for cessation of such bad habits, such unethical strategies and tactics have several effects on society and economy. The use of unethical means can remain unnoticed in the case of everyday consumer items such as soap or toothpaste. However, it can become a significant issue in items of higher importance such as life-saving drugs. But appropriate codes of ethics and regulation can control the unethical and immoral behaviors of marketers.

Ethical codes are advised by international marketing regulating bodies such as American Marketing Association (AMA), Australian Marketing Institute (AMI), Canadian Marketing Association (CMA) and Chartered Institute of Marketing (CIM). These bodies have developed codes of conducts and provide frameworks for self-regulation and stress on high professional skills, ability and integrity in persons involved in marketing and sales of products. However, they have a partial role in implementation, because these are national institutions which are responsible for enforcing these legal and ethical advices. The regulations and ethical boundaries become significant when governing Pharmaceutical marketing because of its direct impact on human health.

Pharmaceuticals' drugs play a critical role in society and economy (Carpenter, 2004; Yu, Li, Shi, & Yu, 2010). These are used in critical conditions to cure illnesses, while in return the industry earns significant profit margins. There is cut throat competition in this very lucrative industry. Corporations employ ethical as well as unethical marketing strategies to increase sales and create a loyal customer base. Thus it is vital for international and national regulatory bodies to enforce ethical guidelines in letter and spirit.

Background of the study

The breakthrough advancement in life sciences, particularly pharmacology, has led the foundation of drug regulation (Rägo & Santoso, 2008). But the process was catalyzed by the tragedy of 1937 when several deaths were reported due to poisoning effects of sulfanilamide elixir. In the preceding year, The

Federal Food, Drug and Cosmetic Act was passed by Congress of United States to ensure public safety and efficacy of drugs (Hutt, 1973). The second catastrophe that triggered drug regulation was the thalidomide disaster which resulted in more than ten thousands babies (born between 1958 and 1960) with phocomelia (a congenital disease with organs deformity). These events have significantly shaped the drug regulatory system. Pharmaceutical industry is one of the highly regulated sectors due to concomitant risks. Nevertheless, this industry has played a pivotal role to uplift the standard of lives of public.

Significance of Pharmaceutical Industry

The healthcare system is owed to the pharmaceutical industry on account of their provision of a variety of treatment options that have saved lives and promoted quality of life. The industry is partially responsible for boosting life expectancy from 68.2 in 1950 to 77.8 in 2006 (Hubbard, 2007) due to healthcare facilitation, and played its active role. The treatments developed by industry are cost effective and reduce overall healthcare expenditures and play a significant role in socioeconomic development of people (Lichtenberg & Brown, 2002). Nonetheless, despite these incredible achievements, the pharmaceutical sector comes under sustained criticism for its malpractices in the form of profiteering and unethical marketing. Thus ethical compliance is crucial for smooth running of the industry.

There is dearth of research on the legal role of DRAP to prevent the current malpractices of Pharmaceutical marketing, which led to the rise of ABR and other drug related side effects due to the misuse and even abuse of drugs, particularly antibiotics. There is also paucity of studies to find out different stewardship programs for preserving the effectiveness of these miracle drugs (antibiotics). Poor surveillance in this area is manifested in the form of antibiotics apocalypse and the subsequent emergence of superbugs pathogens, which are difficult to treat using the current therapeutic drugs. Therefore, this study will be helpful to devise viable policies for evading the overuse and abuse of antibiotics. The study will elaborate how to increase antibiotic access without increasing ABR, accelerating stewardship programs without crippling the commercial objectives of industry, and how to delink R&D from sales volumes?

Problem statement

The study examines the role of DRAP in enforcing ethical marketing in Pakistan. Over marketing is linked with overuse of products. The overuse of FMCGs are not too hazardous for health, but if the products are medicines, they may cause drug related side effects because of the active ingredients they

possess and the chemical reactions that take place in the body. Therefore, over emphasis on drugs' promotion increases usage, which is directly proportional to iatrogenic diseases provided the use is unnecessary and imprudent (Hubbard, 2007). The fiduciary role of DRAP is to ensure the prudent use of antibiotics by governing the behaviors of stakeholders. But nevertheless, a well thought out regulatory mechanism will corroborate ethical behaviors and good marketing practices. The mechanism must incorporate stringent punishments for wrong doers and rewards for those displaying legal and legitimate behaviors. Pharmaceutical marketing embedded with ethics can be used as an important tool to prevent the current practices of industry and pharmacies/drug stores.

Research Question

1. To what extent DRAP is successful in curbing the malpractices of Pharmaceutical companies?
2. What regulatory mechanism exists in the body which materialized enforcement?

Objectives

1. To determine the existing laws and regulations in DRAP
2. To find the current mechanism through which regulations are enforced

Literature Review

US Food and Drug Administration (FDA) is responsible to control drugs in the United States of America. The body influences the marketing and sales activities of pharmaceutical industry not only in States but across the world. The body has a sub-division in the form of Office of Regulatory Affairs (ORA) which acts as its "eyes and ears". In the United Kingdom, Medicine and Healthcare Products Regulatory Agency is responsible for safeguarding public health from medicinal hazards and ensure ethical communication to healthcare professionals. The European Medicines Agency (EMA) is the authority across the European Union for evaluation and regularization of medicinal drugs. The body also aims to harmonize the work of existing local authorities to bring about more safety, efficacy and quality in drugs to benefit public health. It legitimizes a centralized marketing authorization for medicines which is applicable in all member countries. These legislative bodies have a narrow focus on drugs safety and efficacy for patients but they have no laws for curtailing antimicrobial resistance (Hoffman & Outterson, 2015). Therefore, they are not successful to prevent the growing threat of antibiotic resistance on national and global levels.

Drug Regulation in Developing World

The developing world faces either a lack of institutions or they are dysfunctional. The foundation of drug regulation in India was laid in 1940 when the Drug and Cosmetics Act was passed to address the

swift pharmaceutical market expansion (Gupta, Shridhar, Singh, & Khadem, 2017). Drug regulation and access are crucial in achieving the Agenda of 2030 for sustainable development. The Sustainable Development Goal # three is to "Ensure healthy lives and promote wellbeing for all at all ages" (Regmi et al., 2016; WHO, 2016; Zoghbi et al., 2014). Achieving these goals is very difficult and not possible without bringing congruence in actions of national and international regulatory bodies.

In a capitalist market, the focus of marketing is to fulfill demand and sell more to maximize profits without breaching host country laws. This motive is widely accepted due to free market and no moral and ethical questions. But this notion is not acceptable in pharmaceutical industry where social good has primacy over profits. However, current system of pharmaceutical marketing is unethical, both from the consequentialist and deontological viewpoint. The net outcomes of drug sales are large profits for companies which are positive signs for industry, but at the same they have inflicted many diseases like antibiotic resistance (Bowie, 2002; Sen, 2000). The insurmountable increase in prices of drugs is unethical and violates the basic principles of deontological ethics (Alexander & Moore, 2007; Gibson, 2000; Mappes & Zembaty, 1981). According to Kant's categorical imperative, human element should be used as an end not as a means. But contrary to that, pharmaceutical companies are treating patients as a means not ends by charging high prices from them. It is a basic violation of ethics by taking advantage of others for self-interests. In Pakistan, pharmaceutical industry is continuously making cost cutting, excessive profiteering and over marketing to physicians to increase shareholders wealth while putting behind the larger interests of society. Nevertheless, the role of DRAP is questionable in preventing such malpractices.

Drug Regulatory Authority of Pakistan (DRAP)

Drug Regulatory Authority of Pakistan (DRAP) came in to being after the promulgation of DRAP Act 2012 with the aim of providing coordination and enforcement of Drug Act 1976. The body also facilitates the inter-provincial businesses of therapeutic drugs. The World Health Organization (WHO) emphasizes the promotion of healthy lives for all age groups which is also part of the sustainable development goals (SDGs) for the future human progress. These goals can be materialized only if DRAP and Pakistan pharmaceutical industry work in closed coordination.

DRAP Codes of Ethical Marketing

The prime objective of the codes of ethical marketing is to facilitate and ensure morally and ethically patient-centric interactions with physicians provide access to safe and effective medicines and promote transparent business opportunity for industry. Research grants and sponsorship to academic conferences

must base on physicians' research experiences and relevant qualifications and not their capacities to patronize company's products. Lavish meals and accompanying spouses should be avoided in foreign academic trips. The provision of text books and research journals are permissible but giveaways must be strictly prohibited because the burden of these items is put on drug prices which are borne by patients (Verma, 2004). Freebies provided to healthcare professionals are the money of patients used without their permission (Chren, Landefeld, & Murray, 1989). Ethical marketing always interdicts behaviors that exert extra pressure on physicians to prescribe company's products. Personal obligations to physicians create conflicts of interests (Chren et al., 1989; Coyle, for the, Human Rights, & American College of Physicians–American Society of Internal, 2002) which ultimately affects patients. However, these codes of ethical marketing are available only in documentations and patients have not yet reaped their rewards.

Regulatory bodies throughout the world work to legitimize industry interactions with physicians. The interactions with healthcare professionals should be based on integrity, transparency, appropriateness, and ethics to avoid imprudent use of drugs. Another important aspect on which the industry should actively operate is the substantiation of promotional information which is very important to increase physicians' confidence on the drug and further increase its optimum usage. It is the prime responsibility of industry to ensure safety and efficacy of medicines. Safety of drugs minimizes the concomitant risks while efficacy maximizes the likelihood of early recovery from the disease. It is noteworthy that continuous learning is the minimum requirement for success in any field. So, the professional skills of physicians must be upgraded with the passage of time and to make best use of contemporary technologies in the field of medicine. For this purpose, participation in symposia and conferences are an essential part of their career. Physicians' prescribing decisions are mostly proportional to the information presented to them by medical representatives. The accuracy and precision of such information are pivotal for patients' treatments. The overarching principles are to keep the independence of physicians, so that they are free from industry influence and their decisions to prescribe and dispense drugs are in the supreme interests of patients.

These statutory bodies draw lines between ethical and unethical strategies of industry to curtail their immoral influence. So, they have forbidden entertainment and pleasure trips for physicians due to their direct influence on physicians' prescription habits. Educational items such as books, soft copies and free links provided by pharmaceutical companies are legitimate and legal because such activities are helpful in professional advancements of HCPs and an indirect support in patients care. Therefore, continuing medical education (CMEs), academic workshops, seminars and conferences are important to attend

through company sponsorship. The arrangement of these programs ultimately increases doctors' adherence to medical ethics and treatment guidelines. Physicians' samples intended to help poor patients are legitimate but mostly they influence their prescriptions which is illegal.

It is the responsibility of the state to adopt a comprehensive and integrated approach to ensure promotion of public health and inculcate health awareness among them. They should make available all health facilities at affordable cost. It is also state duty to protect citizens from misleading and fraudulent promotional activities. The state not only regulates quality and safety of drugs, but also makes sure that the traffic of promotion is ethical and in accordance with the moral principles. State empowers regulatory bodies to promulgate and exercise laws and directives for proper rationalization of marketing and sales practices. At the same time, these bodies promulgate policies and directives to prohibit healthcare professionals from indulging in all sorts of questionable prescribing practices.

The Asia-Pacific Economic Cooperation (APEC) has endorsed codes of ethics for pharmaceutical industry to avoid unethical practices. These codes contained in two documents (a) The Kuala Lumpur Principles (KLP) Medical Device Sector Codes of Ethics (KLP, 2012); and (b) The Mexico City Principles (MCP) for Voluntary Codes of Business Ethics in the Biopharmaceutical Sector (Amaeshi, Nnodim, & Onyeka, 2013; Valdez, 2016). The prime objectives of these codes are to protect human health from hazards of medicines which arise from the misuse of drugs due to over marketing and excessive promotional activities. The codes emphasize to uphold integrity, transparency, good governance and accountability in industry-physicians interactions to maintain highest professionalism on both sides.

Future Challenges

DRAP is striving hard to setup world class labs for early accreditation with World Health Organization (WHO). It is a great challenge for the statutory body to upgrade to such a high standard. Another confrontation faced by the body is to get its membership with Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S), which facilitates manufacturing, legal and ethical conducts between industry and regulatory bodies. Amendment in current laws is needed on urgent basis to prevent future disasters like "Fake Drug Crisis" of 2012 in Lahore (Rashid, 2015). Lack of resources like personnel, technology, finance and time frame are the major obstacles in the enforcement of regulatory initiatives. But the major predicaments in the way of DRAP are questionable practices, lack of employees' will and nominal punishments for drug stores and industry.

RESEARCH METHODOLOGY

The nature of this study is qualitative which investigates the phenomenon from the perspectives of respondents. The meaning they attribute to their experiences, observations, and interactions with one another. Grounded theory (GT) approach is applied to construct theory from the collected data through appropriate analysis. Constructivist grounded theory which is a sub version of GT, is employed with its inductive, interactive, comparative and iterative strategies to provide meanings to the target population views (Charmaz, 2000, 2012). The researcher chose this method because it was successfully employed in ethical and social marketing with desired results in previous studies (Goulding, 2005). Another reason of deployment of this method is that it answers the "what", "how" and "why" research questions of a social phenomenon (Charmaz, 2014). A single theme evolves from the analysis of interviews conducted from drug regulatory authority of Pakistan.

The inquirer selected the strategies of constructivist grounded theory due its power and potential to explain the construct, "ethical promotion of pharmaceuticals in Pakistan". Constant comparison of data with codes, codes with codes, codes with categories and categories with theme will result in theory development which is grounded in data (Bryant & Charmaz, 2007). The hallmark of this method is categories identification and their integration to establish relationships among them (Kenny & Fourie, 2015). Data collection, coding, analysis and categorization take place simultaneously to derive meanings (Glaser & Holton, 2004; Holton, 2010). The emerging theory is juxtaposed with previous literature. Therefore, this unique characteristic of GT named it constant comparative methodology (Giske & Artinian, 2007; Jones & Alony, 2011).

Coding and Analysis of Data

The audio interviews were transformed to understandable text using a process called transcription by following the principles of (Biber, Nagy, & Leavy, 2006). Analysis process was started through which "data are fractured, conceptualized, and integrated to form theory" (Strauss & Corbin, 1989, p. 3). Open coding is executed, and data is broken down in to different dimensions (Strauss & Corbin, 1998). Paragraph wise coding was materialized by asking the basic question "what is happening here" (Charmaz, 2006). It is a microanalysis which is painstakingly conducted by the researcher with the aim to deeply immerse in the data, which is the prerequisite for theory generation. The bones of research skeleton are built through grounded theory coding while theoretical integration consolidates them to a functional sketch. Nevertheless, coding process provides a strategic connection between the collected data and emerging themes for discerning the phenomenon.

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FINDINGS OF THE DATA

Drug regulatory authority of Pakistan was formed through a presidential order in 2012 for regulating Pharmaceutical activities including marketing and dispensing of drugs. For this purpose, the statutory body framed and promulgated laws to govern the behaviors of industry. But currently the body is weak at the implementation front due to resource deficiency along with associated structural issues. It has developed codes of ethics for improving compliance of pharmaceutical marketing but they have proved to be ineffective due to poor enforcement issues. However, the regulatory bodies of developed countries are working vigorously to ensure ethical communication with healthcare professionals to facilitate the patients' wellbeing (Francer et al., 2014). It is worth mentioning that ethical and moral interactions with physicians not only promote compliance of industry but also guarantees sustainable business.

Theme	Poor Performance of Drug Regulatory Authority of Pakistan
Categories	1. DRAP Weak Enforcement 2. Maladaptation of Drug Act 1976 3. Malpractices of Drug Stores

Performance below Expectations

The contemporary legal system of the developing world is very poor and there are multiple loopholes which give rise to many social issues. Pakistan is also in the transition stage where there is a huge gap between what exists in documented form of the law and what actual practice is. Correspondingly, the Drug Regulatory Authority of Pakistan is dysfunctional and has no control on the activities of Pharmaceutical industry and pharmacies. Therefore, the misuse and overuse of drugs, particularly antibiotics, is on the rise in the market. There are a number of studies that advocates the overuse of antibiotics to burgeoning spikes in antibiotic resistance. The bacteria that cause infectious diseases are immune to the current available antibiotics.

DRAP Weak Enforcement

Effective institutions ostensibly consolidate the rule of law leading to prosperity and build society on sound footings. The current situation of DRAP is quite the opposite because it cannot put in to practice the existing laws due to some ingrained issues. Scarce resources, lack of commitment, absence of checks and balances and deep-rooted corruption are the odds in their way of performance. Apparently, the respondents openly disclosed that DRAP employees are involved in questionable activities at federal,

provincial and district levels, which bills alarms for the healthcare system of the country. There is an urgent need of stringent punitive laws with proper teeth to eradicate the misuse and abuse of controlled drugs.

DRAP Weak Enforcement

Resp#	Line#	11-DRAP is a Dysfunctional Body with weak implementation and pervasive corruption
R2	110	DRAP must guarantee drugs quality for public health
R3	152	DRAP inefficient due to poor implementation and official and unofficial briberies [R8, (l.61), R10, (l.101), R11,(l. 62/95), R12, (l.111)]
R4	154	DRAP developed ethical guidelines to incorporate ethics and morality for Pharmaceutical marketing
R5	129	Drug dispensing can be easily controlled at chemist and patients' levels
R6	150	DRAP is lacking effective mechanism for preventing drugs abuse
R8	54	The limited authority is also a hurdle in circumscribing malpractices
R9	156	The evaluation of physicians' prescriptions is important to remove unnecessary drugs

DRAP is supervising the activities of pharmaceutical industry, pharmacies and drug dispensing while possessing little powers over medical community. PM & DC (Pakistan Medical and Dental Counsel) is the authoritative body responsible for governing the behaviors of healthcare professionals. Poor implementation of existing laws and unrestrained corruption are the key hurdles in their way of duties (R3, R10, R11, R12). At present, the body has no proper controlling mechanism but has constituted the healthcare commission to oversee drug dispensing in the market (R6, R9). The body has framed ethical guidelines but is unable to implement them in their true spirit to benefit patients and the overall profession (R4). Therefore, many respondents were of the opinion that the maladroitness of DRAP is primarily due to lack of control mechanism and official and unofficial bribery, and their satisfaction level is very low from its performance.

"…currently DRAP is not effective due to implementation issues and its involvement in corruption and illegal activities" (Respondent3, line#152). "…there is no such mechanism in DRAP to prevent the misuse of drugs" (R6, line#150). "First reason is that DRAP is not efficient but second thing is that DRAP is earning money" (R12, line#111). "I am absolutely not satisfied with the DRAP role and its effectiveness in this connection" (R11, line#62).

Regular inspection of manufacturing sites and keeping a close eye on the sources and recipients of raw materials will reduce the chances of drug related side effects in masses. The deadly contamination of medicine in the Punjab Institute of Cardiology Lahore is an example of criminal negligence on part of drug regulatory bodies. However, medicine regulatory experts around the world were contacted to set up a body to prevent future incidences.

"DRAP inspectors should regularly inspect the production sites of pharmaceuticals to improve quality of medicines which are quintessential for ailing humanity" (R2, line#110). "The sources and recipients of the raw materials of these drugs are unknown" (R8, line# 61).

Dysfunctional institutions are the dilemma of the developing countries which have failed to work for public interests. Similarly, politicians have used them for protecting their corruptions and prolonging their governance. Public confidence and trust is decreasing on institutions working in political, social and economic arenas.

"DRAP has failed at many fronts due to official and unofficial bribery" (R11, line#95). "You have DRAP which can play a role but it's not doing it. Corruption has strengthened in its roots" (R10, line#101).

It is duty of DRAP's provincial part to control unethical practices of pharmacies, the pharmaceutical industry, and doctors. It may form an ethical committee for critical analysis of clinical practices of physicians and to bring them under the ambit of international SOPs and guidelines.

"Provincial DRAP must ask doctors and retailers to avoid malpractices. Even DRAP must take initiatives to form a committee at each hospital level to accurately evaluate physicians' prescriptions and remove flaws from them" (R9, line#156).

Maladaptation of Drug Act 1976

Drug act 1976 was passed on May 18, 1976, from the National Assembly of Pakistan and its prime aim was to regulate the manufacturing processes, distribution channels, and sales/marketing of medicine to physicians (Atif et al., 2017). It is unfortunate that the act is not properly promulgated to enhance the rational and ethical use of medicines. Inadequate collaboration among key stakeholders and inexplicable political changes in the country resulted in poor enforcement. Therefore, the society and particularly patients did not benefit from this law.

Maladaptation of Drug act 1976

Resp#	Line#	10-Drug act 1976 is poorly enforced
R2	143/146	Weak enactment of drug act 1976 [R6, (l.153), R11,(l.183), R14, (l.222)]
R3	39	Drug act 1976 monitors drugs manufacturing, distribution, and sales (R8, R15)
R8	33	Penalties in the drug act are weak ushering unethical practices(R10, R13)
R12	105	Poor adherence of key stakeholders to drug 1976 act (R9, R7)

DRAP failed to enact in true spirit the drug act 1976 due to multiple reasons. The document clearly advocates dispensing controlled drugs on physicians' prescriptions that include narcotic analgesic for pain management and antibiotics for curing infectious diseases (R2, R10, R14). However, the body is unable to promulgate this act and to halt the abuse of these drugs (R12, R11). Owing to the current behaviors and characters of concerned stakeholders there is an urgent need of uncompromising laws to timely punish the wrong doers and reward the followers (R3, R8). Currently, when pharmacies act against the laws, they are penalized using a very small amount which they easily pay. The respondents were of the view that poor enforcement, lack of proper mechanism and inadequate capacity of DRAP are the central reasons of its failure. But nevertheless, the statutory body is continuously enhancing its capacity and scope to bring all practices related to drugs production, distribution, sales/marketing and dispensing under the ambits of codes of ethics.

"It is not implementing on the ground and only in documents" (R2, line#143). "Drug act 1976 is not implemented in its true spirit so no benefit to the common man" (R14, line#222). "...they have laws but there is a problem in the implementation. They have made laws and kept it to side. So like it's a saying it's something else from the inside and something else from the outside" (R10, line#176).

In Pakistan, the control on drugs is very weak and pharmacies sell all types of medicines over the counter to earn profits. Although, one specific clause of this act forbids the sales of drugs without physicians' prescriptions, but it is very poorly perceived in the market. Even, the sales of antibiotics over the counter are very common.

"There are multiple clauses in the act but one is very clear for the chemist that they should avoid OTC drugs sales" (R11, line#183). "I think there are no flaws in that act but as far as antibiotics are a concern it lacks to regularized its usage to prevent antibiotic resistance" (R6, line#153).

Chemists are profit grubbers and they sell antibiotics to all who come to purchase. There is no control on the over-the-counter sales of drugs. Such practices are very hazardous for patients and may lead to antibiotic resistance. DRAP is failed at this front.

"There is some caution shown in drug act 1976 but chemists are not following that rule. So the narcotic analgesic and antibiotics are used carelessly" (R12, line#105).

The respondents clearly pointed out that there is no control on the behaviors of stakeholders involved in drug production, its distributions and dispensing which has shepherded multiple drug-related adverse effects in patients. It is noteworthy; the concerned regulatory bodies are unable to eliminate these malpractices.

Malpractices of Drug Stores

Drugstores are important parts of healthcare system. A social covenant exists between patients and pharmacies which must be respected. Selling drugs over-the-counter without prescription, prescribing practice, and prescription intervention are some of the unethical practices perpetrated by the chemist community. This study also reveals that majority of them are run by illiterate individuals who have no knowledge of dispensing physicians' prescriptions. They mostly lack the required license provided by Central Pharmacy Council of Pakistan, to run these pharmacies. Therefore, the compliance of these so called drugstores with the current regulations is very poor and needs improvement in leaps and bounds to avoid the associated risks.

Pharmacies Involved in Malpractices

Resp#	Line#	9- Poor enforcement of drug act leads to malpractices
R1	115	Drugstores are involved in unethical practices [R4,(l.47), R8,(l.180), R8, (l.108), R11, (l.188)]
R2	118	Pharmacy license is allowed on the basis of qualified pharmacist [R7, (l.212), R10, (l.167)]
R6	71	Intervention in physicians' prescriptions is common practice

Medication counseling and dispensing practices are the services provided by pharmacies to patients. But it is unfortunate that pharmacies in Pakistan have failed to provide both services to patients due to the absence of skilled and qualified pharmacists. They change physicians' prescription for the sake of their own profits that lead to side effects and AMR in patients (R1, R2, R5, R7). One interviewee responded

by saying that they misguide patients and play a role in developing antibiotic resistance (R6). DRAP law prohibits the sales of antibiotics without authentic physicians' prescriptions because the misuse causes many complications in patients (R4, R8). The respondents criticize the role of chemists in healthcare system with intervening prescription, poor patient counselling and malpractices in drug dispensing. They change physicians' advising drug with a low quality and high price drug that may produce side effects in patients. If the switched product is antibiotic, this may surely lead to antimicrobial resistance.

"Medical store are directly involved in changing prescription which is also a reason for antibiotic resistance" (R1, line#115). "He is the main controller of the physician prescription. Prescription change is a common complaint from chemist side" (R6, line#71).

The respondents expressed their concern that DRAP has permitted drugstores to sell antibiotics without prescription which is prohibited in WHO guidelines as well. They are profiteering with the consent of drugs inspectors because they charge them with a nominal punishment.

"…they should avoid OTC drugs sales. OTC drug lead to self-medication and many side effects" (R11, line#188). "Any drug which is not OTC but chemist sold it without prescription is a crime" (R4, line#47).

Pharmacists are an integral part of healthcare system with relevant technical knowledge and they understand drug-drug interactions, contraindications and other adverse effects. Some respondents have suggested that they should be made an important part of the system to facilitate patients with their appropriate counselling.

"…the existence of pharmacist is very important at that level" (R2, line#118).

The fundamental objectives of DRAP were regularization of pharmaceutical industry and pharmacies and improving ethical dispensing of drugs. However, its success rate very low due to lack of commitment and dedication, scarcity of resources and questionable behaviors of employees. In consequence, drug misuse, overuse and abuse is ubiquitous in Pakistan, thereby causing antimicrobial resistance and making the available antibiotics ineffective against bacteria. The curative power of antibiotics has significantly reduced leading a great setback for medical sciences, with some serious social and economic consequences (Laxminarayan et al., 2013). This is an urgent public health issue and requires global coordinated endeavors to combat it effectively (Barlam et al., 2016; Robinson et al., 2016).

DISCUSSION

DRAP is the statutory body of the Government of Pakistan for controlling drug makers manufacturing

and promotional activities. The questionable marketing strategies are executed to increase prescription from physicians which thus increases sales volumes. Therefore, increasing the usage of drugs, particularly antibiotics, have long term consequences in form of antibiotic resistance. Bacteria become immune to antibiotics, resulting in the apocalypse of these wonderful drugs (Nerlich & James, 2009). Current means of communication have further accelerated the spread of disease. The ineffectiveness of contemporary antibiotics is leading the medical science to post-antibiotics era where morbidity and mortality due to infectious diseases will be on the rise. There will be limited treatment options with physicians for minor infections. Similarly, the concerned participants also pointed out that the antibiotic resistance is spreading in faster way due to the irresponsible behaviors.

Bacteria are challenging human intellect and expertise but through concerted efforts this wonderful discovery of the 20th century can be preserved (Arias & Murray, 2009; Ghafur, 2010). Effective legislation on appropriate use of antibiotics with stringent punishment for wrong doers is vitally important to ensure prudent use. But data obtained from the respondents show that neither the laws nor the ethical and moral values of the healthcare professionals signifies proper usage. However, DRAP recently constituted a healthcare commission to regularize drugs in the market and govern promotional activities of industry.

"Currently there is no such mechanism in DRAP to prevent the misuse of drugs but they have constituted healthcare commission who are working on these lines to streamlines the use of drugs" (Respondent6, Line#148).

The statutory body is weak at the implementation front not only due to the lack of resources and employees' will but also due to involvement in corruption.

"…currently DRAP is not effective due to implementation issues and its involvement in corruption and illegal activities" (R3, line#152).

Weak in institutions and non-compliance of key stakeholders, the drug act 1976 has lost its effectiveness. Poor reinforcement mechanism not only hampers access to essential medicines but also reduces the effectiveness due to improper usage (Pecoul, Chirac, Trouiller, & Pinel, 1999). The respondents were of the same opinion.

"…they have laws but there is a problem in the implementation. They have made laws and kept it to side. So like it's a saying it's something else from the inside and something else from the outside" (R10, line#176).

Pharmacies are lacking qualified personnel and they are pushing high margin drugs for sales instead of standards ones.

"Medical store are directly involved in changing prescription which is also a reason for antibiotic resistance" (R1, line#115).

The burgeoning use of antibiotics in human, animals and agriculture has catastrophic health hazards. Physicians advise one or more antibiotics for treating an infectious disease and sometime increase usage duration to take benefits from pharmaceutical companies. They are also involved in unnecessary prescriptions to patients. The use of this wonderful drug is frequent in non-indicated diseases and patients should be alerted from its misuse (Bauchner, Pelton, & Klein, 1999). Over-the-counter use of antibiotics is associated with increase in morbidity and mortality (Gunn, Taha, Liebelt, & Serwint, 2001). Drugstore workers and medical representatives are responsible for pushing OTC drug sales (Kamat & Nichter, 1998). Pharmaceutical companies offer incentives and bonuses on antibiotics to pharmacies for pushing its sales. However, the unnecessary use of antibiotics can cause drug-related-adverse effects in patients.

"*…it clearly shows that physicians are under the influence of pharmaceutical marketing tactics and activities and prescribe the extra medicines for their personal gains" (R11, Line#38).*

According to WHO estimates "more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly" (WHO, 2002).
There is a myriad of literature that facilitates rational use of drugs, particularly antibiotics. "Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community" (WHO, 2015). Consequently, multiple drug resistance develops in community which is spreading to other members and across the borders as well. Unnecessary antibiotic prescription in children causes disturbance of gut microbiota, leading to complications and infectious diseases (Vangay, Ward, Gerber, & Knights, 2015). There is an appropriate balance in bacterial flora within gastrointestinal gut which coexists in an acceptable ratio. A disruption in this ratio overpowers some bacteria to infect human organs and cause infectious diseases. Therefore, appropriate use of antibiotic should be advised while misprescription must be avoided.

CONCLUSION

Drug Regulatory Authority of Pakistan was established in 2012 through a presidential order with the aim to regularize behaviors of Pharmaceutical companies and drugstores. The criteria for rational

prescription are drug safety, efficacy, and accessibility with appropriate consideration of age, sex, diagnosis, drug and food interactions. Patients' socio-economic and spiritual belief must be taken in to account while writing prescription. Rational prescription can be improved through adopting a two-pronged strategy; targeted approach which focuses on managerial and educational interventions; systemic approach which emphasizes on regulatory and economic intercessions. Physicians should be economically rewarded or reimbursed to avoid the chances of overprescribing. However, the current practices in healthcare system provide little considerations for rational prescription (Krause et al., 1999). Physicians' clinical practices and industry marketing activities are lacking ethics and moral practices. Institutional ethics has a primacy over practice ethics because the former overhauls the whole healthcare system. An effective regulatory mechanism should work to restrict pharmaceutical registration, physicians' prescribing, and medicines dispensing. The respondents of this study conspicuously pleaded that there should be an interdisciplinary body to properly evaluate physicians' prescriptions and remove errors and flaws from them. World Health organization (WHO) also suggests the establishment of an interdisciplinary body to ensure appropriate use of medicines.

The following managerial implication can be devise to make DRAP an efficient body. The current laws must be implemented in letter and spirit to mitigate the misuse of drugs. The codes of ethics developed by DRAP should be employed in marketing practices of industry. Malpractices of pharmacies can be overcome through the active role of the provincial chapter of DRAP. The role of hospitals is crucial in implementing antibiotics stewardship and conservative programs to keep them effective for longer period of time.

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