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Historical Evolution of Drug Laws in Pakistan: Regulating the Regulators and Healthcare Industry

Abstract

The use of healthcare products is as old as the history of human beings. Initially, herbs were the core mode of treatment both for human beings and animals. Latterly, with the advancement of technology, more modes of treatment evolved e.g., unani, ayurvedic, homeopathic, allopathic etc. After the incident of Thalidomide tragedy in 1962 in US and Europe; people demanded from their governments and regulators to make strict rules & regulations to check safety and efficacy before registration of any product which ultimately emerged a new era for the development of drugs laws in the world. After independence of Pakistan, Pharma business was regulated by Drugs Act, 1940 which latterly replaced with Drugs Act, 1976 for manufacturing, distribution, sale, import and export of pharmaceutical products. After 18th Amendment in the Constitution of Pakistan, 1973; the DRAP Act, 2012 was promulgated that is fundamentally an extension of Drugs Act, 1976. Pakistan, being the semi-regulated market of healthcare products has number of challenges including:

i. *Lack of customer / patient trust on the quality of healthcare products*

ii. *Decreasing trend in the export of healthcare products*

iii. *Absence of Pakistani healthcare products in regulated markets i.e. USA, EU, Australia, Canada, Japan etc.*

The trust of customer / patient can be conquered by producing quality healthcare products as per International Standards i.e. FDA, WHO, ICH, PIC/S etc. which ultimately lead to enhance export of healthcare products resulting in valuable exchange for Pakistan. Above milestones can be achieved by aligning following sectors:

i. *Promulgate appropriate drug laws to manufacture safe, effective, and quality healthcare products.*

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ii. Capacity building of Pakistani drug regulatory authorities, industries, and drug courts

iii. Revamp Pakistani government policies to enhance export of healthcare products.

iv. Register/export Pakistani healthcare products in regulated markets.

Keywords: Healthcare products; Drug laws; Government policies; Enhance export

1.0 INTRODUCTION

The use of medicines is as old as history of human being. Initially, herbs were the core mode of treatment both for human beings and animals. Latterly, with the advancement of technology, more modes of treatment evolved e.g., unani, ayurvedic, homeopathic, allopathic etc. The use of herbal medicines declined in late 19th and early 20th centuries[1]. After the incident of Thalidomide tragedy[2] in 1962; in which more than 10,000 malformed births (phocomelia) leading to make strict drug laws to manufacture safe, effective and quality products.

After 1970, most of the countries; developed / revised their drug laws, rules, regulations and guidelines. There was also a paradigm shift to revamp regulatory authorities and build their capacities to regulate pharma business. It was also proposed at international level to harmonize the pharma guidelines for common understanding of industrialists and regulators. The first step was initiated by European Commission (EC) in 1980 to develop single market for pharma products. Later-on US, Europe and Japan jointly discussed to harmonize regulatory requirements which further materialize in 1989 in WHO conference of International Drug Regulatory Authorities (ICDRA) held at France. International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) approached regulatory authorities to harmonize pharma guidelines resulting in conception of International Conference on Harmonization (ICH) guidelines in April, 1990[3].

Before independence of Pakistan, pharmaceutical industry was regulated by the Drugs Act, 1940 in the sub-continent[4]. This Act provided basic guidelines to manufacture, distribution, sale, import and export of drugs. In order to check the standard of the drugs, central drug laboratory was established whereas drug inspectors have been provided for implementation of the provision of this Act. The procedure for certification of the drugs along with issuance of licenses for manufacture, stock, sale and distribution of the drugs was also mentioned.

In 1976, Drugs Act was promulgated in order to cope the scientific advancement and cover the shortcomings of the Drugs Act, 1940. The manufacture, import, export and sales of drugs without license is banned, whereas the sale of the drugs in the streets is prohibited. Like previous Act, the procedure for stock and sale of the drugs is provided along with setup of drug testing laboratory, the registration of drugs is also required, whereas the most important feature of this Act was establishment of drug court headed by chairman (qualified to become the judge of

high court) and two expert members in pharmaceutical or medical field. Later on, following rules were made to strengthen the regulatory system in Pakistan:

- The Drugs (Licensing, Registration & Advertising) Rules, 1976
- The Drugs (Import & Export) Rules, 1976
- The Drugs (Labeling & Packing) Rules, 1986

After 18th Amendment in the Constitution of Pakistan, 1973; Ministry of Health (including Drug Control Administration) devolved at federal level and provinces were empowered to make rules for their pharmaceutical sector. A concern was raised on the devolution of drug regulation at that time when elsewhere in the world countries are moving towards regionalization models of drug regulations. Sooner, it was realized that licensing, registration, pricing, import, export etc. cannot be regulated at provincial levels so all provincial assemblies passed resolutions in favor of parliament asking for federal legislation in pharmaceutical sector. In lieu of that the DRAP Act, 2012 was promulgated; replaced the Drugs Act, 1976 that is fundamentally an extension of the Drugs Act, 1976.

Alternative Medicines (unani, ayurvedic, homeopathic, Chinese, biochemical etc.) & Health & OTC products (probiotics, disinfectants, food supplements, nutraceuticals, baby milk, medicated cosmetics etc.) were non-regulated till promulgation of "Alternative Medicines & Health Products (Enlistment) Rules, 2014". Said legislation is still *sub-judice* which is hampering to regulate Alternative Medicines and Heath & OTC products. Provincial governments are regulating pharma business w.r.t. distribution and sale by following rules:

- Punjab Drug Rules, 2007
- Sindh Drug Rules, 2010
- KPK Drug Rules, 2017
- Baluchistan Drug Rules, 2018

Pakistan, being the semi-regulated market of healthcare products has number of challenges including:

iv. Lack of customer / patient trust on the quality of healthcare products

v. Decreasing trend in the export of healthcare products

vi. Absence of Pakistani healthcare products in regulated markets i.e. USA, EU, Australia, Canada, Japan etc.

2.0 LITERATURE REVIEW

The use of medicinal herbs is as old as the history of mankind but concept of quality of said herbs evolved with the passage of time. The first Pharmacopoeia was issued in Europe as Spanish Pharmacopoeia in 1581[5]. The development of

medicinal regulations started in 19th century which further speed-up after unfortunate event in 1937 when more than 100 people of US died due to poisoning of diethylene glycol being used as solvent in sulfanilamide elixir. This incident instigated the promulgation of Food, Drug and Cosmetic Act, 1938 to get registration before marketing of any new drug.

Another disaster which triggered governments and regulators to promulgate strict rules and regulations for the registration of drugs was "Thalidomide tragedy". In 1958, Thalidomide drug was used as sedative and hypnotic in western Germany but latterly in 1962, it was used in 46 countries for nausea and morning sickness in pregnant women without determining its safety in pregnant women. This resulted in catastrophic incident of 10,000 babies' birth without limbs (phocomelia) and other deformities. The whole world reshaped their drug laws, rules, regulations, guidelines etc. In 1962, US promulgated the Drug Amendment Act, 1962 and made it mandatory for Food and Drug Authority (FDA) to check safety and efficacy data before registration of any new drug. In 1963, UK established a Committee on the Safety of Drugs (CSD) and latterly in 1964, introduced a voluntary Adverse Drug Reaction (ADR) reporting system.

After independence of Pakistan, a number of drug laws/rules were promulgated to regulate pharmaceutical industry. In 2010, health services including drugs were shifted from federal to provincial governments and as a result it became difficult for provincial governments to regulate pharmaceutical industry with reference to licensing, registration, pricing etc. So due to major gaps in its implementation; provincial governments passed their resolutions and requested to federal government to establish centralized drug regulatory authority[6]. As a result, federal government established an independent authority with the name of Drug Regulatory Authority of Pakistan (DRAP) under the ambit of Ministry of National Health Services, Regulations & Coordination[7].

The drug court system of Pakistan is as primitive as other judicial systems of Pakistan. Currently, nine drug courts at Lahore, Gujranwala, Rawalpindi, Faisalabad, Multan, Karachi, Quetta, Peshawar and Islamabad are operating with Chairman and two technical members. Pakistan drug judicial system is too conventional to restrict spurious, sub-standard and counterfeit drugs ultimately creating disruption and disappointment in the society by failing to punish the culprits[8].

3.0 ANALYSIS OF PAKISTANI DRUG LAWS

3.1 The Drugs Act, 1940

Notwithstanding Dangerous Act, 1930, the Drugs Act, 1940 has been declared so as to control, import, trade, manufacture, distribution and offer of medication[9]. The medications have characterized under Section 3 of the Act. Under Section 5 of the Act, drugs technical advisory board was established to guide the central government on specific issues evolving out of organization of the demonstration and doing different capacities doled out to it by this demonstration, under executive ship of Director General Health, Chief of the Central Government Department of the Lab, Executive Central Drugs Lab and Head of the Pakistan

Animal Husbandry Research Institute Foundation or it's ex-office individuals while, there are seven other chosen and one elected member by the Central Council of Pakistan Medical Association. Under Section 6 of the Act, central medications consultative council, to guide the central government and the medications counselling board on any issue having a tendency to secure consistency throughout central laws. Section 10, accommodates preclusion on accommodates utilization of the Customs Act, 1978 import of medications underneath the standard quality, misbranded, denied, or without the recommended permit and so on certain and Section 11 on import of medications. Section 12 accommodates energy of focal government to make rules for import of medications in discussion with board, subject to production in official periodical.

3.2 The Drugs Act, 1976

This Act was promulgated after repeal of Drugs Act, 1940[10], the purpose of repeal of old Act was to introduce a more exhaustive enactment to cope with scientific advancement and cover the areas and violations which were being committed by the drug companies as well as individuals by taking undue benefit of loop holes existing in the previous Act. Another purpose of this Act was to bring harmony in the drug laws of different provinces and areas. The definition of drugs is almost same as in the previous Act; however, the definition of misbranded drugs is made more exhaustive.

Under this Act, other than misbranded medications, bogus drugs, fake medications, debased medications, substandard medications are banned; the offer of any medication after its expiry date, any medication which by methods for any announcement, any medication in the event that is hazardous to wellbeing when utilized as a part of the measurements or with the recurrence or for span determined, prescribed in the naming thereof; or any administer is restricted and sentence has been repudiation of state of permit, which is essential for these reasons.

Under new order supply of mistaken, deficient or deceiving data when required to outfit is an offence; in like manner most comprehensive control of offer of medications in boulevards is given; import, fabricate available to be purchased or offer of any substance or blend or substances which is not a medication yet displayed in a frame or way proposed or prone to cause open trust it to be sedate is precluded; sale of any drug without having warranty, the name and batch number of drugs is prohibited; likewise, in case of manufacture that drug is required; in case of imported drug such license and permission is required by importer and intender; moreover, application of incorrect batch number to a drug is also prohibited and penalty has been provided for such violation under Section 27; like previous act enhanced punishment is provided for repetition of offence under Section 28 and Section 29 provide for forfeiture of drugs or stock of drugs in case of conviction, central licensing board is constituted by Federal Government consisting upon the representatives of Federal as well as Provincial Governments for grant of licenses for manufacture of drugs; the members of board shall exercise powers as may be prescribed, including the powers of an Inspector. An Appellate Board is also provided for referring appeals against decisions of central licensing

board. The registration of drugs and prices of drugs are fixed by federal government whereas sale of drugs is regulated by provincial governments.

The provincial governments are required to setup a Provincial Quality Control Board (PQCB) consisting upon Chairman and Secretary, along with such individuals as government may name now and again. PQCB is involved to inspect any premises where in a medication is being manufactured and sold along with investigating the reports of common-place monitors in regard of repudiations of this demonstration and reports of government examiner in regard of medication sent to them for test and examination along with issuance of guidelines to overseers to the move to be made on such reports. Federal Government may establish a drug testing laboratory and others drugs testing institutes for the purpose of this Act; whereas, Provincial Governments are also permitted to setup such laboratories. Federal Government is empowered to appoint government analysts; however, the inspectors may be appointed by Federal Government as well as Provincial Government, who like previous Act have the powers of inspection, entry search and seizure. They also have the powers of lock and seal of any factory, laboratory shop, building, store house or go-down used for manufacture, store or sale of drugs in contravention of this Act. The procedure for inspection, search and seizure has also been provided. Under Section 31 of the Act, Drugs Courts have been setup by governments who should likewise determine the territorial limits of jurisdiction of court.

3.3 The Drugs (Licensing, Registering & Advertising) Rules, 1976[11]

Licensing is granted for basic, semi-basic, formulation, repacking and experimental manufacturing purposes. Upon satisfactory Good Manufacturing Practices (GMP) compliance mentioned in Schedule B-II of these rules, license is granted for 5 years which is further renewed after every 5 years. Central Licensing Board (CLB) is authorized to issue above license; CLB consists of DRAP officials, experienced professionals of pharmaceutical field along with representatives of provincial regulatory authorities and Pharma Associations. All members of CLB have powers of Drug Inspector to inspect any manufacturing facility with or without prior notice. CLB grants permission of contract manufacturing to licensed manufacturers for their registered products from other manufactures on genuine reasons by complying conditions mentioned in Schedule G of these rules. CLB may revoke / cancel licenses in lieu of any regulatory non-compliance.

Registration of products is the key role of DRAP. Registration of products is granted for local manufacturing and imported products. Drug Registration Board (DRB) is responsible to grant registration of any product upon fulfilling regulatory requirements as mentioned in these rules. DRB comprises of DRAP officials, technical personnel of pharmaceutical / medical field along with representatives of provincial regulatory authorities and Pharma Associations. The members of DRB have powers of Drug Inspector to inspect any facility. The registration is granted for 5 years by fulfilling conditions of registration. The renewal is done after every 5 years. Registration of any product can be revoked / cancelled upon non-satisfactory compliance.

The advertisement of registered products mentioned in Schedule D-1 is permissible on print and/or electronic media by taking requisite DRAP approval. The advertisement of other registered products can be done to healthcare practitioners by just submitting a copy to DRAP. DRAP may modify the submitted advertisement material and/or cancel granted approval. The advertisement material should neither attract self-medication nor discredit other products. The superlative words e.g., the most potent, the most efficacious, effective in all cases etc. are not allowed as per these rules.

3.4 The Drugs (Import & Export) Rules, 1976[12]

The regulations to import and export drugs is indispensable for a country so that quality medicines may be available to patients / consumers for their well-being. The import of Active Pharmaceutical Ingredients (APIs) and finished products is being regulated by regional DRAP offices. The import of APIs and finished products is only permissible to licensed manufacturers and importers respectively who have proper storage and distribution facilities. DRAP officials may inspect at their facilities to check Good Storage and Distribution Practices (GS&DP) compliance and take samples for analysis from government laboratories. Small quantities of APIs/drugs can be imported for clinical trial, analysis, product development, personal use etc. by getting DRAP approval and there is condition to take record of all these products. The import license is being granted for 2 years which can be suspended / canceled if there will be any regulatory non-compliance. The Customs Department will not release any pharmaceutical product until unless there will DRAP approval for the said material. The customs department may take samples of imported products for any investigation thereof as per their rules.

The export of any product is always encouraged by government because it is generating revenue for the country. In lieu of that export of APIs / finished products is permissible subject to fulfilling conditions of said rules. DRAP regional offices are granting No Objection Certificate (NOC) to export pharmaceutical products. The export license is granted for 2 years which may be suspended or canceled due to any violation. The Customs Department may counter check on exported products as per their rules.

3.5 The Drugs (Labeling & Packing) Rules, 1986[13]

The Drugs (Labeling and Packing) Rules, 1986 describe the mandatory packaging requirements to distribute and sell the pharmaceutical products in Pakistan. The packaging components of marketed products should mention brand & generic names; composition & product specifications; instructions & dosage; license, registration & batch number; manufacturing & expiry dates; maximum retail price. Some information i.e., brand name of product, dosage and instructions should be in Urdu language to facilitate layman. Recently, DRAP has implemented printing of 2-D barcoding on pharmaceutical products to eradicate menace of counterfeit products in the market. In addition to above requirements, customized printing will be done e.g. “Physician’s sample: Not for sale”, “Government Supply”, “For veterinary use only”, For external use only” etc. For exported products, the rules of exporting country may be adapted.

3.6 The Drug Regulatory Authority of Pakistan Act, 2012[14]

After 18th amendment in the constitution of Pakistan, there was a huge gap between federal and provincial regulatory authorities to regulate the pharmaceutical business. Federal Ministry of Health including Drug Control Administration devolved and transferred to provincial governments but pharmaceutical industry was very disturbed because of licensing, registration, pricing, import and export matters because there were no laws at the end of provincial governments to settle above matters. Provincial Assemblies passed resolutions, asking the Parliament to make legislation at federal level.

So, the DRAP Act, 2012 promulgated and established a well-defined regulatory authority to regulate licensing, registration, pricing, quality assurance, laboratory testing, controlled drugs, pharmacy services etc., aspects of pharmaceutical industry. The Authority comprises of Chief Executive Officer (CEO) and 13 Directors for smooth working of DRAP.

Alternative Medicines (*unani, ayurvedic, homeopathic, Chinese, biochemical* etc.), Health & OTC products "non-drugs" (*probiotics, disinfectants, food supplements, nutraceuticals, baby milk, medicated cosmetics* etc.), Medical device and Medicated cosmetics were defined and included under drug definition so proper legislation and registration may be done to regulate these disciplines.

3.7 The Alternative Medicines & Health Products (Enlistment) Rules, 2014[15]

The concept of introducing health products is to ensure that they contained effective and save ingredients that can maintain health without physician's care. To ensure the regulation DRAP has made official proclamation of the Alternative Medicines and Health Products (Enlistment) Rules, 2014. Health & OTC products division was made which is responsible for the licensing, assessment and enlistment of Alternative Medicines.

In 2018, it was further urged to enhance pace of the work from now to onward, based upon FIFO policy, record to be maintained accordingly in the division, and cases be processed as per their respective submission[16]. The automation should be used as a tool in order to ensure efficiency & transparency. Specific timelines were suggested for enlistment of Manufacturer/Importer (Form-6), product (Form-7) and contract manufacturing (Form-8) in order to facilitate business development opportunities.

Previously no minimum area was defined of manufacturing units of alternative medicines and units having minimum area of 5 marlas or 10 marlas was also enlisted. However, to provide safe and effective health care product, minimum area requirements were suggested as 2 kanals. Similarly, manufacturing of Alternative medicines and health product in same premises in which allopathic products prepared was discouraged in order to avoid contamination. If dedicated units for alternative manufacturing are located / established in the same area along-with dedicated allopathic facility, shared testing label are made available for both categories. No other common usage will be acceptable.

DRAP is authorized to establish laboratory to certify quality of alternative medicines and Health & OTC products in the market. For this purpose, Central Drug Laboratory (CDL), Karachi was equipped with logistics and responsible for testing / analysis of all such products. In order to cater the work load other labs also shared the responsibilities.

DRAP was in the course of developing software to gratify the enlistment of the alternative medicines as per practice of stringent regulatory bodies.

3.8 The Punjab Drug Rules, 2007[17]

Enforcement of Punjab Drug Rules, 2007 was made to ensure all federal and provisional pharmaceutical legal and regulatory compliance. The government appointed representatives of Provincial Quality Control Board (PQCB), District Quality Control Board (DQCB). The members of Board shall exercise the powers including the power of government analyst/inspector. The government analyst/inspector is responsible for the submission of monthly report on Form 1 and Form 2 to District and Provisional Boards.

An Inspector who is appointed under this Act is responsible for the proper investigation, record maintenance, seizures of drugs or equipment and report submission. During a period of inquiry analyst will not disclose any information to unauthorized person regarding samples that was picked up, properly sealed and sent to drug testing laboratory to assure the quality. A report shall be generated and proper record was submitted to government for seeking further investigation. The overall summary of all records shall be maintained by District Board and Provincial Board for proper review of performance of manufacturers and sellers. The Government (Provincial and District Boards) arrange a meeting as to highlight issues and resolve and to have grip on situation regarding quality and availability of drugs in the market.

In case, any act against the rule is observed by the Provincial or District Board, show-cause notice is issued to the person providing him a chance for hearing before taking the action for recommending cancellation and suspension of license. In minor situation, the Provincial or District Board may forbid a person either manufacturer or seller for period not more than 3 months with condition of improvement in product quality and distribution along with instruction of de-sealing, removing or disposing drug and in other cases recall a batches. Case shall be referred to Drug Courts if serious misconduct was committed by the company, corporation, firm or seller who is responsible for the quality, maintenance and effective distribution of drug. In exercise of the Punjab Drug Rules, 2007 a specific condition was implemented for the issuance of license. Licensing authority may responsible for the issuance of license (Form 9 & Form 10) of pharmacy and medical store.

An authorized person who is qualified as per Pharmacy Act, 1967 shall supervise sale of drug and maintained record for at least 3 years. The license shall remain in force for two years after the day of issuance. With subject to rules, drugs that fall under the category of schedule G, B & D should sell under specific conditions, on prescription and proper record should be maintained by an authorized person.

Drugs that is present in schedule E fall under list of poison and are placed in separate section. All these drugs should be dispensed with proper labelling mentioning word 'poison' on it. On 10th February, 2010, the Governor[18] of the Punjab pleased to make amendments in order assure the quality, safety, distribution of drugs, according to which drugs should be properly distributed and sold under supervision of an authorized person who should be a pharmacist and qualified from a recognized university.

3.9 The Sindh Drug Rules, 2010[19]

The Drug Rules, 1979 were amended by the Sindh Government in March, 2010 without taking into confidence the stakeholders. All amendments were associated with health department in which it was considered compulsory that board members, inspectors & analysts must be pharmacy graduates and should have relevant experience. Board members consist of Secretary, Additional Secretary, officer of Provisional Drug Administration, one member of pharmacy profession, pharmacologist and one professor of medicine. Meeting of the Board shall be mandatory at least once in every two months. Provided further, person appointed as inspector or analyst must have a pharmacy degree from a Pakistani recognized university and must be responsible for submission of monthly report to the Board.

Furthermore, licensing authority made it mandatory that person who is willing to grant registration, renewal of sale license shall submit written authorization. The licensing authority shall submit report on monthly basis to the Board containing all relevant details of the person who made application for grant of registration, renewal of sale license. Written application consists of details of facility, stocking, storage of drugs and facility of refrigerator in order to preserve the medicines. Sale of drugs will be carried under the supervision of authorized person who is registered as a pharmacist as per Pharmacy Act, 1967. Proper record must be available of any drug sold and shall be archived at-least for three years. Moreover, drugs fall under Schedule B, E & F shall not be sold by way of retail except on prescription of a doctor. Such drugs shall be stored in a separate drawer in lock & key and proper registered must be maintained relating to sale of drugs.

These amendments were made to improve the quality of healthcare services and prohibiting quackery in the Province of Sindh. These rules have brought at brink employment of hundreds of youths besides generating problems for traders, complained of. The Association had on April 29, 2012 sent proposals to Health Secretary for inserting in it amendments but without any response. Unfortunately, the Sindh Government did not take into consideration the licence of wholesalers for running the business. There are around 20,000 wholesalers in the Province. The B. Pharmacy Council had made mandatory for dispensers doing refresher training courses. The disparity would likely hit the medicine trade in Sindh as no dispenser would get his licence renewed without undertaking the refresher course, adding new rules required a dealer to obtain two licenses, one for retail business and another for trading.

3.10 The KPK Drug Rules, 2017[20]

The Drug Rules, 1982 were amended by the KPK Government in 2017. The Government decided to amend the rules to cater current challenges and support important segments. Rules limitations were also observed by the Provincial Quality Control Board during examining the cases as put by drug inspectors and took decisions for prosecution to drug court. The KPK Drug Rules, 2017 imposed strict conditions to operate pharmacies, medical stores and wholesale outlets including sale of drugs under the supervision of qualified person only. As long as sale outlet is open, qualified person must be in the premises. Sale of drugs will be done on doctor's prescription only. Pharmacies, medical stores and wholesale outlets will display their licenses at visible place. The signboard of pharmacies will be of red color with white writing whereas medical store signboard will be green with white writing and wholesale signboard will be of black color with white color writing.

In amended rules, it was required to construct sale outlets with concrete structure and take measures to avoid exposure of sun and dust. It was also required that the temperature of sale outlets should be controlled as per storage conditions of drugs and for temperature sensitive drugs, refrigeration facility should be available in the premises. Drug inspectors were made bound to issue licenses within stipulated time. There is urgent need to implement good storage and distribution practices (GS&DP) as per international standards or as specified by DRAP. There is also need to ensure 100% presence of qualified person on sale outlets.

3.11 The Baluchistan Drug Rules, 2018[21]

Rule of law is the most important priority of Government of Baluchistan which has taken a solid step by inaugurating the Drug Delivery Unit with the cooperation of United Nations Office on Drugs and Crime (UNODC). In 2018, the Baluchistan Government passed the Drug Rules with intention to restrict sale of fake and counterfeit medicines and promote sale of quality medicines under the supervision of qualified persons. As per amended rules, commissioners of all divisions will chair Quality Control Board whereas deputy commissioners, drug inspectors and health department officials will be its members. If there will be any non-compliance of the rules as observed by drug inspector, board has authority to take strict action and prosecute the matter in the Drug Court.

Baluchistan Government established a special task force to eradicate menace of spurious and counterfeit drugs. Special task force took crackdown against drug mafia and prosecuted a number of culprits. There are still gaps for the implementation of Drug Rules, 2018 resulting in sale of fake and counterfeit medicines. Sale outlets are not maintaining their proper sale record including controlled drugs which is mandatory as per rules. Sale of medicines without prescription and in the absence of qualified persons are still grey areas.

4.0 ANALYSIS OF DRUG REGULATORY AUTHORITIES OF PAKISTAN

4.1 Drug Regulatory Authority of Pakistan (DRAP)[22]:

Drug Regulatory Authority of Pakistan was established in lieu of DRAP Act, 2012 to regulate manufacturing, storage, distribution, sale, import and export of therapeutic goods in Pakistan. DRAP's main objective is to ensure safety, efficacy

and quality of medicinal products for the people, patients and consumers of Pakistan. DRAP has following 13 divisions under the leadership of Chief Executive Officer (CEO):

1. Licensing
2. Pharmaceuticals Evaluation & Registration (PE&R)
3. Biological Drugs
4. Controlled Drugs
5. Health & OTC
6. Medical Devices & Medicated Cosmetics (MD&MC)
7. Pharmacy Services
8. Quality Assurance & Laboratory Testing (QA&LT)
9. Costing & Pricing
10. Legal Affairs
11. HR & Administration
12. Management Information System (MIS)
13. Budget & Accounts

Licensing Division is responsible to grant license to Active Pharmaceutical Ingredient (API) and Finished Pharmaceutical Product (FPP) manufactures and also handle its associated matters. It's all the times objectionable that why even a single unit among 700 DRAP approved units could not qualify USFDA standards. There is need to upgrade licensing requirements as per international standards so that said units may qualify stringent regulatory authorities (SRA) requirements which ultimately will uplift Pakistan's image and enhance export. There is also need to facilitate companies to produce APIs in Pakistan.

PE&R Division is responsible to grant registration of pharmaceutical products for human and animals after requisite assessment & evaluation. PE&R is also performing other functions as assigned by the Board. PE&R has upgraded and implemented its product registration requirements (Form 5-F / CTD) as per ICH guidelines in Mar, 2018 but there are still missing some key contents including:

1. PE&R is not fixing the API source at the time of registration which give leverage to registration holder to change API source without DRAP approval.
2. DRAP is granting generic products registration without requiring Bio-equivalence (BE) studies which is even mandatory in African countries so effectiveness of Pakistan generic products is debatable.
3. PE&R has granted registration of more than one lac products including irrational formulations whose safety and efficacy need to be verified. These products can be filtered out at the time of renewal by requiring CTD dossier.

4. Delay of registration of products is also grey area in PE&R which can be overcome by providing ample trained resource to evaluate the submitted dossiers within 60 days. For DRB approved products, price fixation should be done within 60 days. There is need to rationalize the registration time but should not be more than 240 days.
5. Registration letter is issued by mentioning number of products at one letter. There is need to issue separate registration letter for each product mentioning key features of registered product including registration number, complete composition, pack size, approved price, source of API, approved specifications of FPP etc.
6. Product registration renewal is also dreary area which is needed to be upgraded. CTD dossier should be required for the renewal of products so the number of registered products may be rationalized as per renewal. Proper product renewal letter should be issued as per registration letter.
7. There is a need to train DRAP and pharmaceutical industry to develop/register the products as per ICH guidelines so said products may be able to register in developed countries which will urge Pakistan export.

Biological drugs division is responsible for the registration of biological products for human and animal after requisite assessment & evaluation. WHO guidelines are being followed for the registration of biological products. Most of the biological products are being imported which need to be produced at local level. Delay in registration of biological products need to be addressed so timely supply of said biological products may be given to patients.

Controlled drugs division is responsible to allocate quota of controlled substances including psychotropic, narcotics and precursor chemicals. Said quota is allocated jointly with Ministry of Narcotics Control which ultimately delay the process. The allocated quantity is too short to meet the requirements of *bona fide* manufacturers resulting in shortage of controlled drugs in the market. There is need to re-visit the allocated quantity and control mechanism for genuine manufacturers.

Health & OTC products is an emerging division of DRAP which is still under litigation since promulgation of Alternative Medicines & Health Products (Enlistment) Rules in 2014. This division is responsible for the licensing of and enlistment of manufacturers/products including herbal, unani, ayurvedic, Chinese, homeopathy, nutraceuticals and food supplements both for human and animals. The limited staff and long queue to H&OTC applications is challenge for this division which ultimately affecting the DRAP performance and triggered litigation. Currently, Enlistment Evaluation Committee (EEC) minutes are not being uploaded on DRAP website which made curiosity among applicants for fair evaluation and enlistment. H&OTC Division is not following any proper international reference regulatory authorities (RRAs) guidelines which may be compared and justified.

MD&MC Division is responsible for the registration of medical devices & medicated cosmetics both for human and animals. MD&MC is the most primitive division of DRAP which needs to be developed as per international standards. Medical Device Rules, 2018 are under revision just after 2 years of its

promulgation which shows haste formation of said rules. Till yet, medical devices are being sold in the market without registration. The rules for the registration of medicated cosmetics are yet to be notified which provide leverage to said products' manufacturers resulting in dubious quality products in the market.

Pharmacy Services Division is responsible for the implementation of best pharmacy practices in Pakistan but selling of prescription medicines without prescription in each and every corner of Pakistan shows performance of this Division and provincial regulatory authorities. In addition, medicines are being sold in the absence of Pharmacist which is also debatable. The monitoring and reporting of Adverse Drugs Reactions (ADRs) of healthcare products is not being done which shows professional attitude Healthcare practitioners and Pharmacists.

Quality Assurance and Laboratory Testing Division has 3 prime responsibilities. First role is to assure GMP compliance of manufacturing facilities which are questionable. For this purpose, this Division has its regional offices at Lahore, Karachi, Peshawar and Quetta and appointed insufficient number of area Federal Inspector of Drugs (FIDs) who are not well trained to follow and implement WHO, PIC/S guidelines in the manufacturing facilities. Second role is to monitor post-marketing surveillance of marketed products w.r.t. safety, efficacy and quality including product recall. This function is not being done at its true spirit. Third role is to implement Good Laboratory Practices (GLP) in public laboratories so random checking of products may be done. There is need to upgrade said laboratories and get international certification i.e. WHO etc. so that the public may rely on the results of said laboratories.

Costing & Pricing (C&P) Division is responsible for the fixation of prices of pharmaceutical products but all stakeholders i.e. industry, public, government etc. criticize C&P due to sluggish and ambiguous working. Industry criticizes them for delay fixation of prices including poor support in price hardship cases. That's why low price products discontinued or remained short in the market. There is need to speed-up the price fixation process within 60 days including both from DRAP and Cabinet. The uniform generic prices should be fixed and uploaded on DRAP website and price difference of generic and brand leader should not be more than 20%. Annual price increase as per Pricing Policy, 2018 should be allowed without DRAP approval and uploaded on DRAP website.

Legal Affairs Division is responsible to handle legal matters of DRAP within DRAP and outside e.g., misc. boards, courts etc. This Division has key role for rational promulgation of rules and regulations in line with international guidelines and to protect DRAP from un-necessary litigation. The lack of technical capabilities of legal officials of this Division, list of courts cases is becoming long day-by-day. There is an urgent need to hire those advocates who have pharmacy background so DRAP may drive in right direction by putting off un-necessary litigation.

Human Resource & Administration Division is responsible for hiring and developing of DRAP officials along with administrative matters. Currently, DRAP is operating without 70% directors of concerned Divisions including CEO so how an organization can give its excellent performance in such lack of officials. There

is urgent need to fill all vacant posts through internal promotions and/or external professionals through transparent hiring.

Management Information Services (MIS) division is responsible for the automation of all DRAP functions but till yet basic functions could not be transformed into digital. There is urgent need for digital transformation which will speed-up the process and bring transparency in functions. All requisite information should be uploaded on the DRAP website like FDA, WHO etc. websites.

Budget & Accounts Division is responsible to provide budget for DRAP day-to-day maters and future projects. There is need to utilize Central Research Fund (CRF) to upgrade DRAP / pharma industry with joint venture to achieve higher goals e.g. FDA, WHO, PIC/S etc.

5.0 CONCLUSION

The promulgation of drug laws in Pakistan remained least priority for any government. The first drug law was promulgated in 1976 after 29 years of independence of Pakistan. Later-on drug rules were notified but weak implementation of these rules could not elevate drug regulatory and pharmaceutical systems in Pakistan. This was the time when spurious and counterfeit drug mafia deeply rooted in Pakistan. At one side, federal regulatory authority could not upgrade pharmaceutical industries to manufacture pharmaceutical products as per international standards i.e. FDA, EMA, WHO etc. On the other side, provincial regulatory bodies could not upgrade sale & distribution systems. Even today, drugs are being sold as grocery items without doctor's prescription and in the absence of qualified pharmacist.

There was a hope that after promulgation of DRAP Act, 2012; there will be a paradigm shift in society but after passing of 8 years, DRAP could not be equipped with sufficient human resource and vision which they have to achieve. Even today, Pakistan drug regulatory system is weak than African countries. In Pakistan, more than 700 pharmaceutical units are operating with DRAP approval but most of them have aim to make money rather than to produce quality medicines as per international standards. That's why, Pakistani pharmaceutical industries are unable to export their products to developed countries and graph of export is stagnant and/or negative.

There is need to promulgate and upgrade drug laws in line with international guidelines e.g., WHO, ICH, PIC/S etc. who have established their standards to produce quality products.

6.0 RECOMMENDATIONS

1. DRAP must be an autonomous body like Securities and Exchange Commission (SECP) and Competition Commission of Pakistan (CCP) rather than a joint ministry i.e. Ministry of National Health Services, Regulations & Co-ordination.
2. DRAP needs to be a centralized regulatory body to regulate medicines manufacturing, importation, exportation, distribution, selling,

advertisement and Pharmacovigilance as per international standards i.e. FDA, WHO, ICH, PIC/S etc. and provincial regulatory bodies should be linked with DRAP.

3. Training of DRAP and provincial regulators must be done from WHO, ICH, PIC/S officials on international standards and only trained staff should be allowed to work.
4. Ample resources (HR, finance, technology etc.) must be given to DRAP and provincial regulatory bodies to turn-around drug regulatory frame-work in Pakistan.
5. Dispensing of medicines must be done in the presence of qualified pharmacist on centralized prescription system and non-complying pharmacies should be closed.
6. In the light of international standards, promulgation, and enforcement of drug laws to produce safe, effective and quality medicines.
7. Quality Control Boards and Drug Courts needs to be more professional and empowered to resolve the matters at earliest.
8. The Central Research Fund (CRF) of DRAP must be allowed to revamp regulatory bodies system and to subsidize BE studies for registration / export of medicines.
9. Government must give subsidy to those industries who export their products to regulated markets i.e. FDA, EU, Japan, Canada, Australia etc.
10. Regional and Global harmonization of DRAP should be done like Gulf Cooperation Council (GCC), ASEAN, European Union (EU), European Medicines Agency (EMA) etc.

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