

Impact of the Drug Regulatory Authority, Pakistan: An Evaluation

Hira Rashid
University of Delaware

Drug regulation has been identified as a crucial impediment to the progress of Pakistan's health sector, particularly in the wake of the 'Fake Drug Crisis' of 2012. In 2010, control of the Drug Regulatory Authority of Pakistan (DRA), shifted from the federal government to provincial governments. However, after two years, the Drug Act of 2012 re-established direct federal jurisdiction over the DRA. Since its formation, the media and the international community have criticized the DRA. However, to date there have been no official or academic performance evaluations of the DRA. This paper aims to add to the limited body of literature analyzing DRA's effectiveness in the following areas: regulating the pharmaceutical industry, encouraging its development and, managing the supply of therapeutic products in the country. This research supports that there are significant policy shortfalls in the DRA's operational functions, organizational and financial structure, that limits the impact of the organization and its constituent units in regulating the pharmaceutical industry in Pakistan. Finally, crucial policy recommendations are highlighted that focus on maximizing the efficacy of the DRA while taking into account the contextual political, social, and economic factors in which it operates.

Introduction

Since its formation in 1947, Pakistan has passed 12 pieces of legislation pertaining to the pharmaceutical industry regulations and drug delivery mechanisms of health service facilities. In 2010, control of the Drug Regulatory Authority of Pakistan (DRA), shifted from the federal government to provincial governments. The DRA has the responsibility of implementing policies and protocols laid out in the Drug Act of 1976. However, the Drug Act has many exploitable covenants and gaps that have emerged as a result of recent trends in technology, advertising, and WTO agreements. (Nishtar, 2012). Many provisions of the Drug Act of 1976 have been poorly executed in the past due to bureaucratic hurdles that emerged as a consequence of direct

Hira Rashid¹ is a Fulbright Scholar and a graduate student at the University of Delaware pursuing a Master of Arts degree in Urban Affairs and Public Policy. Her research interests are health equity, social determinants of health and public health delivery systems. She has worked in public health infrastructure development and community health projects. **Email:** hrashid@udel.edu

¹ Hira Rashid is an Associate Editor for *New Visions for Public Affairs*. Her identity was not disclosed to other members of the board as they considered whether to accept this piece for the peer-review process. Rashid recused herself from voting on this piece. The only board member aware of the author's identity as an Associate Editor prior to publication was the Editor-In-Chief.

federal control, unclear designation of responsibilities, and the absence of an accountability structure. One such piece of legislation remains in the pipeline, the Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal and other non-Allopathic Medicine Act, 2008. The Drug Act of 2012 reinforced the Drug Act of 1976 and broadened the scope of federal regulation. The DRA operates within a complex socio-economic, political, and cultural context. Rates of drug prescription and consumption in Pakistan are higher than the average rates in developing countries (Zaidi, Bigdeli, Aleem, & Rashidian, 2013). This culture of pharmaceutical use largely stems from patient's perception that they have received inadequate care if medication is not prescribed during a provider-patient encounter (Sudhinaraset, Ingram, Lofthouse, & Montagu, 2013). The public health system faces significant challenges in terms of the availability of essential drugs in pharmacies and drug stores (Zaidi et al., 2013). Due to production shortages and regulatory lags in licensing and distribution, only 15 percent of the demand for essential drugs in the public sector and 31 percent in the private sector is being met (Zaidi et al., 2013). Despite pricing regulations enforced by the DRA, proliferation of originator brands and wide price variability raise concerns about the affordability for consumers (Zaidi et al., 2013).

The purpose of this paper is to identify criteria for evaluating the DRA's effectiveness, to discuss the measures it has taken to fulfill its role, and to examine its impact on health service delivery. This paper also identifies the broader nexus of supply-side issues, reliability of health systems, government regulation, and access to medicines. The conclusion outlines policy recommendations to improve DRA's efficacy and expand its scope of service.

Political Background

The 18th Amendment, voted into Pakistan's constitution in 2010, dissolved the Federal Ministry of Health and its constituent units, including the DRA. The administrative and regulatory powers were delegated to the five provincial health departments. This decentralization initiative proved to be disastrous for Pakistan's health service delivery system because the provincial governments lacked the resources as well as the administrative infrastructure. Furthermore, the political turmoil surrounding the passage of the 18th Amendment prohibited the possibility of establishing an accountable and coordinated decentralized health system. Both the pharmaceutical industry and public health advocacy groups stressed the need for a federally administered drug regulatory body. The provincial governments, particularly Punjab, resisted federal regulation even after it became clear that a vacuum had been created in pharmaceutical regulation after the passage of the 18th amendment in 2010. This resulted in a two-year political scuffle between the two tiers of government, which precluded effective drug regulation at the national or the provincial level (Nishtar, 2013).

Amidst an outbreak of multiple communicable diseases such as dengue virus, malaria, measles, and polio in January 2012, 125 cardiac patients died at the Punjab Institute of Cardiology (PIC) in Lahore. This tragedy came to be known as the "Fake Drug Crisis". An investigation ordered by the Supreme Court traced the responsibility of this incident to three laboratories supplying medicines to PIC, who were found to have been operating with expired licenses. The medicines that caused the deaths were found to be spurious, which in this case meant that they contained traces of medication used to treat malaria. This incident focused national attention on the repercussions of the ineffective decentralized drug regulatory system that had been in place since 2010. In response, the President of Pakistan, Asif Ali Zardari, authorized the creation of a Federal Drug Regulatory Authority by signing the Drug Act of 2012 into law in November 2012. The DRA was established as an autonomous body under the administrative control of the Federal Government and includes an independent policy board (Senate Secretariat, 2012).

Legislative Groundwork

Under Part II of the Federal Legislative List, regulation of manufacturers of consumer goods and services falls under the purview of the Federation. Since the passage of the Drug Act 2012, several regulatory institutions are under the domain of the National Health Services, Regulations and Coordination Division (NHSRC). In 2011, one year after the abolition of the Federal Ministry of Health, Article 144 of the

constitution established the NHSRC as a Federal governance body to oversee the operations of the decentralized health system. The DRA serves an important function in this structure. The regulatory framework and revised responsibilities of the DRA were outlined in the Drug Act of 2012 and were published in two documents in January and November 2013 respectively: “Regulatory Framework on Health and OTC Products” and “Medicines and Health Products (Enlistment) Rules”. These documents detailed the scope of authority of the DRA, and came into effect immediately, thereby establishing the DRA’s judicial control over all domains of operation laid out in the Drug Act of 2012 which are discussed in the subsequent section of the paper.

Financial Structure

A wide network of monitoring and accountability frameworks will be required to fully assess the policy implications of the DRA’s revised responsibilities since the Drug Act of 2012. In order to institute these accountability frameworks, the DRA must focus on recruiting qualified personnel. It will also require a significantly larger allocation of funds, for which no efforts have been initiated to date. In fiscal year 2013, the DRA operated with only 500 employees, and an insufficient budget of USD 5 million. The sources of DRA’s funding are:

- Federal grant-in-aid in for salaries and retirement benefits of existing staff.
- Donations and endowments.
- Grants and loans provided by the Federal and Provincial Governments
- Grants and loans that the Federal and Provincial Governments receive from national and international agencies that are to be allocated to the DRA.
- Charges and fees collected by the DRA to recover the costs of regulation activities and services, including Inspection Services for local or imported pharmaceutical products, or sale of any publications produced by pharmaceutical companies.
- Proceeds from investments made by the DRA with prior approval of the board.
- Central Research Fund collected by the DRA from the pharmaceutical industry as a part of the licensing and operation costs (Senate Secretariat, 2012).

Because the Federal Government allocates funding only for existing employees, the DRA cannot carry out the workforce expansion that is so critical to its successful functioning. According to the Senate Secretariat, the DRA holds the authority to “create an organizational structure for employees and appoint employees, consultants and experts as deemed necessary on prescribed terms and conditions including their salaries and remunerations with consultation and approval of the (Policy) Board” (2012, p. 6). The NHSRC’s authority does not extend to the financial operations of the DRA because the DRA’s federal funding is directly allocated, rather than being channeled through the NHSRC. This combination of organizational autonomy, financial entitlement, and limited financial accountability to the Federal Government has created a situation in which the DRA’s current administrative members receive substantial remuneration, benefit packages, and are reluctant to expand (Senate Secretariat, 2012).

Organizational Structure and Functions

The DRA is comprised of four administrative boards: the Policy Board, the Central Licensing Board (CLB), the Registration Board (RB), and the Provincial Quality Control Board. These boards are responsible for implementing the policy guidelines laid out by the Drug Acts of 1976 and 2012. The DRA also includes 13 divisions that ensure adherence to the decisions of the respective boards. The CLB and RB are responsible for the licensing of new pharmaceutical manufacturing units and registration (or changes in labeling) of new therapeutic products, as well as the regulation of imports (quota setting), exports, advertisement, distribution, and market availability of therapeutic goods. Finally, they are responsible for ensuring adherence to the prescribed cautionary steps for scheduling and labeling of drugs in the Drug Act of 1976. Pricing of therapeutic products also falls under the purview of the RB, and these price regulations are enforced by the Board’s Cost and Pricing Division (Senate Secretariat, 2012).

The Appellate Board is a subset of the Policy Board which is responsible for responding to complaints against the CLB or RB, as well as to appeals submitted for further reconsideration in the event that an application by pharmaceutical manufacturer or distributor to the CLB and RB has been denied (Senate Secretariat, 2012). While quality control and supervision is conducted at the provincial level, DRA's Provincial Quality Control Board inspectors have the authority to inspect, seize, and submit for quality assessment, any product being manufactured or sold as a therapeutic product, and to inspect the manufacturing unit where such products are being produced (Senate Secretariat, 2012). The DRA also provides policy guidelines to provincial health departments and consults with provincial governments to ensure that performance standards are met and regulatory laws are enforced. It also conducts safety inspections of drug related research initiatives and drug manufacturing to ensure strict adherence to drug specifications and laboratory practices (Senate Secretariat, 2012).

The DRA is also responsible for capacity building measures such as awareness campaigns, health seminars, development and promotion of pharmacy services, safety guidelines, and training of technical staff. The Federal Government has also encouraged the DRA to push for the pharmaceutical industry's adherence to internationally recognized quality assurance guidelines in order to expand the market share of Pakistani pharmaceutical exports (Senate Secretariat, 2012). The DRA's policy-making mandate and regulatory prerogatives complement one another. Their mutually beneficial relationship is crucial to achieving greater uniformity in the pharmaceutical sector, as well as the broader outcome of improving Pakistan's health indicators (Nishtar, 2013).

Existing Conditions

Approximately two years after the DRA was established by the Drug Act of 2012, its impact on integrating the health delivery systems and the pharma-industry has been negligible. Nishtar states, "as it stands today, the DRA is no different from previous regulatory arrangements of the Ministry of Health" (2013, p. 62). Nishtar goes on to say that "Substandard and/or counterfeit medicines are burgeoning, as are incentive-intense marketing practices, and inappropriate prescribing and dispensing" (2013, p. 62).

The Pharmaceutical Industry

Production

The pharmaceutical industry in Pakistan has rapidly developed since the country's independence in 1947. There are 411 registered manufacturing units and 30 multinational companies in the country that meet approximately 35 percent of domestic demand. Raw materials for local drug production are almost entirely imported (Zaidi et al., 2013). The total size of the pharmaceutical market stands at USD 2.2 billion and the export share of the pharmaceutical industry stands at USD 190 million (Rind, 2014).

In terms of drug development and registration, there are 1,100 – 1,200 registered molecules, and 50,000 registered drug products. Pakistan's Essential Drug List (EDL) currently comprises 335 medicines and this list of medicines is informed by reviewing the needs of 80 percent of public sector facilities (Zaidi et al., 2013). There are regulatory provisions with respect to pricing of therapeutic products targeted at manufacturers, wholesalers, and retailers (Zaidi & Nishtar, 2011). Flat price control on the sale of the majority of pharmaceutical products has prevented manufacturers from increasing the prices of over 40,000 drugs ("Senate Body Meeting", 2013). The issue of counterfeit and spurious drugs has also raised concerns internationally. In the wake of the 2012 Fake Drug Crisis, Sri Lanka banned pharmaceutical imports from Pakistan. Reports from pharmaceutical manufacturers of the European Union and US Trade Office have claimed that nearly 50 percent of the drugs being sold in Pakistan are spurious or counterfeit (Nishtar, 2006).

Quality assurance ideally must have two tiers of policy regulation: at the production level and at the provider level. The deficiency in quality assurance policy at the production level is evident from the fact that there are no drug manufacturing units that are internationally recognized or accredited. This condition also limits the export of domestically produced drugs (Nishtar, 2010). In addition, Nishtar (2010) notes that wide variation in the quality of registered production units indicates that legal provisions requiring manufacturers

to be licensed and to comply with Current Good Manufacturing Practices (CGMP) have been ineffective. It is pertinent to note that CGMP was adopted from manufacturing standards employed in the UK and USA (Zaidi et al., 2013). However, Pakistan lacks the technological capacity to ensure adherence to these practices, which has led to difficulties in implementing effective licensing practices.

In the vacuum created by scarce inspection and ambiguous standards of quality, pharmaceutical manufacturing entities attempt to avoid the costs of regulatory compliance by pressuring regulators to get their products registered, speed up approval processes, and get favorable prices or have their drugs included in the pharmacies of various hospitals and institutions (Nishtar, 2010). Although market surveillance conducted by the provincial departments of health involves sampling of drugs on the market, Nishtar (2010) points out there continues to be a high proportion of counterfeit drugs. This may be attributed to the presence of unqualified retailers serving as pharmacists, who are unable to recognize spurious drugs when purchasing them from suppliers (Butt, Gillani, Nanan, Shiekh & White, 2005). The DRA must mandate a multistage program to bridge the gap between the locally and internationally accepted quality assurance standards for therapeutic products.

Data and exclusive marketing rights are not protected by law in Pakistan, which has led to excessive registration of drugs without any regard for patent rights. According to one estimate, as many as 125 drugs with duplicated labels are currently registered (“Non-functioning of DRAP”, 2014). Multiple generic copies of patented drugs are in circulation in the market, despite the internationally well-recognized convention of releasing generic versions of drugs only after a drug’s patent expires (Zaidi et al., 2013). The agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1995) has allowed pharmaceutical companies the use of patents and protect intellectual property rights. However, the limited capacity and ambiguous quality standards of local pharmaceutical manufacturers have thwarted the implementation of TRIPS in Pakistan (“Non-functioning of DRAP”, 2014).

Provision

Private retail outlets are the predominant sources of drugs for both private and public sector patients. However, the existence of nearly 80,000 drug stores, one of the highest rates among developing countries, makes general regulation an insurmountable challenge. Most of these outlets are manned by untrained shopkeepers instead of qualified pharmacists. (Zaidi & Nishtar, 2011). Pharmacist availability is low across public and private sector, with only 0.06 pharmacists available per 10,000 people, far below the recommended ratio of 5 pharmacist per 10,000 people (Zaidi et al., 2013). While licensing and registering provisions for pharmacies and pharmacists exist, National Good Pharmacy Practice Guidelines published by the Pharmacy Council in 2011 have not been made public by the government (Jooma, 2011). In 2009, a Pharmacy Council was formed to develop and oversee standards of conduct for pharmacists and allied staff, standards of accreditation for pharmacists, to maintain registers of qualified pharmacists and pharmacy technicians, and to coordinate continuing training programs (Pharmacy Council Act, 2009). However, the Pharmacy Council’s authority is limited to the relatively few licensed pharmacists in the country. The Council has no jurisdiction over the vast number of unregistered pharmaceutical stores and untrained and unlicensed sellers of pharmaceuticals (Jooma, 2010).

Another serious breach of operating procedures occurs in the domain of public sector drug facilities. A survey of public sector facilities found that the manual for procedures was available in only five percent of these facilities, refrigerators were working in 60 percent and temperature control was present in 24 percent (Hafeez, Kiani, Din & Muhammad, 2004). Supply management in the private health sector is also substandard. According to Hafeez et al. (2004), only 50 percent of private facilities comply with the national EDL and only 19 percent of drug retail outlets meet licensing requirements. Likewise, drug dispensing does not adhere to standard safety measures, while delays in dispensing drugs prevent patients from properly following medical instructions. Drug dispensing at community pharmacies is also problematic because there is very little restriction on over-the-counter medicine purchases by patients (Hafeez et al., 2004).

At the moment, there are 130,000 traditional practitioners in the country that do not fall under the purview of the Drug Act of 2012 (Nishtar, 2013). Similarly, due to weak regulation, only four percent of pharmaceutical product sales are reported to come from trained pharmacists (Sharif & Anis, 2012). Eighty-eight percent of medications are prescribed by their brand names, indicating that pharmaceutical companies are influencing prescription practices by providing incentives to physicians (Zaidi & Nishtar, 2011). An evident distribution chain malpractice is the collusion between pharmaceutical industry representatives and health providers to promote the use of particular medicines, products, and technologies without regard for cost, quality or appropriateness of use (Nishtar, 2010).

Pakistan Medical and Dental Council (PMDC), which operates under the NHSRC has passed an ordinance on the relationship between the pharmaceutical industry and registered doctors and dentists, however the parameters of this regulation are vague at best. It stipulates that pharmaceutical companies may give gifts, inducements, or promotional aids to registered practitioners, provided these transfers do not compromise professional integrity (PMDC, 2011). In response to the wide exploitation of this ill-defined provision, the Awareness and Prevention Division of the National Accountability Bureau tasked the DRA in April 2014 with instructing all pharmaceutical companies to share on their websites information on marketing expenditures and incentives given to doctors (“Drug regulator’s initiative”, 2014). So far, three pharmaceutical companies have been instructed by the DRA to share this information (“Drug regulator’s initiative”, 2014). It is pertinent to note that DRA was instructed by the State Minister for NHSRC, Saira Afzal Tarar, to upload information regarding pharmaceutical companies on the DRA website in February 2014, but so far the DRA’s only action in this regard was to send letters to three pharmaceutical companies (“Drug regulator’s initiative”, 2014).

Weak advertising regulations for pharmaceutical products have also promoted irrational drug use in Pakistan (Vakani, Naqvi & Amin, 2011). A sample study of the pharmaceutical advertisements in Karachi found that a considerable portion of the advertisements issued by the pharmaceutical companies are poorly organized and contain what Vakani et al. describe as “irrelevant and misleading claims” (2011, p. 168). In particular, “the term ‘safety’ was used frequently without supporting scientific evidence. Essential information was missing, inaccurate, or illegible due to being printed in small, difficult-to-read fonts” (Vakani et al., 2011, p.168). Furthermore, price information was left out in most of the advertisements (Vakani et al., 2011). These practices are in violation of the advertisement guidelines laid out in the Drug Act of 1976, the enforcement of which falls under the purview of the DRA (Drug Act, 1976). Vakani et al. (2011) state that physicians in Pakistan view drug advertisements as a means to keep up to date on new products, and therefore these advertisements have a strong influence on prescribing behavior. MNC’s are reported to be more stringent in following the codes of advertisements as compared to local manufacturers, possibly because of the stricter checks on adherence to company laws (Vakani et al., 2011).

Access

Despite pricing measures, drug affordability continues to present problems, mainly due to proliferation of originator brands and wide price variability. The amount spent on drugs in the public sector is below the critical threshold of \$2 per capita per year recommended by the WHO to avoid medicines shortages (Zaidi et al., 2013). The shortage of price controlled essential drugs for generic conditions leads to a shift from the public sector towards informal providers, which increases the risk of exposure to counterfeit drugs. Additionally, the price ratio of branded products to international reference price ranges between 0.72 and 26.2, showing excessive price variability (Zaidi et al., 2013). According to Zaidi et al. (2013), the cost of managing chronic conditions in Pakistan is almost 7 times as prescribed by the WHO’s Affordability Index (which has a threshold of one day’s income for lowest paid government worker for one month’s standard treatment of chronic illness or for one episode of acute illness). This shortcoming in price regulation leads to the bulk of the health care costs being borne by households, for whom medicines account for a substantial 43 percent of total household health expenditure (Zaidi et al., 2013).

Irrational drug use is also a widely prevalent issue that drives up costs, and makes access to medicines more difficult (Zaidi et al., 2013). Zaidi et al (2013) find that the average number of drugs prescribed per patient in Pakistan is over 3, compared to an average of 2–3 in Low and Middle Income Countries. The prescription rate is even higher in the private sector in Pakistan, at 4.5 prescriptions, compared to 2.77 in the public sector (Zaidi et al., 2013). They also note that 60 percent of patient encounters involve an injection and high rates of antibiotics use continues to lead to antibiotics resistance in the long term and preventable side effects (Zaidi et al., 2013). As noted earlier, interaction between health care providers and the pharmaceutical industry is not restricted and visits by pharmaceutical sales representatives to health care providers are linked with increased prescription of the sponsored medications (Zaidi et al., 2013).

Impact of the Drug Regulatory Authority

After its inception in June 2012, the DRA levied numerous excessive taxes and fees for provision of services during its first meeting (Junaidi, 2013). Junaidi (2013) states that in the initial phase of processing long-pending drug registration applications, manufacturing license applications and contract extensions, the DRA accrued as much as USD 4 million in 2 months. The pharmaceutical industry has expressed outrage over this spike in manufacturing costs, as it is already operating within the confines of high production costs, inflation, and a 12-year moratorium on prices of 40,000 drugs (Khan, 2013). Pakistan Pharmaceutical Manufacturers Association (PPMA) has also criticized the DRA for incompetence and for driving numerous MNCs out of the country (Khan, 2013).

Since 2012, the DRA registered 3,295 drugs in the short span of one year (January 2014) and approved 29 new drug manufacturing licenses and 61 new drug manufacturing investments (Achakzai, 2014). On the other hand, a recent report shows that 125 drug labels registered in the country have been registered twice for separate medications (“Non-functioning of DRAP”, 2014). The DRA has advocated for eliminating pharmaceutical companies that are noncompliant with the practices standards set by the Drug Act 1976, and has withdrawn manufacturing contracts for 198 pharmaceutical products (Achakzai, 2014). The DRA also restricted the outsourcing of drug manufacturing to third party firms and denied big pharmaceutical companies the required licenses to continue production (Achakzai, 2014). This hasty process of registration, contract-cancelling, and duplication raises questions about the integrity and functions of the DRA.

The DRA has been operating with a total of 225 drug inspectors for over 80,000 dispensing units across the country (Zaidi & Nishtar, 2011). Analyzing these figures with regards to access, quality and market share, the measures taken by the DRA have had no impact outside of generating more profits for pharmaceutical companies by registering more drugs (Amin, 2011). The DRA’s failure to regulate price setting by has also diminished the market share and profits of foreign companies. Eleven foreign pharmaceutical companies have closed their operations in Pakistan due to poor law and order, the energy crisis, and the high cost of doing business (Amin, 2011). At the same time, the manufacturing of about forty essential drugs has been stopped due to Rupee devaluation, inflation, and escalated expenses, which reflects on the unfavorable political and economic climate of Pakistan (“Essential drugs not being produced”, 2013).

The task of revising the EDL, previously under the federally administrated Ministry of Health, now rests with the DRA. Since provincial health departments must comply with the EDL in procuring drugs, they must report issues of drug availability to the DRA. The RB within the DRA must then issue ‘show cause’ notifications to the licensed manufacturer for its lag in production and failure to meet market demands. Although noncompliance regarding availability of registered drugs in the market is a punishable offence (u/s 4 of section 27 of Drug Act, 1976), the RB has never exercised the option of prosecution in Drug Court on contravention of this condition of registration.

One year after inception, the DRA had inadequate service, financial or operational capacities, which bring into question the legitimacy of its activities during this time. In response to increasing demand by the pharmaceutical sector to raise prices of essential medicines (previously on a 12-year moratorium) by at least 15 percent, the DRA issued a notification on November 27, 2013 raising the cost of all essential medications,

except lifesaving drugs (Junaidi, 2014). On November 28, Prime Minister Sharif instructed the DRA to withdraw the notice. Despite this, in April 2014, it was brought to the attention of the Federal Government that the DRA had allowed drug prices to go up by 30 percent during the past five months, suggesting that DRA officials had colluded with pharmaceutical companies to enable this price hike (Junaidi, 2014).

The DRA has emphasized increasing the pharmaceutical industry's manufacturing capacity to meet the export target of \$1 billion by the end of fiscal year 2015-16, an increase from the current export of \$200 million ("Pharma industry", 2013). However, the DRA has provided little to no support in matching the efforts of the pharmaceutical companies ("Pharma industry", 2013). Furthermore, the DRA's own lack of coordination and capacity has led to active protests by the pharmaceutical giants ("Pharma industry", 2013). According to a recent report, DRA regulations have brought about a significant decline in the growth of the country's pharmaceutical exports: 17 percent during 2012-2013 compared to 35 percent growth in the preceding year ("Essential drugs not being produced", 2013).

Structural Deficiencies of the Drug Regulatory Authority

The Pharmaceutical Industry Expo Center

The major public health challenge facing Pakistan, now delegated as the responsibility of the DRA, is to ensure the safety, quality, and affordability of medicines. However, the DRA has thus far focused primarily on promoting the export potential of the pharmaceutical industry. These activities have been counterproductive to the DRA's main responsibility of regulating the pharmaceutical industry. Increasing export revenue should not be a function of the DRA, as evidenced in how this role affects similar regulatory bodies worldwide (Nishtar, 2013).

Composition of the Governing Board

The DRA's four constituent boards are lopsided in terms of representativeness and conflicts of interest. In particular, the Policy Board is comprised of representatives from key ministries, the provinces and experts from the public and private sectors (Senate Secretariat, 2012). The autonomous function of the DRA in the Drug Act of 2010 is significantly undermined by the presence of government-appointed bureaucrats on the Board. A clear conflict of interest exists as other Policy Board members have been drawn from the pharmaceutical industry, with two seats held by public health specialists (Senate Secretariat, 2012). Therefore, the DRA's ability to fulfill its intended role in a highly politicized system continues to be a challenge.

Funding of DRA

The two major issues concerning DRA's funding are:

1. Lack of a sustainable funding source: The DRA is primarily financed by the Federal Government. A clear indication of the DRA's underfunded state is that it has operated with a mere 225 drug inspectors in the past two years. Despite severe regulatory shortcomings, only 52 new appointments have been made, none of which have been finalized.
2. Absence of accountability to the NHSRC (Federal Government): The DRA is only accountable to its own board members for allocation of funds. This limited accountability has disincentivized the DRA to take necessary steps to regulate the pharmaceutical industry at the national level.

Uncertain Dynamics

In May 2013, the NHSRC issued a notification to remove the controversial Senior Joint Secretary Arshad Farooq Fahim (Acting CEO of the DRA) in the wake of a drug pricing scam. The National Accountability Bureau (NAB) charged the former CEO with raising the prices of drugs to benefit a few select drugs manufacturers ("DRAP CEO Sacked", 2013). This incident has led to a severe dip in national confidence in the DRA. It is also one of the most significant reasons for the departure of numerous multinational pharmaceutical companies from Pakistan in late 2013 ("Non-functioning of DRAP", 2014). Compounding the unstable regulatory mechanism of the DRA is the fact that the organization has never had a permanent

CEO. The post has been temporarily occupied by acting CEO's with inadequate credentials and limited authority to formulate and enforce legislation. The DRA has acted in contradiction with its own constitution by undertaking numerous actions that in principal could not have been initiated under an acting CEO. Most significantly, it has violated the rule that an acting CEO will not occupy this post for over three months (Senate Secretariat, 2012).

Limited Authority

The Drug Act of 2012 gives the DRA more regulatory powers than any drug regulation system in the past. This brief has argued that the DRA's major shortcomings lie with the implementation of existing policy. However, there are certain deficiencies in policy that enhance this policy-practice gap.

1. Federal government employees that have been found to be involved in rampant corruption in drug regulation do not fall under the jurisdiction of the Anti-Corruption Establishment (ACE); "the substandard interferon vaccine case is one example whereby many senior officials were arrested by the provincial units of ACE but could not be convicted" ("Substandard medicines", 2013, p. 1).
2. Healthcare providers such as hospitals and clinics do not have qualified pharmacists capable of identifying fake or spurious drugs. Staff members who act in these capacities also play a role as middlemen, putting new price tags on medicines before selling them, thereby undermining the authority of the DRA. These practices make it difficult to identify the parties responsible for unregulated price increases (Wasif, 2013).
3. Many NHSRC officials argue that the inadequate sentencing practices for offenders involved in the manufacture and sale of spurious or counterfeit medicines do nothing to disincentivize the growth of the black market. The average sentence for an individual convicted in such a case is three to eleven years (Maqbool, 2014; "Dangerous Medication", 2014). The manufacturer of the medicines responsible for the deaths of 125 cardiac patients was held liable for only USD 5,000 per patient ("Contaminated Medicine", 2013).
4. Raids to seize counterfeit or spurious drugs and manufacturing-related items are under the purview of the Federal Investigation Authority (FIA). A raid however, cannot be conducted without the area drug inspector accompanying FIA's team. Subsequent bureaucratic hurdles in the prosecution process, such as gaining permission from the Quality Control Board, take up valuable time and resources (Kharal, 2014).

Conclusion

Drug regulation in Pakistan has been hindered by a persistent policy void between the health sector and the pharmaceutical industry. This disconnect creates shortages in therapeutic products and access to adequate health care services. Healthcare seekers are forced to turn to informal health services where care providers are usually unlicensed, quality of care is frequently substandard and inconsistent, and the volume, quality and authenticity of drugs prescribed and/or sold are unregulated. In the absence of regulatory structures and sufficient resources, the Drug Act of 2012 has failed to significantly impact any aspect of the health sector. It has led to the creation of largely ineffective institutions for regulating the pharmaceutical industry and bridging the gap between production and demand of drugs. These institutions are not regulated and lack accountability mechanisms. Policy interventions must therefore aim at streamlining the process of production and procurement of essential drugs to eliminate drug shortages, and address the issue of cost escalation to ensure access to formal medical treatment options. On the demand side, the DRA must initiate awareness

² In 2009, a severe form of drug-resistant Hepatitis-C virus spread in various parts of Pakistan due to the use of substandard Chinese biomedicine being used in government -run programs. The drugs, procured by the federal and provincial governments under the Prime Minister's and Chief Ministers' Program for Hepatitis Control, led to the discovery of deep rooted corruption in these programs. In the aftermath of the hepatitis surge in 2009, legal action against the officials involved was taken by the supreme court of Pakistan (Naurukh, 2009).

campaigns to enable consumers to make informed decisions regarding health seeking behavior. While an extensive policy reform is needed to address the declining health status of Pakistan, this paper captures the role of health financing, human resource planning, service delivery and governance structures in regulating the pharmaceutical industry of the country. Future research should analyze policy options to address the institutional deficiencies of the DRA, recommend best pharmaceutical practices within the Pakistani context, and explore opportunities for greater integration of the pharmaceutical industry into the health delivery system of the country.

References

- Achakzai, J. (2014, January 06). "DRAP okaying drugs even earlier than western counterparts: chief?". *The News International*. Retrieved from <http://www.thenews.com.pk/Todays-News-6-224778-DRAP-okaying-drugs-even-earlier-than-western-counterparts-chief>
- Amin, T. (2013, December 05). "11 foreign pharmaceutical companies closed business, Senate body told". *Business Recorder*. Retrieved from <http://www.brecorder.com/business-and-economy/189:pakistan/1261235:11-foreign-pharmaceutical-companies-closed-business-senate-body-told?date=2013-12-05>
- Butt, Z.A., Gilani, A.H., Nanan, D., Shiekh, A.L., & White, F. (2005). Quality of pharmacies in Pakistan: A cross-sectional survey. *International Journal for quality in Healthcare* 17(4), 307-313. Retrieved from <http://intqhc.oxfordjournals.org/content/17/4/307>
- Contaminated medicine: Supreme Court orders manufacturers to raise compensation. (2013, December 25). *The Express Tribune with the International New York Times*. Retrieved from: <http://tribune.com.pk/story/650137/contaminated-medicine-supreme-court-orders-manufacturers-to-raise-compensation/>
- Dangerous medication: Health minister for amending drug act to enhance punishment. (2014, April 4). *The Express Tribune with the International New York Times*. Retrieved from: <http://tribune.com.pk/story/691109/dangerous-medication-health-minister-for-amending-drug-act-to-enhance-punishment/>
- DRAP CEO Sacked. (2013, May 31). *Pakistan Today*. Retrieved from <http://www.pakistantoday.com.pk/2013/05/31/city/islamabad/drap-ceo-sacked/>
- Drug regulator's initiative 'to increase transparency.' (2014, April 22). *The Express Tribune with the International New York Times*. Retrieved from <http://tribune.com.pk/story/698607/drug-regulators-initiative-to-increase-transparency/>
- Essential drugs not being produced. (2013, October 4). *Dawn News International*. Retrieved from <http://www.dawn.com/news/1047348>
- Government of Pakistan, The Drugs Act, 1976 (XXXI of 1976). Islamabad: Government of Pakistan. Retrieved from <http://www.ppma.org.pk/pdf/The%20Drugs%20Act,%201976.pdf>
- Government of Pakistan, Pharmacy Act 2009. Islamabad: Government of Pakistan. Retrieved from <http://www.pcdapakistan.com/wp-content/uploads/2013/04/Proposed-New-Pharmacy-Act-2009.pdf>
- Hafeez, A., Kiani, A.G., Din, S., & Muhammad, W. (2004). Prescription and dispensing practices in public sector health facilities in Pakistan: Survey report. *Journal of Pakistan Medical Association*, 54(4), (pp.187-191) Retrieved from <http://jpma.org.pk/PdfDownload/381.pdf>
- Hussain, S., Malik, F., Khalid, N., Qayyum, M.A. & Riaz, H. (2012). Alternative and traditional medicines systems in Pakistan: History, regulation, trends, usefulness, challenges, prospects and limitations. Bhattacharya, A. (ed.), *A Compendium of Essays on Alternative Therapy* (pp. 89-108). Retrieved from <http://cdn.intechopen.com/pdfs-wm/26489.pdf>
- Jooma, R. (2010). Pakistan: pharmaceutical country profile. Ministry of Health, Pakistan. World Health Organization, Retrieved from <http://www.who.int/medicines/areas/coordination/pakistan.pdf>
- Junaidi, I. (2013, June 19). Prices of pharmaceuticals likely to increase. *Dawn News*. Retrieved from <http://www.dawn.com/news/1019253>
- Junaidi, I. (2014, March 29). Prices of life-saving drugs increased by around 30pc..*Dawn News*. Retrieved from <http://www.dawn.com/news/1096281>

- Khan, A.S., (2013, April 13). Moratorium on drug prices imposed. *Dawn News*. Retrieved from: <http://www.dawn.com/news/802197/moratorium-on-drug-prices-imposed>
- Kharal, A., (2013, April 27). Bad medicine: Over 450 pharmacies selling spurious drugs in Lahore. *The Express Tribune with the International New York Times*. Retrieved from: <http://tribune.com.pk/story/700743/bad-medicine-over-450-pharmacies-selling-spurious-drugs-in-lahore/>
- Khowaja, K. (2009). Healthcare systems and care delivery in Pakistan. *The Journal of Nursing Administration*, 39(6), (pp.263-265) Retrieved from http://www.nursingcenter.com/lnc/journalarticle?Article_ID=865859
- Legatum Institute. (2013). Prosperity index. Retrieved from <http://www.prosperity.com/#!/country/PAK>
- Maqbool, S. (2014, April 4). Saira wants stricter penalties for spurious drug manufacturers. *The News International*. Retrieved from <http://www.thenews.com.pk/Todays-News-6-242156-Saira-wants-stricter-penalties-for-spurious-drug-manufacturers>
- Nafees, A.A., Nayani, N. (2011). Stewardship in Health Policy and its relevance to Pakistan. *Journal of Pakistan Medical Association* 61(8) pp. 795-800. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/22356005>
- Naurukh (2009). Substandard interferon spreading worst form of Hepatitis-C in Pakistan. *Health Aware*. Retrieved from: <http://healthcommunicationforum.blogspot.com/2009/12/substandard-interferon-spreading-worst.html>
- Nishtar, S. (2006). Pharmaceuticals – Strategic considerations in health reforms in Pakistan. *Journal of the Pakistan Medical Association* 56 (12 Suppl 4), S100-11. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/17595837>
- Nishtar, S. (2010). Choked Pipes: Reforming Pakistan’s Health System. Oxford: Oxford UP, 2010. ISBN 978-0-19-547969-0
- Nishtar, S. (2013). Handover papers. Federal Minister for Education and Trainings; Science and Technology; and Information Technology and Telecom. *Government of Pakistan*. Retrieved from: <http://sanianishtar.info/handoverpapers.php> (not available online)
- Non-functioning of DRAP: 'Pharmaceutical MNCs diverting investments to India, Bangladesh. (2014, March 19). *Business Recorder*. Retrieved from <http://www.brecorder.com/business-economy/189/1164140/>
- Pakistan Medical and Dental Council. (2011). *Code of ethics of practice for medical and dental practitioners*. Islamabad: Pakistan Medical and Dental Council. Retrieved from <http://www.pmdc.org.pk/LinkClick.aspx?fileticket=v5WmQYMvHz4%3D&tabid=292&mid=845>
- Pakistan Bureau of Statistics. (2014). *Pakistan Employment Trends 2013* Islamabad: Pakistan Bureau of Statistics. Retrieved from http://www.pbs.gov.pk/sites/default/files/Labour%20Force/publications/Pakistan_Employment_2013.pdf
- Pharma industry: PPMA sets \$1b export target by 2015” (2013, October 2). *The Express Tribune with the International New York Times*. Retrieved from <http://tribune.com.pk/story/612135/pharma-industry-ppma-sets-1b-export-target-by-2015/>
- Rind, H.M. (2014, March 19). Pharma industry in doldrums. *The News – International*. Retrieved from <http://www.thenews.com.pk/Todays-News-3-239019-Pharma-industry-in-doldrums>
- Senate Secretariat. (2012, November 13). Drug Regulatory Authority of Pakistan Act 2012”, *The Gazette of Pakistan*. Retrieved from: http://www.na.gov.pk/uploads/documents/1352964021_588.pdf
- Senate body meeting: Drug pricing policy being prepped, says health ministry. (2013, December 5). *The Express Tribune with the International New York Times*. Retrieved from <http://tribune.com.pk/story/641202/senate-body-meeting-drug-pricing-policy-being-prepped-says-health-ministry/>
- Shaikh, B.T., & Hatcher, J. (2004). Health seeking behaviour and health service utilization in Pakistan: Challenging the policy makers. *Journal of Public Health* 27(1), 49–54. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/15590705>

- Sharif, F., & Anis, K. (2012, May 17) Stopping fake drugs from Pakistan - Is it too late for Victims? *Bloomberg News*. Retrieved from <http://www.bloomberg.com/news/articles/2012-05-17/stopping-fake-drugs-from-pakistan-is-too-late-for-victims>
- Substandard medicines: Court directs NAB to probe spurious drug suppliers. (2013, October 23). *The Express Tribune with the International New York Times*. Retrieved from <http://tribune.com.pk/story/621082/substandard-medicines-court-directs-nab-to-probe-spurious-drug-suppliers/>
- Sudhinaraset M., Ingram M., Lofthouse H. K., & Montagu, D. (2013). What is the role of informal healthcare providers in developing countries? A systematic review. *PLoS ONE* 8(2), e54978. doi: 10.1371/journal.pone.0054978. Retrieved from <http://www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0054978&representation=PDF>
- Sumbal, M. A. (2014, May 13). How to resolve Pakistan's polio crisis. *Aljazeera*. Retrieved from <http://www.aljazeera.com/indepth/opinion/2014/05/how-resolve-pakistan-polio-crisis-2014512183943196148.html>
- Vakani, F., Naqvi, K., & Amin, A. (2011). Content audit of drug advertisements in Pakistan. *Indian Journal of Medical Ethics* 8(3) pp. 167-169. Retrieved from <http://ijme.in/~ijmein/index.php/ijme/article/view/232/403>
- Wasif, S. (2013, December 03). Medicines: Sans approval, pharma companies hike prices. *The Express Tribune with the International New York Times*. Retrieved from <http://tribune.com.pk/story/640284/medicines-sans-approval-pharma-companies-hike-prices/>
- Yip, W.C., Wang, H & Liu, Y. (1998). Determinants of patient choice of medical provider: a case study in rural China. *Health Policy and Planning*. 13(3). 311-322. Oxford: Oxford UP. Retrieved from http://archives.who.int/tbs/ChinesePharmaceuticalPolicy/English_Background_Documents/ArticleReprints/Determinantspatientchoicemedicalprovider.pdf
- Zaidi S., Bigdeli M., Aleem N., & Rashidian A. (2013). Access to essential medicines in Pakistan: Policy and health systems research concerns. *PLoS ONE* 8(5), e63515. doi: 10.1371/journal.pone.0063515.
- Zaidi S., & Nishtar, N. A. (2011, August). *Access to essential medicines: Identifying policy research and concerns*. . Aga Khan University, Karachi, and the Alliance for Health Policy & Systems Research, WHO. Retrieved from http://www.who.int/alliance-hpsr/projects/alliancehpsr_atmreportpakistan.pdf