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Hanns Seidel Foundation
Pakistan Office

Legal and Regulatory Strategies

for the Coordination and Commercial Oversight of Pakistan's Response to COVID-19

The Right to Health and Access to Safe, Effective, Quality and Affordable Therapeutic Goods

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Sep, 2020

About the Publication

This Publication is the result of a collaboration between HSF Pakistan and the CCLS at SAHSOL, Lahore University of Management Sciences (LUMS).

The onslaught of the COVID-19 pandemic has brought into sharp focus the need to improve policymaking in the healthcare sector. The CCLS and HSF Pakistan entered into this partnership with the aim of contributing towards the research for healthcare reform in Pakistan. The Centre is grateful to HSF Pakistan for sponsoring this project, and hopes that it can be used as a focal point for further policymaking in Pakistan's healthcare sector.

Acknowledgements

We take this opportunity to offer our gratitude to Mr. Ayyaz Kiani, Mr. Ahmed Qadir, Mr. Abdul Mughees Muddassir, Mr. Sayed Kashif, and Mr. Zain Rizvi. We have benefitted from their knowledge and expertise, and gratefully acknowledge the same.

We extend our thanks to Mr. Rao Manzar Hayat and Mr. Asif Hyder Shah for their guidance and useful suggestions.

We acknowledge the other interviewees, who have chosen to remain anonymous, for their cooperation and insight.

Lastly, we appreciate the support provided by Ms. Minahil Toor and Mr. Abeer Mustafa in the administration, management, and coordination of the project, as well as the efforts of Ms. Zoya Wasif and Ms. Hira Farooq in helping us compile this paper.

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c.facilitate exchange programs for students and faculty with leading universities, centres, and think tanks abroad; and

d. liaise with leading universities, centres, and think tanks domestically and globally to build a strong network for research, policy, and expertise.

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Disclaimer

The authors are Policy Consultants at the CCLS, SAHSOL, LUMS. This research was conducted by the CCLS and was supported by the Hanns Seidel Foundation (HSF) Pakistan. The opinions expressed in this article are those of the authors and do not reflect the official position of LUMS or HSF.

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Abbrevations

ACT - Access to COVID-19 Tools

CCP - Competition Commission of Pakistan

COVID-19 - Coronavirus Disease 2019

CPI - Consumer Price Index

CRF - Central Research Fund

CSC - Clinical Studies Committee

DC - Deputy Commissioner

DPC - Drug Pricing Committee

DPP - Drug Pricing Policy

DRAP - Drug Regulatory Authority of Pakistan

EC - European Commission

EU - European Union

FDA - Food & Drug Administration, United States

GMPs - Good Manufacturing Practices

HTA - Health Technology Assessment

ICH - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

ICT - Islamabad Capital Territory

ICTRP - International Clinical Trials Registry Platform

IP - Intellectual Property

IPRs - Intellectual Property Rights

LMICs - Low and Middle Income Countries

MNCs - Multinational Companies

MoNHSRC - Ministry of National Health Services, Regulation and Coordination

MOU - Memorandum of Understanding

MRPs - Maximum Retail Prices

NAP - National Action Plan

OECD - Organisation for Economic Co-operation and Development

PHEIC - Public Health Emergency of International Concern

PIC - Punjab Institute of Cardiology

PKR - Pakistani Rupee

PPE - Personal Protective Equipment

PQCBs - Provincial Quality Control Boards

QMS - Quality Management System

R&D - Research and Development

S&F - Substandard and Falsified

SDGs - Sustainable Development Goals

TRIPS - Trade-Related Aspects of Intellectual Property Rights

USD - United States Dollar

UDHR - Universal Declaration of Human Rights

UHC - Universal Health Coverage

UNODC - United Nations Office on Drugs and Crime

GSMS - Global Surveillance and Monitoring System

WHO - World Health Organization

WIPO - World Intellectual Property Organization

WTO - World Trade Organization

EXECUTIVE SUMMARY

The international human rights regime imposes upon governments a legal obligation to progressively realize the right to health. Health is a fundamental human right that is both dependent upon, and essential to, the exercise of other rights, including the right to life itself. States have a duty to support the realization of this right by allocating to it the maximum available resources. The capacity of Pakistan to develop and implement effective policies for prioritizing public health objectives is dependent upon the exercise of good governance, which according to the World Health Organization (WHO), entails 'stewardship'- the cautious and responsible management of tasks that authorities have been entrusted with. Pakistan's ability to maximize the legitimacy of a reform building process in the health sector is contingent upon ensuring a careful exercise of authority, and putting the health interests of the public first. The promotion of principles of accountability, transparency, fairness and the rule of law are quintessential to strengthening the system of healthcare. Further, post 18th Amendment, the devolved system of government has necessitated the existence of improved intergovernmental and inter-agency coordination at the federal and the provincial levels to achieve healthcare goals.

The outbreak of the coronavirus disease (SARS-COV-2), declared by the WHO as a public health emergency of international concern (PHEIC), has laid bare the fragile foundations of Pakistan's healthcare system. As the need to move from containment to the phases of diagnosis, treatment, and prevention of the coronavirus emerges, the challenges that Pakistan faces in its capacity to ensure the health-care needs of its population, including access to therapeutic goods, become prominent. Therapeutic goods include but are not limited to essential medicines, health-related items such as hand sanitizers, gloves, face masks, gowns, goggles and other personal protective equipment (PPEs), as well as vaccines.

Access to safe, effective, quality and affordable therapeutic goods has been hampered by numerous factors, including, (a) the rise of unfair commercial practices of hoarding, the creation of artificial scarcity, and excessive pricing in Pakistan; (b) the circulation of substandard and falsified (S&F) medical products in the market; and (c) the contrast between the objectives of international intellectual property regimes and human rights law, especially, public health

aims.This policy paper explores each of these areas of response and provides recommendations to assist the government of Pakistan in strengthening healthcare governance. In this manner, the policy paper seeks to supplement the National Action Plan (NAP) for Coronavirus Disease (COVID-19) Pakistan, and improve the country's emergency response preparedness for health crises.

UNFAIR COMMERCIAL PRACTICES

During the COVID-19 pandemic, the demand for essential medicines and health supplies, among other goods, has increased, whereas, supply has decreased as a result of various factors, including supply chain disruptions, and the tendency of consumers to stock up. Certain 'bad actors' have profited off of the emergency by engaging in exploitative practices of hoarding, artificial scarcity, and excessive pricing of drugs and health-related items.

The Drug Regulatory Authority of Pakistan (DRAP) is responsible for regulating the pharmaceutical sector in Pakistan. From licensing to registration and pricing, the sector is completely regulated by DRAP. This federal-level regulation is supplemented by the four provincial health departments which comprise the Provincial Quality Control Boards (PQCBs). Despite the imposition of price ceilings by DRAP, and efforts to check illegal price spikes, Pakistan has repeatedly encountered the issue of unauthorised increases in the prices of drugs. This problem has been exacerbated with the occurrence of the COVID-19 pandemic. A pandemic-driven hoarding of essential health supplies has also been observed which has led to artificial shortages, excessive pricing, and consumer exploitation. Pakistan's NAP for COVID-19 stresses upon the need to ensure 'commodity security' and a sufficient provision of essential supplies. Consequently, it is vital to curb unfair commercial practices, and explore policy options for the same.

A. Drug manufacturers in Pakistan have decried price regulation, and blame the government for failing to take into consideration the fluctuating market dynamics, rising costs of production, high dependence on imported raw material, and the depreciating Pakistani currency. An inadequate price setting mechanism has paved the way for practices of excessive pricing. Accordingly, Pakistan's drug pricing mechanism must be improved by reviewing it in light of national requirements, and international health guidelines.

B. A confusion over the regulatory jurisdiction of health-related items has provided an opportunity for sellers to exploit consumers by charging exorbitant prices. Therapeutic goods, as defined under section 2(xxxvi) of the DRAP Act, 2012 include drugs, alternative medicine, medical devices, and other related products as notified by DRAP. The definition of medical devices specified in Schedule I of the DRAP Act, 2012 should be extended to specifically include health-related items covering PPEs and safety apparel, including but not limited to, hand sanitizers, face masks, gloves, surgical gowns, and goggles.

C. The Competition Commission of Pakistan (CCP) is mandated to preserve unhindered competition in all areas of commercial and economic activity with the aim of promoting economic efficiency and protecting consumers from anti-competitive practices. Invoking the jurisdiction of the CCP for cases of excessive pricing will require the establishment of either abuse of dominant power or the existence of prohibited agreements. During times of crisis, 'situational monopolies' may be created which justify the intervention of competition authorities. The CCP has repeatedly been requested to aid in checking exploitative practices in the provision of essential food items. DRAP must also call upon the CCP to coordinate efforts in ensuring the provision of drugs and health-related items at fair prices whilst ensuring the eradication of unethical commercial behaviour.

D. The importance of DRAP in implementing price controls cannot be undermined. The capacity of the National Task Force comprising federal and provincial drug inspectors must be increased to ensure effective monitoring of adherence to authorized prices. The CCP can aid DRAP in this regard. The CCP can also analyse market and company behaviour to distinguish between lawful and unlawful pricing practices with respect to health-related items. In many instances, the competition authority can simply make it clear to the market that it is closely monitoring price trends and is ready to intervene on a prompt basis.

E. A collaboration between federal and provincial authorities is essential in adopting a plan of action for enhancing an effective conduction of inspections. Drug inspectors operating at the federal level, and those affiliated with the provincial health ministries, should operate under harmonious standards to conduct inspections, and

register price violations of therapeutic goods by sellers. With respect to the stockpiling of certain health-related items, the recent anti-hoarding laws passed by the federal and provincial governments in the context of COVID-19 allow deputy commissioners, or officers authorized by deputy commissioners, to enter and search premises on the suspicion of hoarding. Thus, a strong network of information-sharing between the federal health ministry, DRAP, provincial health departments, deputy commissioners in the respective districts, and the CCP must be developed.

F. Business exploitative practices can only be deterred if the costs associated with these unethical actions outweigh their benefits. The choice to indulge in unfair market practices is influenced by several factors, including the likely financial gains of the violations, the likelihood of being caught, severity of the punishment rendered, and exposure to other costs such as a loss of brand repute. In order to deter potential violators, the associated costs of these crimes, including sanctions, should be increased so as to far outweigh the utility of possible rewards. A deterrent effect can only be created if legislation is backed by strong enforcement agencies so as to ensure that offenders are punished.

THE SALE OF S&F MEDICAL PRODUCTS

With the rise of the coronavirus, experts have warned of a "parallel pandemic" of S&F products. The fake pharmaceutical industry triggered by COVID-19 has been found to exist in growing volumes, particularly, in developing countries. The demand of essential items such as hand sanitizers have outstripped their supply leading to the entry of substandard products in the market. The current pandemic has, thus, necessitated an improvement of Pakistan's regulatory and legal frameworks, along with enforcement mechanisms, to counter the menace of S&F medical products.

A. The circulation of S&F medical products must be curbed by way of strengthening quality assurance mechanisms in the pharmaceutical industry of Pakistan. This can be done through an increase in the budget and capacity-building of DRAP, as well as an enhancement of inter-government and inter-agency coordination. DRAP must work with relevant departments in the provincial governments to define standard operating procedures (SOPs) for cooperation and knowledge-sharing to enhance the enforcement of Good Manufacturing Practices

(GMPs). This entails collaborations with provincial health departments, law-enforcement agencies and legislators. The capacity of DRAP to enforce GMPs must be increased through additional training programs which can be achieved through collaborations with experts from the private sector and foreign regulatory authorities. This will both add to DRAP's internal capacity and make it eligible for international certification schemes. DRAP must also collaborate with international law enforcement agencies, such as Interpol, to facilitate information-sharing to prevent the trafficking of S&F medical products. This will not only result in increased vigilance, but also serve to incentivise local manufacturers to invest in good-quality drugs to meet public demand.

B. Clinical trials are key to advancing medical knowledge and ascertaining the safety and efficacy of new drugs. In order to increase Pakistan's capacity to conduct clinical trials, a thorough system of oversight must be implemented. Any new health technology or essential drug must be evaluated for its effectiveness, side effects and public health consequences in the final stages and subsequent to completion of the clinical trial. A national public registry must be established for clinical trials taking place in Pakistan, based on WHO's guidelines. This will enhance the overall quality of health research in Pakistan by making medical data available, and, ultimately, aid in policy decisions. Moreover, the research capacity, resources, and quality of both public and private hospitals must be assessed. Models from hospitals with high standards of pharmacovigilance should be used to train researchers and improve clinical study capacity across Pakistan.

C. Public-Private partnerships between institutes of medical education and hospitals should be enabled to enhance the quality and growth of the research and development (R&D) sector in Pakistan. Through these partnerships, researchers can pool resources and be more likely to produce research that meets international standards. This will also allow researchers in public institutions to access a variety of resources unavailable to them due to a lack of funding in the public sector. In order to build the capacity of local researchers, in both the public and private domain, collaborations with international researchers must be enabled. This must include information-sharing agreements with reputed foreign institutions for medical research, funding for local researchers to be trained by international experts, and clear targets for collaborative research enhancement.

In order to produce drug testing data, investment in R&D must be accompanied by a database on the quality and public health impact of all imported and locally-produced drugs.

D. Despite repeated announcements of the introduction of the National Medicine Policy aimed at reforming the pharmaceutical industry of Pakistan, the government has failed to launch it. In this context, the untimely resignation of Dr. Zafar Mirza, who strongly advocated for the introduction of the National Medicine Policy, is deeply regretted. The federal government must issue the policy and move towards its implementation on a prompt basis.

E. Organized criminal groups circulating S&F products exploit gaps existing in legislative frameworks which include a lack of medical product specific laws. Schedule II of the DRAP Act, 2012, prohibits the manufacture, sale, export or import of all unregistered, spurious, counterfeit, misbranded, adulterated, substandard and expired therapeutic goods. Schedule III goes on to prescribe the relevant punishments. Each of these terms have been defined in Section 3 of the Drugs Act, 1976. As mentioned above, if the definition of therapeutic goods is extended to include health-related items, the legal framework necessary for the regulation of therapeutic goods will exist in Pakistan. The legislative framework must then be followed by adequate enforcement to successfully curb the menace of S&F products.

F. For an investigation into any offences or contraventions to begin, the crimes must first be detected and reported. The ability to detect S&F goods requires a certain level of technical capability. It is, therefore, essential to ensure that the officials or inspectors charged with detecting such goods have the requisite training, skill and knowledge. Evidence collection and chain of custody need to be smooth so as to strengthen prosecution, and enhance the likelihood of possible convictions.

G. The most effective means of dealing with crimes of S&F medical products is to engender an effective collaboration between the regulatory agencies, police departments, and judicial authorities. Hence, exchange of information and inter-agency cooperation is vital for detecting and responding to crimes of S&F medical products.

H. If it is discovered that the crimes in question can be traced back to international trafficking, efforts must be made by the international community to improve collaboration between national and international crime agencies. Countries must publish regular reports to provide updates on the status of S&F medical products so as to strengthen international action against criminal groups. In this regard, the role of WHO Global Surveillance and Monitoring System (GSMS) for S&F medical products is crucial. Pakistan must play its role by lending support to this global initiative, and using it as a point of reference for policymaking in the medical product sector.

I. The gaps in healthcare demonstrate the existence of a vacuum in the field of healthcare policy-making in Pakistan. One method of filling this gap is by implementing a multi-disciplinary method of assessing various aspects of health technology provision, such as the Health Technology Assessment (HTA). The purpose of HTA is to evaluate a technology before it becomes part of established clinical practice, allowing clinicians to make informed choices regarding whether a technology should be used and what its impact on public health would be. It is, thus, relevant to all aspects of drug accessibility including clinical trials, development, manufacturing and its impact on public health. Establishing a centre to conduct HTA will enable health policies to reflect science-based findings as well as aid clinicians, including analysis of evidence regarding clinical effectiveness, safety, cost-effectiveness, ethical, legal and social aspects of health interventions.

COVID-19 AND ACCESS TO A POTENTIAL VACCINE

In accordance with the prescription of the Alma Ata Declaration, it is vital to recognize that gross inequalities exist between the healthcare facilities available to the people of developing and developed countries, and these differences are 'politically, socially, and economically unacceptable'.They are, therefore, a matter of common concern for all nations, and signify the critical role of international cooperation in realizing the right to health. In order for healthcare access to be equitable, vaccines or technology essential for their development must be be readily available to nations which need them the most. Related to this is the regime of intellectual property rights (IPRs) that runs the risk of effectively barring the poorer nations of the world from accessing health technology.

Since a crucial element of the global COVID-19 response is the treatment of the disease itself, it is necessary to analyze the measures that can be adopted within the existing intellectual property (IP) regime to ensure the provision of quick and affordable access to a potential COVID-19 vaccine.

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) grants protection to inventions, including both products and processes in all technological fields. It allows the owner of pharmaceutical products to prevent third parties from developing, utilizing, selling or importing the patented product. Thus, patents over potential COVID-19 vaccines will, effectively, grant the patent owners the right to choose who may or may not use their product till the patent expires. It is likely that patentees will seek to recoup their investments by charging exorbitant prices for the vaccines developed, which third-world countries, such as Pakistan, would be unable to pay.

In this context, a reliance on compulsory licensing can prove to be advantageous, especially for developing countries. The compulsory licensing regime, enshrined in Article 31 of the TRIPS agreement, envisages the issuance of a license by a government to a third party or a government authority to use a patent without the consent of the patentee. In return, remuneration is to be paid to the right holder as compensation for the utilization of the patent rights. Following the lead of countries such as Canada and Germany, Pakistan must review its existing legal framework to promote the issuance of compulsory licensing. It must enact legislation to expand the scope of compulsory licensing under the existing Patents Ordinance, 2000. The Controller of Patents must be authorized to grant compulsory licenses over all COVID-19 related therapeutic goods on a prompt basis. Pakistan can make use of compulsory licensing by either producing or importing an affordable generic vaccine. In this regard, it is essential to exercise adequate quality controls and improve the regulation of the pharmaceutical industry so that Pakistan may benefit from the compulsory licensing flexibility afforded under the TRIPS agreement.

Measures that can be taken by developing countries to promote access to health products within the existing IP regime are not limited to compulsory licensing. Article 73 of the TRIPS agreements provides that nothing in the agreement can be interpreted to preclude a member state from taking decisions or actions "which it considers necessary for the protection of its essential security interests...taken in time of war or other emergency in international relations". Since public health crises, according to the Doha Declaration, can be classified as national emergencies, it follows, that a pandemic can be interpreted as an emergency in international terms. Further, given the severity of the current situation, and considering the number of deaths caused by COVID-19, the provision of effective treatment options by a state for its citizens can safely be construed as a measure to further 'essential security interests.' Accordingly, to uphold public health interests, the TRIPS agreement allows countries to take measures such as the grant of indemnity against enforcement of IPRs and infringement claims. This means that states can enact legislations to suspend the implementation of IPRs in the context of IP protected COVID-19 products. Moreover, pursuant to Article 6 of the TRIPS agreement, states are allowed to carry out parallel importation of essential products. Thus, a balance can be struck between IP regimes and health security by utilizing the flexibilities afforded within the TRIPS agreement.

The health-related flexibilities offered by the TRIPS agreement must, in general, be incorporated in the domestic intellectual property regime. As observed above, the national law on patents in Pakistan contains provisions relating to the authorization of compulsory licensing which need to be expanded under the current circumstances. An implementation of the aims and objectives of the IP flexibilities afforded under the TRIPS agreement requires consistent policymaking, and a coordination between various government ministries and divisions of Pakistan, including, but not limited to, health, commerce, finance, science and technology, law and justice, planning and development, and ministry of interprovincial coordination. Coherence on a national level, in this regard, requires coordination between the federal and provincial governments, and cooperation on an inter-provincial level as well.

CONCLUSION

Health, a fundamental human right, is intrinsically linked to the right to enjoy a dignified existence. Therapeutic goods are crucial for the fulfillment of healthcare needs of the population, and for the attainment of sustainable development. Obstacles in accessing high-quality, affordable therapeutic goods pose a challenge to human dignity, development and health objectives. Pakistan must view health as a fundamental goal of its policies and programmes, and strive to surpass existing barriers so as to strengthen its national health system. Measures must be enacted to eradicate crimes in the health sector, including unfair commercial practices of hoarding and excessive pricing, as well as acts of manufacturing, distribution or sale of S&F medical products. Additionally, the government must take steps to effectively utilize the flexibilities afforded under the TRIPS agreement so as to ensure access to a potential COVID-19 vaccine to Pakistan's population. Access to therapeutic goods must be viewed as a vital component of the national strategy to deal with the coronavirus disease, and secure public health objectives. This, in turn, is dependent upon good governance practices, strong regulatory structures, improved oversight mechanisms, inter-agency cooperation, accountability and transparency in public service. Further, the promotion of dialogue between the federal and provincial governments is essential for achieving national coherence in the policy response to public health emergencies, such as the one at hand. Political will and a united front at all tiers of government can significantly improve access to therapeutic goods and health service delivery in Pakistan.

INTRODUCTION

The international human rights regime imposes upon governments a legal obligation to progressively realize the right to health. Health is a fundamental human right that is both dependent upon, and essential to, the exercise of other rights, including the right to life itself. States have a duty to support the realization of this right by allocating to it the "maximum available resources"[1]. The capacity of Pakistan to develop and implement effective policies for prioritizing public health objectives is dependent upon the exercise of good governance. The World Health Organization (WHO) has identified 'stewardship', the cautious and responsible management of tasks that authorities have been entrusted with, as a key component to good governance.[2] Pakistan's ability to maximize the legitimacy of a reform building process is contingent upon ensuring a careful exercise of authority, and putting the health interests of the public first. The promotion of principles of accountability, transparency, fairness and the rule of law are quintessential to strengthening the system of healthcare.

In December, 2019, the WHO's Country Office located in China, based on a media statement picked up from Wuhan, reported cases of a 'viral pneumonia of unknown cause' which was eventually determined to be the novel coronavirus (SARS-COV-2), commonly referred to as COVID-19.[3] The first imported case of coronavirus was reported by Thailand on 13 January, 2020. As cases of the virus began to be reported by other countries, a rapid spread of the disease throughout different regions of the globe became evident. On 30 January, 2020, the WHO declared the novel coronavirus outbreak to be a public health emergency of international concern (PHEIC), the highest degree of alarm

[1]WHO. (n.d.). Human Rights and Health.
https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health

[2]WHO. (n.d.). Good governance in the process of public health law reform.
https://www.who.int/healthsystems/topics/health-law/chapter5.pdf?ua=1

[3]WHO. (n.d.). Timeline: Covid-19 Response. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/interactive-timeline?gclid=CjwKCAjwkJj6BRA-EiwA0ZVPVl20g7nhSZu5bjjnUpy7X0zZDuix0XETrjNgNQ2ZZqazecYx1y12dxoC4iQQAvD_BwE#event-42.

prescribed by WHO.[4] Pakistan reported its first two cases of coronavirus on 26 February in Karachi with both cases imported from Iran.[5] An exponential increase in cases was set off and enhanced massively with the return of pilgrims from Iran, who were made to quarantine at Taftan. With overcrowding, unhygienic conditions and lack of proper regulations, not only did the Taftan quarantine center itself become a major initial cluster of the virus but also became a key source of internal transmission of the virus to other provinces. The spread of the COVID-19 disease laid bare the fragile foundations of Pakistan's healthcare system. As the need to move from containment to the phases of diagnosis, treatment, and prevention emerges, the challenges that Pakistan faces in its capacity to ensure the health-care needs of its population, including access to essential medicines and health-related equipment, become prominent.

The significance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" is recognized as a central element of the provision of Universal Health Coverage (UHC) under the Sustainable Development Goals (SDGs).[6] The SDGs, also known as the Global Goals, are the blueprint for an improved and sustainable future for all[7], and have been adopted by all United Nations (UN) Member States[8]. While the recent announcement of Khyber Pakhtunkhwa being the first province to offer UHC to all residents[9] is nothing short of a historic development, many areas crucial to therapeutic good policies in Pakistan need to be addressed, especially, in the context of the COVID-19 pandemic. Throughout this paper, the term 'therapeutic goods' has been used to include drugs, vaccines, and health-related items such as hand sanitizers, gloves, face

[4] *Ibid.*

[5] *Sameer Mandhro. (2020, March 13). First locally transmitted coronavirus case emerges in Karachi. https://tribune.com.pk/story/2175648/first-locally-transmitted-coronavirus-case-emerges-karachi.*

[6] *World Health Organization . (n.d.). Sustainable Development Goals (SDGs). Sustainable Development Goal 3.8 https://www.who.int/health-topics/sustainable-development-goals#tab=tab_2*

[7] *UN. (n.d.). About the Sustainable Development Goals. https://www.un.org/sustainabledevelopment/sustainable-development-goals/*

[8] *Ibid.*

[9] *Jamal, S. (2020, August 21). Pakistan: Khyber Pakhtunkhwa becomes first province to introduce universal health coverage for all residents. https://gulfnews.com/world/asia/pakistan/pakistan- khyber-pakhtunkhwa-becomes-first-province-to-i ntroduce-universal-health-coverage-for-all-residents-1.73333156*

masks, gowns, goggles and other personal protective equipment (PPE). Under the ambit of advancing equitable access to affordable, safe, qualitative and effective therapeutic goods, this paper identifies and explores three key areas which have been highlighted by the onslaught of the COVID-19 pandemic- (a) enhancing access to affordable therapeutic goods by targeting unfair commercial practices of excessive pricing and hoarding; (b) assuring the quality, efficacy and safety of therapeutic goods by curbing the circulation of substandard and falsified (S&F) medical products; and (c) ensuring access to a potential COVID-19 vaccine within the context of trade and intellectual property policies and human right objectives, especially, health security. Each of these areas is discussed within the broader contexts of improving regulatory structures, enhancing operational capacity, strengthening inter-government coordination, and ensuring accountability to bring Pakistan at par with international best practices in healthcare management.

UNFAIR COMMERCIAL PRACTICES

During disasters, typical supply and demand curves are upended. The demand for essential medicines and health supplies among other goods increases, whereas, supply decreases as a result of various factors including supply chain disruptions, and the tendency of consumers to stock up. Certain 'bad actors' attempt to profit from emergencies and engage in unethical commercial practices of hoarding, artificial scarcity, and excessive pricing. In this context, the COVID-19 pandemic has opened the floodgates for exploitation of consumers with respect to therapeutic goods. The following sections will shed light on such exploitative practices in the context of (i) drugs, and (ii) health-related items including PPEs, and suggest policy options.

Drugs: Regulation, Pricing Framework and 'Excessive Pricing'

In Pakistan, drugs, among other therapeutic goods, are governed under the Drugs Act of 1976 and the Drug Regulatory Authority of Pakistan (DRAP) Act of 2012. From licensing to registration and pricing, the sector is completely regulated by the State.[10] Primarily, the Drugs Act, 1976 authorized the federal health ministry to regulate the pharmaceutical sector. Subsequently, as a result of the Constitution (18th Amendment) Act, 2010, health was devolved to the provinces and the functions under the Drugs Act, 1976 were transferred to the Cabinet Division.[11] Later on, DRAP was created under the DRAP Act, 2012, and though the authority is an independent body, it functions under the administrative control of the Ministry of National Health Services, Regulation and Coordination (MoNHSRC).[12] DRAP comprises three administrative boards and several divisions. The federal-level regulation of drugs by DRAP is supplemented by the four

[10] *Dawani K, Sayeed A. (2019). 'Pakistan's pharmaceutical sector:issues of pricing, procurement and the quality of medicines'. ACE SOAS Consortium, p. 9.*

[11] *Ibid.*

[12] *Ibid.*

provincial health departments which, in turn, comprise the Provincial Quality Control Boards (PQCBs).[13]

Section 4 of DRAP Act, 2012 provides that the division of costing and pricing at DRAP is responsible for their pricing. Currently, the maximum retail prices (MRPs) of drugs have to be approved by the Federal Cabinet after receiving recommendations from the Drug Pricing Committee (DPC) constituted under the costing and pricing division of DRAP.[14] The Drug Pricing Policy (DPP) 2018 specifies that drugs for human use include the drugs and biologicals listed in the National Essential Medicines List, and all other drugs. According to Paragraph 7(2) of the DPP 2018[15], once the MRPs of drugs are set, manufacturers and importers can increase the MRPs of essential drugs "(excluding lower priced) equal to 70% increase in CPI (with a cap of 7%)", and the MRPs of other drugs "up to increase in CPI (with a cap of 10%)", subject to certain conditions listed therein. Paragraph 7(2)(vii) provides that the federal government may exclude specific drugs or biologicals from the application of the provision allowing the increase in MRPs. Thus, the term 'excessive pricing', in the context of drugs, is defined as the setting of prices above and beyond that authorized by the government.

Despite the imposition of price ceilings by DRAP, Pakistan has repeatedly encountered the issue of unauthorised increases in the prices of drugs. In 2019, a countrywide public outcry was reported by leading Pakistan dailies over an increase in the prices of drugs over and beyond what had been allowed by the federal government.[16] In response, DRAP launched a crackdown to counter a spike in the prices of drugs. Dr. Asim Rauf, the CEO of DRAP, commented that the authority would issue notices to pharmaceutical companies responsible for causing unpermitted price hikes,and legal action would be initiated against them in the Drug Courts.[17] However, the problem of excessive pricing continued

[13] *Ibid, p. 10.*

[14] *Dawani, K., Sayeed, A. (2019). 'Pakistan's pharmaceutical sector:issues of pricing, procurement and the quality of medicines'. ACE SOAS Consortium, p. 15.*

[15] *As amended on 15.07.2020 vide Notification No.F.11-2/2020-DD(P).*

[16] *Malik, A. (2019, April 5). Price-hike of medicines leads to public outcry. https://www.thenews.com.pk/print/453525-price-hike-of-medicines-leads-to-public-outcry*

[17] *Ibid.*

to prevail, and has worsened amidst the COVID-19 pandemic.

Health Related Supplies and Abusive Practices

This year, shortly after the lockdown in March, a pandemic-driven hoarding of food items such as sugar and wheat was observed. Simultaneously, fuel shortages were experienced in various cities. It was reported that suppliers were causing artificial scarcity by means of hoarding in order to drive up prices amidst the outbreak of the disease.[18] This trend then moved towards the hoarding of health-related supplies. In June 2020, the Supreme Court took note of the shortage caused by the hoarding of oximeters, oxygen cylinders and related products, and ordered the federal and provincial authorities to take strict action against all exploitative elements.[19] The Court noted that hoarding led to excessive pricing, and effective steps had yet to be taken against such unethical commercial practices.[20] Additionally, a petition filed by the Judicial Activism Panel before the Lahore High Court blamed DRAP for failing to control the prices of crucial health supplies and life-saving drugs.[21] When asked to comment on this matter, a Deputy Drugs Controller claimed that while DRAP exercises jurisdiction over drugs, it does not regulate the prices or the quality of health-related supplies at the time being.[22]

In the absence of any authority imposing a price ceiling upon health-related supplies, the question then becomes, what selling price can be termed 'unfair' for these products? Courts in other jurisdictions have interpreted unfairly high prices to be prices which have 'no reasonable relation to the economic value of the product'.[23]

[18] *Kazi, Z. (2020, July 17). Pandemic-driven hoarding. https://nation.com.pk/17-Jul-2020/pandemic-driven-hoarding*

[19] *The Express Tribune (2020, June 26). Action ordered against Covid-19 drug hoarders. https://tribune.com.pk/story/2251052/action-ordered-covid-19-drug-hoarders*

[20] *Ibid.*

[21] *The News (2020, June 16). LHC seeks Drap's reply in face masks, drugs at high prices. https://www.th enews.com.pk/print/673462-lhc-seeks-drap-s-reply-in-face-masks-drugs-at-high-prices*

[22] *Personal Interview with a Deputy Drugs Controller, Primary & Secondary Healthcare Department, Punjab.*

[23] *OECD.org/Coronaviris. (2020, May 26). Exploitative Pricing in the time of Covid-19. https://www.oecd.org/competition/Exploitative-pricing-in-the-time-of-COVID-19.pdf p. 3*

Further, in such cases, the price cost margin is proved to be excessive, and the price charged is either simply unjust in itself, or in comparison to competing products.[24]

The Government's Response

The federal and provincial authorities took several measures to respond to practices of hoarding and profiteering. In order to target price gouging, the Islamabad police in February 2020 set up a helpline to register complaints against the sale of face masks at exorbitant prices.[25] Next month, the Sindh High Court ordered the constitution of anti-profiteering task forces in all districts of the province.[26] In June 2020, Office of the Chief Drugs Controller in the Department of Health, Punjab, started close monitoring of the sale of Dexamethasone, a drug which was approved by Oxford University as a life-saving medicine for critical patients of COVID-19.[27] The Federal Minister of Law and Justice in Pakistan, Dr. Farogh Naseem, warned that those involved in the illegal activities of hoarding and profiteering would be dealt with an 'iron fist' and receive severe punishment.[28] In order to curb hoarding practices, the federal government enacted the COVID-19 (Prevention of Hoarding) Ordinance, 2020 for the Islamabad Capital Territory (ICT). Similar laws were passed in the provinces of Punjab and Khyber Pakhtunkhwa, while Balochistan and Sindh were urged to do the same.[29] It is clear that the federal and provincial governments recognize the risks posed by unfair commercial practices during

[24] *Ibid.*

[25] *LEAD Pakistan; Lead to Read (2020, February 29). Helpline set up for action against surgical masks profiteers in Capital. https://leadpakistan.com.pk/news/helpline-set-up-for-action-against-surgical-masks-profiteers-in-capital/ p.1*

[26] *Tanoli, I. (2020, April 2015). Anti-profiteering task force in all districts of Sindh ordered. https://www.dawn.com/news/1549284*

[27] *Malik, A. (2020, June 17). To prevent drug's hoarding, profiteering, govt starts monitoring sale/ distribution of dexamethasone. https://www.thenews.com.pk/print/673882-to-prevent-drug-s-hoarding-profiteering-govt-starts-monitoring-sale-distribution-of-dexamethasone*

[28] *Virk, S. (2020, April 20). Law minister warns hoarders of strict action. https://tribune.com.pk/story/2202239/1-law-minister-warns-hoarders-strict-action*

[29] *Ahmad, T. (2020, April 28). Library of Congress Law. https://www.loc.gov/law/foreign-news/article/pakistan-federal-government-introduces-ordinance-to-ban-food-hoarding-by-traders-capitalizing-on-covid-19-pandemic/*

the COVID-19 crisis, and are pushing to deal with them effectively. Further, Pakistan's NAP for COVID-19 stresses upon the need to ensure 'commodity security' and a sufficient provision of essential supplies.[30] In this regard, it is vital to take a deeper look into the foundations of exploitative market practices.

The Foundations of Price Gouging and the Need for Intervention

Price gouging occurs when sellers attempt to profit off of disasters by excessively raising the prices of critical goods and services.[31] According to traditional microeconomics theory, the price of an item is determined by an interaction of demand and supply. All points on the supply curve are reflective of how much goods sellers are willing to provide, and the points on the demand curve reflect the amount that buyers are willing to pay for those items.[32] When disasters such as pandemics occur, the demand for essential items rises, and the demand curve shifts to the right causing an increase in prices. Further, supply chains are disrupted, and it becomes difficult for sellers to obtain sufficient amounts of goods. Problems in production and distribution, such as those caused by confinement measures in epidemics, also lead to a shortage of critical items. In certain cases, some bad actors attempt to create artificial shortages by hoarding items which shifts the supply curve to the left. Hoarding, in this scenario, refers to the excessive stocking or storing of an item on an industrial level with the aim of driving up the price of the items in question.[33] This excludes buying or storing items for a personal use.[34] A shift in the

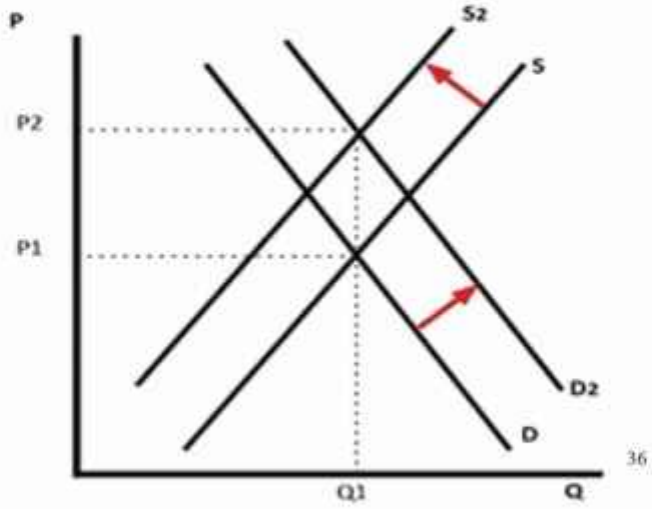
[30]*The Government of Pakistan Ministry of Health Services,Regulations and Coordination.. (2020). National Action Plan for CoronaVirus Disease (Covid 19) Pakistan. p. 11*

[31]*Frosh, B. E. (n.d.). Price Gouging is Illegal. Office of the Maryland Attorney General: https://www.marylandattorneygeneral.gov/Pages/CPD/price_gouging_faq.aspx#1*

[32]*Bae, E.B. (2011). 'Are Anti-Price Gouging Legislations Effective Against Sellers During Disaster?'. Entrepreneurial Business Law Journal Vol 4: 1 p. 81*

[33]*See Carter, J. L. (2020, April 27). Home> Podcasts > Antitrust during COVID-19 Part 2: Price gouging and hoarding of supplies. https://www.antitrustlawsource.com/podcast/antitrust-during-covid-19-part-2-price-gouging-and-hoarding-of-supplies/*
Ibid.[34]

supply curve thus caused, moves the prices to an even higher point against the same quantity of goods[35], thereby, raising the prices to excessive levels.



[36]

Certain economists argue that high prices are just another form of equilibrating supply and demand, and markets should be left free to determine them. They attribute a functional role to prices in an economy, and comment that prices act as both signals and incentives.[37] Others, on the other hand, contend that excessive pricing allows sellers to take unfair advantage of consumers during times of crises, and it is the responsibility of governments to intervene.[38] They acknowledge scarcity as the actual problem, and price increase as merely a symptom, but urge the government to address both the cause and the symptom.[39] Legislators justify intervention by highlighting the tremendous amount of public resentment over excessive pricing.[40] The right to life is interlinked with the right to health which entails access to affordable medicines and essential health-related items. This, in turn, justifies government intervention. Further, the Organisation for

[35]*Bae, E.B. (2011), 'Are Anti-Price Gouging Legislations Effective Against Sellers During Disaster?' Entrepreneurial Business Law Journal Vol 4: 1 p. 81*

[36]*Pettinger, T. (2019, September 3). Diagrams for Supply and Demand. https://www.economicshelp.org/blog/1811/markets/diagrams-for-supply-and-demand/*

[37]*OECD Competition Division (2020, June 15). John Davies on excessive pricing interventions in times of crisis [Video File]. https://www.youtube.com/watch?v=0YS4Ur488Fc*

[38]*Ibid.*

[39]*Ibid.*

[40]*Bae, E.B. (2011), 'Are Anti-Price Gouging Legislations Effective Against Sellers During Disaster?'.Entrepreneurial Business Law Journal Vol 4: 1 p. 81*

operation and Development (OECD) has observed that while price spikes may result from an increase in the costs of sellers during pandemics, they may also be reflective of 'exploitative business practices' which need to be curbed.[41]

Price ceilings are a form of price control mechanism. They indicate the legal maximum price that can be charged for a particular good or supply. Price ceilings, such as the ones imposed by DRAP on drugs in Pakistan, are criticized on the ground that their imposition interferes with the operation of a free market price determination, and causes either excess supply or excess demand.[42] However, in low and middle income countries (LMICs), high prices serve as a significant barrier in access to drugs[43], which, some argue, justifies the regulation of prices by government authorities.

Improving Pricing Mechanism

Despite the option to update prices on an annual basis, drug manufacturers have decried price regulation by the government.[44] They blame the government for failing to take into consideration the fluctuating market dynamics, rising costs of production, high dependence on imported raw material, and the depreciating Pakistani currency.[45] An inadequate price setting mechanism has paved the way for practices of excessive pricing. Experts have commented that it is high time for Pakistan's drug pricing mechanism to be fine tuned in light of national requirements and international health guidelines.[46]

[41] *OECD.org/Coronaviris. (2020, May 26). Exploitative Pricing in the time of Covid-19. https://www.oecd.org/competition/Exploitative-pricing-in-the-time-of-COVID-19.pdf p. 1*

[42] *Spaulding W. (n.d.). Price Controls. https://thismatter.com/economics/price-controls.htm*

[43] *Dean, E. B. (2019). 'Who Benefits from Pharmaceutical Price Controls? Evidence from India'. Centre for Global Development. p. 1*

[44] *Dawani K, Sayeed A. (2019).' Pakistan's pharmaceutical sector:issues of pricing, procurement and the quality of medicines'. ACE SOAS Consortium p. 15*

[45] *Ibid.*

[46] *Lee, K. S., Shahidullah, A., Zaidi, S., Patel, R. P., Ming, L. C., Tariq, M. H., Malik, O., Farrukh, M. J., Khan, A., Yee, S. M.,& Khan, T. M. (2017). 'The Crux of the Medicine Prices' Controversy in Pakistan'. Frontiers in pharmacology, 8, 504. https://doi.org/10.3389/fphar.2017.00504*

Reviewing the Legal Framework on Health-Related Items

A confusion over the regulatory jurisdiction of health-related items has provided an opportunity for sellers to exploit consumers by charging exorbitant prices. Therapeutic goods, as defined under section 2(xxxvi) of the DRAP Act, 2012 include drugs, alternative medicine, medical devices, and other related products as notified by DRAP. It is argued that the definition of medical devices specified in Schedule I of the DRAP Act, 2012 should be extended to specifically include health-related items covering PPEs and safety apparel, including but not limited to, hand sanitizers, face masks, gloves, surgical gowns, and goggles. An examination of the legislation of Australia reveals that PPEs, that serve to prevent transmission of disease between people, including all the above listed items, are treated as medical devices and regulated under the legislation on therapeutic goods.[47] A similar approach can be adopted in Pakistan to include PPEs within the ambit of therapeutic goods which are regulated by DRAP. This will allow the establishment of a clear demarcation of responsibility and enhanced accountability.

Invoking the Jurisdiction of the Competition Commission of Pakistan

Several countries have sought to apply competition laws to address exploitative pricing practices during the COVID-19 pandemic. In fact, during this crisis, competition agencies world-wide have taken it upon themselves to challenge unfair pricing behavior so as to advance consumer protection.[48] The Competition Commission of Pakistan (CCP) is mandated to preserve unhindered competition in all areas of commercial and economic activity with the aim of promoting economic efficiency and protecting consumers from anti-competitive practices. Section 28 of the Competition Act, 2010, prescribes the functions and powers of the Commission, and obliges the Commission to enquire into the matters of any and all undertakings to give effect to the purposes of the Act;

[47] *Regulation of Personal Protective Equipment and COVID-19. (2020, August 13). . https://www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19*

[48] *OECD.org/Coronaviris. (2020, May 26). Exploitative Pricing in the time of Covid-19. https://www.oecd.org/competition/Exploitative-pricing-in-the-time-of-COVID-19.pdf p. 7*

to indulge in competition advocacy; and take all actions necessary for the purposes of the Act. Invoking the jurisdiction of the CCP for cases of excessive pricing will require the establishment of either abuse of dominant power[49] or the existence of prohibited agreements[50]. While abuse of dominant power entails "practices which prevent, restrict, reduce, or distort competition"[51] through, amongst others, reducing production and sales, and causing an unreasonable rise in prices; prohibited agreements include, but are not limited to, "fixing the purchase or selling price or imposing any other restrictive trading conditions"[52] with the aim of disrupting competition within the relevant market.

It is submitted that during times of crisis, 'situational monopolies' may be created which justify the intervention of competition authorities. Emergencies may trigger limitations in supply and impose restrictions upon circulation of products. Additionally, barriers in production and supply chains caused by disasters coupled with increasing demand and a restricted ability of consumers to move around in search of necessary goods, can lead to individual suppliers becoming crucial for the provision of essential commodities within identifiable areas.[53] In such circumstances, even local shops can end up gaining significant market power, and enjoy the ability to substantially raise prices with the aim of maximizing profits. Hence, the idea of excessive pricing as a result of time-limited significant market power should be tested under competition law.

The CCP has repeatedly been requested to aid in checking exploitative practices in the provision of essential food items.[54] DRAP must also call upon the CCP to coordinate efforts in ensuring the provision of drugs and health-related items at fair prices whilst ensuring the eradication of unethical commercial behaviour.

[49] *Government of Pakistan. (n.d.).Section 3, The Competition Act 2010. The Gazette of Pakistan. http://www.na.gov.pk/.*

[50] *Ibid, Section 4, The Competition Act 2010*

[51] *Ibid, Section 3(2), The Competition Act 2010*

[52] *Ibid, Section 4(2)(a), The Competition Act 2010*

[53] *OECD.org/Coronaviris. (2020, May 26). Exploitative Pricing in the time of Covid-19. https://www.oecd.org/competition/Exploitative-pricing-in-the-time-of-COVID-19.pdf p. 5*

[54] *NPMC calls for provision of food items at affordable prices. (2020, May 20). https://profit.pakistantoday.com.pk/2020/05/20/npmc-calls-for-provision-of-food-items-at-affordable-prices/*

Effective Oversight to Ensure Compliance

With respect to curtailing the excessive prices of drugs and health-related items, the importance of DRAP in implementing price controls cannot be undermined. The capacity of the National Task Force comprising federal and provincial drug inspectors must be increased to ensure effective monitoring of adherence to MRPs. Studies have noted that the inability of DRAP and provincial health departments to monitor pricing stems from an acute shortage of human resources.[55] Thus, it is of utmost significance to increase the numbers of federal and provincial inspectors to enhance drug price regulation, and keep corruption at bay.[56]

The CCP can aid DRAP in monitoring and curbing the excessive pricing of drugs. The CCP can also analyse market and company behaviour to distinguish between lawful and unlawful pricing practices with respect to health-related items. In many instances, the competition authority can simply make it clear to the market that it is closely monitoring price trends and is ready to intervene on a prompt basis.[57] The issuance of general and individual warnings may have the effect of rectifying abusive behaviour while saving the resources required for commencement of formal proceedings.

Enhancing Coordination between Federal and Provincial Agencies

A collaboration between federal and provincial authorities is essential in adopting a plan of action for enhancing an effective conduction of inspections. Drug inspectors operating at the federal level, and those affiliated with the provincial health ministries, should operate under harmonious standards to conduct inspections, and register price violations of therapeutic goods by sellers.

[55] *Lee, K. S., Shahidullah, A., Zaidi, S., Patel, R. P., Ming, L. C., Tariq, M. H., Malik, O., Farrukh, M. J., Khan, A., Yee, S. M.,& Khan, T. M. (2017). 'The Crux of the Medicine Prices' Controversy in Pakistan'. Frontiers in pharmacology, 8, 504. https://doi.org/10.3389/fphar.2017.00504*

[56] *Ibid.*

[57] *OECD.org/Coronaviris. (2020, May 26). Exploitative Pricing in the time of Covid-19. https://www.oecd.org/competition/Exploitative-pricing-in-the-time-of-COVID-19.pdf p. 9*

With respect to the stockpiling of certain health-related items, the recent anti-hoarding[58] laws passed by the federal and provincial governments in the context of COVID-19 allow deputy commissioners, or officers authorized by deputy commissioners (DCs), to enter and search premises on the suspicion of hoarding. The offence of hoarding is then summarily tried by special magistrates.

The above discussion clearly establishes the need to develop a strong network of information-sharing between the federal health ministry, DRAP, provincial health departments, DCs in the respective districts, and the CCP to enable a mechanism of effective checks and balances against exploitative business practices.

Increasing Associated Costs of Violations

Practices of profiteering through hoarding and excessive pricing can only be deterred if the costs associated with these unethical actions outweigh their benefits. The choice to indulge in exploitative market practices is influenced by several factors, including the likely financial gains of the violations, the likelihood of being caught, severity of the punishment rendered, and exposure to other costs such as a loss of brand repute.[59] In order to deter potential violators, the associated costs of these crimes, including sanctions, should be increased so as to far outweigh the utility of possible rewards. A deterrent effect can only be created if legislation is backed by strong enforcement agencies so as to ensure that offenders are punished.

[58] *COVID-19 (Prevention of Hoarding) Ordinance 2020; The Punjab Prevention of Hoarding Act 2020 (XV of 2020)*

[59] *Shah S.A and Kayani U.J. (2020, August 15). The Effectiveness of Anti-Hoarding Legislation. https://www.pakistantoday.com.pk/2020/08/15/the-effectiveness-of-anti-hoarding-legislation-2/*

COVID-19 AND THE SALE OF SUBSTANDARD AND FALSIFIED (S&F) MEDICAL PRODUCTS

In March this year, the emergence of trafficking in PPE sounded an alarm worldwide. It represented a pattern in the behaviour of organized criminal groups that was linked directly to a rise in the demand of certain essential medical products, including hand sanitizers, face masks, thermometers, testing kits, chloroquine, surgical gowns, oxygen cylinders and other medical equipment, amidst the COVID-19 pandemic.[60] These groups exploited the gap between the supply and demand of relevant medical products by providing S&F items. Substandard medical products, as defined by the United Nations Office on Drugs and Crime (UNODC), include "authorized medical products that fail to meet either their quality standards or specifications, or both"[61], and falsified medical products purposely "misrepresent their identity, composition or source and include intentionally manufactured substandard medical product(s)"[62]. Moreover, criminal groups advertised non-existent supplies to defraud customers and deprive them of the purchase price. In April 2020, Interpol uncovered a large-scale false scheme which involved 'compromised emails, advance-payment fraud and money laundering'[63]. The WHO Global Surveillance and Monitoring System (GSMS) for S&F medical products reported the circulation of various falsified chloroquine products in the WHO regions of Africa and Europe.[64] The UNODC has predicted that as the world moves towards the phases of treatment and prevention of COVID-19, the focus of such groups will shift to trafficking in COVID-19 medicines and vaccines.[65]

[60] *The United Nations Office on Drugs and Crime. (2020). COVID-19-related Trafficking of Medical Products as a Threat to Public Health. Vienna: UNODC Research. p. 7*

[61] *Ibid, p. 9*

[62] *Ibid, p. 9*

[63] *Unmasked: International COVID-19 Fraud Exposed. (2020, April 14). https://www.interpol.int/en/News-and-Events/News/2020/Unmasked-International-COVID-19-fraud-exposed*

[64] *World Health Organization. (2020). Medical Product Alert N°4/2020. Falsified chloroquine products circulating in the WHO regions of Africa and Europe (pp. 1-2). Geneva: World Health Organization*

[65] *The United Nations Office on Drugs and Crime. (2020). COVID-19-related Trafficking of Medical Products as a Threat to Public Health. Vienna: UNODC Research. p. 7*

Pakistan and the Prevalence of S&F Pharmaceuticals

The issue of poor-quality, substandard and counterfeit pharmaceuticals in Pakistan gained prominence after the ingestion of contaminated cardiovascular drugs and cough syrups caused the deaths of hundreds of people in 2011[66] and 2012[67], respectively. In December 2011, numerous cardiac patients died at the Punjab Institute of Cardiology (PIC) by the administration of a substandard antihypertensive drug, which was contaminated by an antiparasitic drug 'pyrimethamine'[68] due to a manufacturing error[69]. The drug was fourteen times its normal dosage, causing folate deficiency, destroying platelets in the bone marrow, and resulting in heavy internal bleeding in the patients.[70] This was found to be manufactured by a well-established company that went by the name, 'Efroze Chemicals'. The WHO investigated the incident based on a request from the Government of Punjab, and found that a 45kg drum of pyrimethamine had gone missing and was accidentally added to the batch of cardiac medicine 'isotab'.[71] This 'Fake Drug Crisis' paved the way for the establishment of DRAP, and highlighted the need to improve the pharmaceutical regulatory structures at both the federal and provincial levels.

DRAP was established with the aim to develop a Quality Management System (QMS)[72] for drug production, and put in place standardised Good Manufacturing Practices (GMPs). The country was yet again shocked when an inability to identify significant levels of toxic levomethorphan in samples

[66] *Pakistan Heart Drugs: Lahore Death Toll Reaches 100. (2012, January 26). https://www.bbc.com/news/world-asia-16742832*

[67] *Perur, S. (2018, November 1). Fake drugs: The global industry putting your life at risk. https://edition.cnn.com/2018/10/30/health/fake-medicine-partner/index.html*

[68] *Johnston A, Holt DW. (2014) Substandard drugs: a potential crisis for public health. 78(2):218-243. doi:10.1111/bcp.12298*

[69] *WHO. (2013, March). Deadly medicines contamination in Pakistan. https://www.who.int/features/2013/pakistan_medicine_safety/en/*

[70] *Ibid.*

[71] *WHO. (2013, March). Deadly medicines contamination in Pakistan. https://www.who.int/features/2013/pakistan_medicine_safety/en/*

[72] *Hussain, S. (2017). 'Drug Regulatory Authority of Pakistan: Organizational Structure, Functions and Future Challenges'.*

of a substandard cough syrup claimed the livesof many.[73] These incidents brought to light the major health concerns plaguing Pakistan in the form of S&F medical products.

With the occurrence of the COVID-19 crisis, it has become essential for the dangers posed by S&F medical products to be dealt with. Experts have gone as far as to warn of a "parallel pandemic" of S&F products with the rise of the coronavirus.[74] The fake pharmaceutical industry triggered by COVID-19 has been found to exist in growing volumes, particularly, in developing countries.[75] The demand of essential items such as hand sanitizers have outstripped their supply leading to entry of substandard products in the market.[76] Earlier this year, a petition was filed before the Sindh High Court alleging the supply of substandard antibiotics by Ms. Baxter pharmaceuticals to Civil Hospital Karachi.[77] The current pandemic has necessitated an improvement of the regulatory and legal frameworks along with their enforcement mechanisms to counter the menace of S&F medical products.

Improving Quality Assurance

In order to put in place robust mechanisms for drug provision in Pakistan, it is important to assess the various facets of the pharmaceutical industry that impact healthcare provision which entails the provision of essential medicines. Pakistan's capacity to produce high-quality essential medicines provides insight into its emergency response preparedness. With the two largest producers of pharmaceutical raw materials- India and China- incapacitated due to the pandemic

[73] *Aziz, U. (2013, January 28). WHO finds 'lethal' substance in cough syrups. https://www.pakistantoday.com.pk/2013/01/28/who-finds-lethal-substance-in-cough-syrups/*

[74] *Vitelli, R. (2020, April 22). Health Experts Warn of "Parallel Pandemic" of Fake Coronavirus Cures. https://drvitelli.typepad.com/providentia/2020/04/health-experts-warn-of-parallel-pandemic-of-fake-coronavirus-cures.html*

[75] *OECD/EUIPO (2020), Trade in Counterfeit Pharmaceutical Products, Illicit Trade, OECD Publishing, Paris. https://doi.org/10.1787/a7c7e054-en.*

[76] *USAID From the American People. (2020, April 23).Ensuring the Availability of Quality hand sanitizers during the Covid-19 outbreak in Pakistan. https://www.usaid.gov/pakistan/news/ensuring-availability-quality-hand-sanitizers-during-covid-19-outbreak*

[77] *Khurshid, J. (2020, March 15). SHC seeks report on action taken against pharma company for making substandard antibiotic. https://www.thenews.com.pk/print/629208-shc-seeks-report-on-action-taken-against-pharma-company-for-making-substandard-antibiotic*

and unable to meet the global demand, it is pertinent for Pakistan to assess its own production capacity. Although the requisite infrastructure exists, the country's pharmaceutical industry relies entirely on imported raw materials to produce drugs, including the 'active ingredients' which contain medicinal properties to produce the required therapeutic effect.[78]

There are substantial gaps in access to essential medicines in Pakistan, due to a weak healthcare system and inadequate pharmaceutical regulations.[79] In addition, the data relating to essential medicines from LMICs, including Pakistan, is generally fragmented.[80] This presents challenges to the provision of essential medicines, particularly during health crises such as epidemics. Pakistan faces obstacles in the provision of quality essential medicines owing to a lack of capacity to develop and manufacture efficacious drugs, and an inability to prevent the sale of S&F drugs.

Despite this, it is potent to highlight that Pakistan is amongst the LMICs that have experienced considerable growth in their drug manufacturing industry.[81] The drugs produced by local manufacturing industries meet 70-80% of the country's medicinal needs.[82] However, studies on drug quality have found cases of numerous drugs containing incorrect amounts of active ingredients, traces of impurities, and production errors.[83] Furthermore, in spite of the growth in manufacturing firms, there is a lack of literature on Pakistan's GMPs standard compliance and the challenges faced by regulatory authorities in harmonising domestic standards of quality with international standards.[84]

[78] *Merchant, H. A. 2020, May 30. Why Pakistan cannot produce essential medicines. https://www.dawn.com/news/1560343*

[79] *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. https://doi.org/10.1371/journal.pone.0063515*

[80] *Ibid.*

[81] *Aamir M, Zaman K. 2011. 'Review of Pakistan pharmaceutical industry: SWOT analysis'. International Journal of Business Information Technology 1: 114–7*

[82] *Ibid.*

[83] *Johnston A, Holt DW. 'Substandard drugs: a potential crisis for public health'. Br J Clin Pharmacol. 2014;78(2):218-243. doi:10.1111/bcp.12298*

[84] *Tauqeer F, Myhr K, Gopinathan U. (July 2019). 'Institutional barriers and Enablers to implementing and complying with internationally accepted quality standards in the local pharmaceutical industry of Pakistan: a Qualitative Study', Health Policy and Planning, Volume 34, Issue 6, pp. 440–449, https://doi.org/10.1093/heapol/czz054*

In order for Pakistan to improve its capacity to produce therapeutic goods, it is important to review the gaps in the existing legal and policy framework on production of medicines.

i. Upgrading Quality Assurance Mechanisms

Pakistan's ability to produce efficacious and affordable essential medicines, particularly during health emergencies, is dependent on the quality assurance mechanisms of its locally-produced drugs. The international standard of assessing drug quality is provided in the form of the guidelines for Good Manufacturing Practices (GMPs). GMP guidelines aid regulators in ensuring that products are consistently produced and controlled according to quality standards.[85] GMPs cover all manufacturing processes, including quality management, sanitation, hygiene, qualification, validation, complaints, product recalls, self-inspection, personnel, premises, equipment, materials, documentation, production, quality control and more.[86] Various guidelines relating to GMPs have been laid out by institutions such as the WHO, United States Food & Drug Administration (FDA),[87] European Commission (EC)[88], and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[89]. GMPs are essential to ensuring adequate standards of drug manufacturing practices and countering S&F medicines, which are associated with mortality and morbidity, particularly in LMICs.[90] In Pakistan, no manufacturing units have received approval from the aforementioned

[85] *WHO. (n.d). Question and Answers. https://www.who.int/medicines/areas/quality_safety/quality_assurance/gmp/en/#;~:text=Good%20manufacturing%20practice%20(GMP)%20is,through%20testing%20the%20final%20product*

[86] *Ibid.*

[87] *U.S. Food and Drug Administration. (2018). Current Good Manufacturing Practice (CGMP) Regulations. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm*

[88] *European Commission (EC). (2018). EudraLex—Volume 4—Good Manufacturing Practice (GMP) Guidelines. https://ec.europa.eu/health/documents/eudralex/vol-4_en*

[89] *International Conference on Harmonization (ICH). (n.d). Quality Guidelines. https://www.ich.org/page/quality-guidelines*

[90] *Newton PN, Green MD, Fernández FM. 2010. 'Impact of poor-quality medicines in the 'developing' world'. Trends in Pharmacological Sciences 31: 99–101.*

authorities, with only one company possessing GMP certification issued by the European Medicines Agency.[91]

The manufacturing units in Pakistan are required to comply with a national system of GMPs. Under Section 4(c) of the DRAP Act 2012, the Director Quality Assurance and Laboratory Testing is responsible for the enforcement of current GMPs under the Act along with the testing and research of drugs.[92] GMPs are defined under the Drugs (Licensing, Registering And Advertising) Rules, 1976 as quality assurance which ensures products are consistently produced and controlled to the quality standards appropriate for their intended use as required by the marketing authorization or product specification; and diminishes the risks, inherent in any pharmaceutical production, including contamination, cross-contamination and mix ups that cannot be detected completely through the testing of final products.[93] This definition is identical to the definition of GMPs provided in the guidelines issued by the WHO.[94]

Based on the above definition, the Division of Quality Assurance uses a 'cGMP Audit Proforma' which provides a detailed criteria against which the compliance of drug manufacturers is assessed for purposes of panel inspection, grant of GMP certification, re-inspection after non-compliance report, grant of registration, and renewal of drug manufacturing license.[95] The Division of Quality Assurance operates through five regional offices, one in each provincial capital and the Islamabad Capital Territory.[96]

[91] *Rasheed H, Hoellein L, Bukhari KS, Holzgrabe U. 'Regulatory framework in Pakistan: situation analysis of medicine quality and future recommendations'. J Pharm Policy Pract. 2019;12:23. Published 2019 Sep 11. doi:10.1186/s40545-019-0184-z*

[92] *Section 4(c), DRAP Act, 2012.*

[93] *Section 2(t), The Drugs (Licensing, Registering And Advertising) Rules 1976.*

[94] *WHO Technical Report Series, No. 961, 2011.*

[95] *Drug Regulatory Authority of Pakistan (DRAP). (n.d). cGMP Audit Proforma https://www.dra.gov.pk/Home/Download?ImageName=SCHEDULEB_IIcGMPPerforma_updated.pdf*

[96] *Drug Regulatory Authority of Pakistan. Home page. Islamabad, Pakistan. 2020. http://www.dra.gov.pk/.*

Despite the existence of this framework for oversight and enforcement, presence of poor-quality drugs in the market continues to be a cause of concern, as demonstrated by the upsurge of S&F drugs during the Covid-19 pandemic. One identifiable cause of weak enforcement is the federal-provincial divide; the federal government is responsible for medicine licensing, manufacturing, registration, pricing, imports, and exports, whereas distribution and sales are regulated by the respective provincial governments.[97]

In February 2020, DRAP announced its plans of commencing a new phase of inspections to identify manufacturers that need frequent visits to ensure compliance with GMPs, and stated that those that fall below the requisite standards will be closed permanently.[98] As part of this initiative, DRAP inspectors were trained by international experts to build internal capacity.[99] The aim of this was also to increase Pakistan's potential to obtain membership to the Pharmaceutical Inspection Scheme Cooperation,[100] which is a non-binding cooperative arrangement between regulatory authorities to work towards compliance of GMPs.

This indicates that Pakistan not only has a basic framework in place to ensure compliance with GMPs, but also a willingness to increase its capacity through increased monitoring and compliance with international standards of drug quality. This can be enhanced through strengthening national pharmacovigilance mechanisms,[101] such as implementation of voluntary recalls of substandard medicines and reporting on suspicious or substandard medicines.[102]

[97] *Ibid.*

[98] *Junaidi, I. (2020, February 9). DRAP to begin benchmarking pharmaceutical units tomorrow. https://www.dawn.com/news/1533340*

[99] *Ibid.*

[100] *Secretariat. (2017). Annual Report. London: Pharmaceutical Inspection Convention. Pharmaceutical Inspection Convention Pharmaceutical Inspection Co-operation Scheme*

[101] *WHO (n.d). Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem' https://www.who.int/medicines/areas/quality_safety/safety_efficacy/pharmvigi/en/*

[102] *Ibid.*

In order to enhance vigilance, there is a need to prioritise drug regulation in budgetary considerations. Budgetary constraints appear to be one of the foremost hindrances in DRAP's ability to function efficiently. Under section 19 of the DRAP Act 2012, the authority is entitled to withdraw funds from the DRAP Fund to meet expenses incurred in the course of performing its functions.[103] According to an official in the Quality Assurance Division, resources in the DRAP Fund are severely limited, preventing the authority from adopting more efficient mechanisms of quality assurance.[104]

With regards to intergovernmental coordination for the purposes of enforcement of quality standards, some issues relating to cooperation between federal and provincial authorities are circumvented due to DRAP's direct federal jurisdiction. The presence of field offices in all provinces allows for swift decision-making and autonomy, which was not possible in the pre-DRAP structure. However, there is still a need for greater cooperation between the federal regulatory authority and provincial governments, particularly with regards to health regulations. This will allow for harmonisation of standards and enforcement of GMPs across the country.

In addition to harmonisation, greater inter-provincial coordination can improve enforcement of GMPs through information-sharing and cooperation to decrease violations. The impact of an overall increase in enforcement of required quality standards and information-sharing between enforcement agencies will increase the capacity of Pakistan to produce and ensure provision of good-quality drugs and health-related products to the public.

ii. Increasing Core Health Research Capacity

Investment in Research and Development (R&D) is essential to raising the quality of locally produced drugs, as well as assessing the effectiveness of imported drugs on community health. Scholars have contended that increasing the core health research capacity improves national health systems by boosting a country's resilience to

[103] *Section 19, DRAP Act, 2012.*

[104] *Personal Interview with Assistant Director, Quality Management System, DRAP.*

epidemics.[105] In spite of the WHO's call to LMICs to strengthen their health research capacity[106], the area has remained low-priority in Pakistan.[107] Further, there is a dearth of scientific data and literature on medicine quality[108] despite repeated cases of therapeutic failure in medicines[109] in the country. This can be attributed to the absence of publicly accessible drug testing data and a lack of technical and financial support to produce evidence-based studies.

In Pakistan's first National Science, Technology and Innovation Policy developed in 2012[110] by the Federal Ministry of Science and Technology, commitment to capacity-building of R&D in pharmaceutical manufacturing was emphasised. However, between 2007 and 2013, Pakistan's GDP allocation to R&D dropped from 0.63% to 0.29%[111]. Section 12(1)(b) of the Drugs Act, 1976, empowers the federal government to declare a specific percentage of the profits earned by the manufacturers of drugs to be utilised for purposes of advancing research in drugs. All manufacturers are required to contribute 1% of their gross profit before income-tax deduction to the Central Research Fund (CRF) which is maintained by the federal government, and utilized subject to the Drugs

[105] *Zachariah R, Maher D, Aseffa A et al. 'Strengthening the core health research capacity of national health systems helps build country resilience to epidemics: a cross-sectional survey' [version 2; peer review: 4 approved]. F1000Research 2020, 9:583 (https://doi.org/10.12688/f1000research.24192.2)*

[106] *WHO. The WHO strategy on research for health. Geneva, Switzerland: World Health Organization, 2012.*

[107] *Fatima R, Yaqoob A, Qadeer E, et al. 'Building sustainable operational research capacity in Pakistan :starting with tuberculosis and expanding to other public health problems'. Glob Health Action. 2019;12(1):1555215. doi:10.1080/16549716.2018.1555215*

[108] *Ibid.*

[109] *Ibid.*

[110] *Government of Pakistan, Ministry of Science and Technology, (October 2012). 'National Science, Technology and Innovation Policy 2012' https://most.comsatshosting.com/Policies/National%20Science,%20Technology%20and%20Innovation%20Policy%202012.pdf*

[111] *UNESCO. 'UNESCO Science Report 2013' pg. 49. https://unesdoc.unesco.org/ark:/48223/pf0000235406*

(Research) Rules, 1978.[112] In 2007, the fund reportedly amounted to 467 million Pakistani Rupees (PKR), with 75-85 million being collected annually.[113] Unfortunately, there is a lack of transparency in the utilisation of the CRF and what impact it has had on the R&D sector. According to independent analysts, R&D is almost non-existent in Pakistan.[114] The growing pharmaceutical manufacturing industry does not invest in R&D as the government's price-setting mechanisms present barriers for manufacturers who spend large sums of money in the development of drugs.[115] The practice of imposing prices of essential drugs on manufacturers, instead of allowing them to set their own prices, diminishes the incentive for producers to invest in the R&D of new drugs. As a result, Pakistan relies largely on health research from other countries.[116]

In order for Pakistan to become a knowledge economy capable of producing good-quality drugs and assessing their public health consequences, it must boost the uptake of secondary education, formulate funding and prioritisation mechanisms to generate more research on drug quality in Pakistan. In addition, private sector stakeholders should be provided incentives to invest in development of high-quality and affordable drugs, such as tax exemptions.[117] Scientific mobility can also be improved through international research collaborations, a trend already observed in Pakistan where a great majority of scientific articles are co-authored by international researchers.[118] This increases the research capacity of educational and research institutes, enabling them to achieve internationalisation as full-fledged research partners in international scientific co-operation.

[112] *Rule 19(14), Drugs (Licensing, Registering And Advertising) Rules, 1976*

[113] *Subohi A. (2007, December 10). Drug research fund lies idle. https://www.dawn.com/news/279566.*

[114] *Mansoor, H (2016, October 16). The politics of medicine pricing, https://www.dawn.com/news/1289752*

[115] *Pakistan Pharmaceutical Manufacturers' Association 'Pakistan's Pharmaceutical Industry' July 2017. p. 22.*

[116] *Ibid.*

[117] *UNESCO. 'UNESCO Science Report 2013' p. 49.*

[118] *Ibid, p. 75*

Pakistan must invest in the consolidation and expansion of the R&D sector, primarily, through larger budget allocations and capacity-building of research institutes. Pakistan already has a research partnership in place to conduct clinical trials for a COVID-19 with China.[119] This establishes a framework for collaborative research and information-sharing that could place Pakistan amongst countries at the forefront of COVID-19 related research, and pave the way for its establishment as a knowledge economy.

Through strengthening the overall capacity for health research, researchers will be able to identify locally produced S&F products, effectiveness of the drugs produced and their impact on public health. This will equip regulators and policy-makers to identify gaps in all tiers of pharmaceutical regulations and their enforcement.

iii. Initiating Clinical Trials

A high standard of clinical studies is important for both locally developed drugs and generic medicines manufactured in Pakistan. At present there are 150 vaccines for COVID-19 in the phase of development globally, which will lead to clinical trials.[120] China's decision to run a clinical trial for a vaccine produced by CanSinoBio[121] and the China Institute of Biotechnology[122] in Pakistan can give impetus to development in the country's potential for clinical studies. This is the first Phase-III trial to be conducted for any vaccine in Pakistan and the collaboration with China could lead to international cooperation for more clinical trials in the country. Additionally, through its economic and development partnership with China, Pakistan can acquire research, technology and funding support. This trial will, thus, serve as an important view into Pakistan's ability to hold clinical trials

[119] *Khan, R (2020, August 18). Pakistan green-lights Phase III trials for Covid vaccine. https://tribune.com.pk/story/2260053/pakistan-green-lights-phase-iii-trials-for-covid-vaccine*

[120] *Mckeever, A. (2020, August 27). Dozens of COVID-19 vaccines are in development. Here are the ones to follow. https://www.nationalgeographic.com/science/health-and-human-body/human-diseases/coronavirus-vaccine-tracker-how-they-work-latest-developments-cvd/*

[121] *A China-based vaccine developer.*

[122] *RadioFreeEurope (2020, August 19). Pakistan Approves Phase III Human Trials Of Experimental Chinese Coronavirus Vaccine. https://www.rferl.org/a/pakistan-china-coronavirus-vaccine/30790731.html*

for drugs in the future. In order to increase its potential as a site for clinical trials, regulatory authorities must enforce the highest standards of clinical study practices in local hospitals.

Clinical trials in Pakistan are regulated under the Bio-study Rules, 2017, which have been formulated by DRAP by virtue of the powers conferred by the DRAP Act, 2012. In order to initiate a clinical trial, the applicant must obtain ethical clearance[123] and prior approval[124] from the National Bioethics Committee[125] and Clinical Studies Committee (CSC)[126], respectively. The Pakistan Good Clinical Practice Guidelines[127], published by the federal government, provide guidelines for the conduct of clinical trials. Clinical trials may also be subject to the ICH guidelines, if required by the CSC.[128] DRAP, as the national regulatory authority, is responsible for issues related to the safety, quality, efficacy, handling and use of investigational products.[129]

In order to ensure quality and ethical compliance, the institutions conducting clinical trials are responsible for carrying out a periodic review and submitting reports to the CSC.[130] Additionally, the sponsor[131] of the trial must develop and implement a centralised monitoring procedure.[132] The CSC may also carry out random inspections of clinical trials to monitor their compliance to the approved study protocol.[133]

[123] *Rule 9, Bio-study Rules, 2017.*

[124] *Rule 14(2), Bio-study Rules, 2017.*

[125] *Ibid.*

[126] *Rule 13, Bio-study Rules, 2017.*

[127] *Rule 4(iii), Bio-Study Rules, 2017.*

[128] *Ibid.*

[129] *Bio-study Rules, 2017*

[130] *Rule 9(5), Bio-study Rules, 2017*

[131] *An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.*

[132] *Rule 9(2), Bio-study Rules, 2017*

[133] *Rule 11(1), Bio-study Rules, 2017*

Based on the Rules and Guidelines alone, there is a framework in place to monitor and review clinical trials at all stages. However, in spite of the oversight of the CSC and the National Bioethics Committee, their ability to monitor and review all aspects of trials has been questioned by experts.[134] Pakistan, owing to its large patient pool, high burden of communicable diseases, and internationally accredited institutions, is an ideal setting for clinical trials but regulatory hurdles such as licensing and intellectual property laws, make the process of initiating clinical trials lengthy and complicated.[135]

Another aspect that is a disadvantage to Pakistan's capacity to conduct clinical trials efficiently is the absence of a clinical trial registry which would provide free and open access to data relating to clinical trials conducted in Pakistan. Pakistani researchers currently register their trials on international registries,[136] such as the WHO International Clinical Trials Registry Platform (ICTRP).[137] Such registries minimise risk of selective reporting, publication bias and replication of trials. In order to improve Pakistan's internal capacity to conduct trials as well as support its R&D sector, it requires a central database of both completed and discontinued trials. This will allow for open collaboration, reconstruction and reinvestigation of failed clinical trials[138]. Furthermore, it will enable DRAP to collect more technical data on clinical trials. Creating a public registry supervised by DRAP will benefit healthcare researchers in Pakistan, and increase its capacity and infrastructure to conduct clinical trials. This will also increase the ability of researchers to

[134] *Waheed S, Siddiqui E.(2013) 'The unseen and untold issues of clinical trials and research ethics in Pakistan'. Int J Med Biomed Res;2(2):161-162 doi: http://dx.doi.org/10.14194/ijmbr.2211*

[135] *Rehman H, Ahmed Z (2017). 'Missed Opportunities in Pakistan: The Never-ending struggles and Challenges in Clinical Research'. Ann Clin Lab Res.*

[136] *Osama M., Malik R.J., Azim M.E. 'Clinical Trial Registry: An essential requirement for physical therapy and health researchers in Pakistan' Vol.68, No.7, July 2018 pp. 1079. https://jpma.org.pk/article-details/8774*

[137] *WHO. (n.d.). Welcome to the WHO ICTRP. https://www.who.int/ictrp/en/*

[138] *Office of the United Nations Secretary-General. 'Report Of The United Nations Secretary-general's High-level Panel On Access To Medicines' September 2016. pp.11. https://static1.squarespace.com/static/56209dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf*

conduct trials efficiently and make Pakistan's medical institutions competent to host international trials for vaccines.

iv. Rooting out Corruption

Experts in health policy purport that the pharmaceutical sector is rife with corruption at all levels, from registration of manufacturing facilities and medical products to setting prices, and from quality assurance during the manufacturing process and in the supply chain to prescriptions written by doctors.[139] In the context of corruption in the public sector, the role of the Policy Board of DRAP is crucial since it is charged, under Section 11(a) of the DRAP Act, 2012, with monitoring the implementation and performance of guidelines relating to good governance and accountability within the authority. In spite of the internal accountability mechanisms, DRAP has been subject to allegations of corruption.[140]

With regards to corruption by private entities, marketing practices of pharmaceutical drugs facilitate corruption as manufacturers primarily market their products to doctors, creating transactional relationships between pharmacists and physicians.[141] A relevant stakeholder commented that pharmaceutical companies producing substandard medicines collude with pharmacists and doctors to sell substandard products.[142] The prevalence of corruption and smuggling of originally manufactured drugs[143] also diminishes the incentive to invest in the production of generic versions of drugs locally. This not only results in dominance of S&F products in the market but prevents good-quality drug producers from entering the market.

[139] *Kiani, A. (2018). Health-sector turnaround. https://www.dawn.com/news/1436081/health-sector-turnaround*

[140] *Health ministry sacks 'whistle-blower' in Drap. (2020, January 15). https://www.dawn.com/news/1528309*

[141] *Ibid.*

[142] *Personal Interview with a retired BPS-21 grade officer.*

[143] *Ahmad, M. (2020, July 14). Drug pricing dilemma. https://www.thenews.com.pk/print/686418-drug-pricing-dilemma*

v. Developing a Clear Regulatory Framework for All Medical Products

As observed above, a Deputy Drugs Controller at DRAP, in an interview with the research team, commented that while medicines, medical devices and biologicals come within the jurisdiction of DRAP, there is no regulatory authority in place to check the quality of locally produced health-related items. Further, a surgeon employed at Children's Hospital, Lahore, on the condition of anonymity, commented that like several other public hospitals, the hospital had procured and approved extremely low-quality surgical gloves for usage which were causing a lot of problems for doctors, including an allergic reaction in the hands.[144] Thus, in the absence of any functioning regulatory body over certain health supplies, it is quite easy for poor-quality products to enter the market. As suggested above, these items should be brought within the jurisdiction of DRAP who will then be responsible for ensuring their quality.[145]

Reviewing the Legislative Framework

The UNODC argues that organized criminal groups circulating S&F products exploit gaps existing in legislative frameworks which include a lack of medical product specific laws.[146] Schedule II of the DRAP Act, 2012, prohibits the manufacture, sale, export or import of all unregistered, spurious, counterfeit, misbranded, adulterated, substandard and expired therapeutic goods. Schedule III goes on to prescribe the relevant punishments. Each of these terms have been defined in Section 3 of the Drugs Act, 1976. If the definition of therapeutic goods is extended to include health-related items, the legal framework necessary for the regulation of therapeutic goods will exist in Pakistan. The legislative framework must then be followed by adequate enforcement to successfully curb the menace of S&F products.

[144] *Personal Interview with a Pediatric Surgeon at Children's Hospital, Lahore*

[145] *It is essential to point out that the Pakistan Standards and Quality Control Authority (PSQCA) is currently monitoring the quality of hand sanitizers. However, one regulatory body should be made incharge of the quality assurance of health-related items.*

[146] *The United Nations Office on Drugs and Crime. (2020). COVID-19-related Trafficking of Medical Products as a Threat to Public Health. Vienna : UNODC Research. p. 13.*

Ensuring Compliance with Regulations

Section 11 of the Drugs Act, 1976, provides for the establishment of PQCBs which have the power to inspect drug manufacturing and sale premises, and examine the reports of the provincial inspectors. They are also required to advise provincial governments on the means of ensuring drug quality control in the respective provinces. Additionally, under Section 18 of the Drugs Act, 1976, federal and provincial inspectors are empowered to (a) inspect all premises used for manufacturing or sale of drugs; (b) take samples of such drugs; (c) seize drugs that may be used as evidence of the commission of an offense; and (d) seal factories, laboratories, shops or godowns etc used for the manufacturing or sale of drugs for contravention of the Act. It is argued that these powers should be used to regulate all therapeutic goods as defined above. Effective oversight or monitoring will facilitate compliance with rules and regulations. Further, the accountability mechanisms of the federal and provincial drug inspectors should be strengthened so as to ensure an effective functioning of the system to check the circulation and sale of S&F medical products.

Strengthening Detection, Investigation and Prosecution

For an investigation into any offences or contraventions to begin, the crimes must first be detected and reported. The ability to detect S&F goods requires a certain level of technical capability. It is, therefore, essential to ensure that the officials or inspectors charged with detecting such goods have the requisite training, skill and knowledge. Additionally, enforcement authorities must be made aware of the tremendous amounts of risks posed by S&F medical products. This is because authorities may deliberately overlook the supply of such items under the impression that it is better to have these products than none at all.[147] Evidence collection and chain of custody needs to be smooth so as to strengthen prosecution, and enhance the likelihood of possible convictions. Combatting the crime related to S&F medical products will require a focused effort towards criminalising behaviour that seeks to threaten the health of the public at large.

[147] *Ibid, p. 15.*

Enhancing National Coordination and Uniformity

Section 13 of the Drugs Act, 1976 obliges the federal government to issue directions to the provincial governments for ensuring the supply of good quality drugs at affordable prices, and to ensure uniformity in this regard. Additionally, in accordance with section 7(d) of the DRAP Act, 2012, DRAP must coordinate with the respective provincial governments, and relevant national and international organizations in promoting awareness campaigns, training, workshops and seminars to enhance capacity building. In light of sections 7(f) and 7(v), DRAP must also provide policy guidance to provincial governments so as to bring harmony and uniformity in the relevant functions of the governments, including an effective implementation of laws.

The most effective means of dealing with crimes of S&F medical products is to engender an effective collaboration between the regulatory agencies, police departments, and judicial authorities. Hence, exchange of information and inter-agency cooperation is vital for detecting and responding to crimes of S&F medical products.

Boosting International Collaboration

If it is discovered that the crimes in question can be traced back to international trafficking, efforts must be made by the international community to improve collaboration between national and international crime agencies. In such cases, trafficking groups obtain products from the origin production countries, pass through transit countries, and eventually supply them in destination countries.[148] Countries must publish regular reports to provide updates on the status of S&F medical products so as to strengthen international action against criminal groups.

Utilizing the WHO GSMS for S&F Medical Products

The urgency of establishing a global system to alert nations to the risks posed by S&F medical products was highlighted by the series of contaminated cough medicine incidents that caused many fatalities. Worrying similarities were found by the WHO between the deaths reported in Paraguay in September 2013, and those reported in Pakistan, by ingesting large quantities of cough syrups containing a cheaper version of the active ingredient dextromethorphan.

[148] *Ibid, p. 18.*

It was later discovered that the cough medicines that caused the deaths of numerous children in Paraguay contained dextromethorphan that had been imported from the same Indian manufacturer that had supplied the ingredient to Pakistan. Batches of the chemical were exported to other countries as well but were recalled in time.[149] This led to the development of WHO's surveillance system for the monitoring of S&F medical products. The GSMS has been issuing medical product alerts to warn authorities against rising numbers of falsified medical products that advertise the capacity to detect, prevent or treat COVID-19.[150] Pakistan must not only lend support to this global initiative, but also use it as a point of reference for policymaking in the medical product sector.

Encouraging Policy-Making in the Field of Healthcare

The gaps in healthcare, as outlined above, show that there is a vacuum between health and policy-making. One method of filling this gap is by implementing a multi-disciplinary method of assessing various aspects of health technology provision, such as Health Technology Assessment (HTA). HTA is a system used to assess the clinical, social, ethical and financial impacts of new health technologies.[151] The purpose of HTA is to evaluate a technology before it becomes part of established clinical practice[152], allowing clinicians to make informed choices regarding whether a technology should be used and what its impact on public health would be. It is, thus, relevant to all aspects of drug accessibility including clinical trials, development, manufacturing and its impact on public health. Establishing a centre to conduct HTA will enable health policies to reflect science-based findings as well as aid clinicians, including analysis of evidence regarding clinical effectiveness, safety, cost-effectiveness, ethical, legal and social aspects of health interventions.

[149] *WHO. (2017). WHO Global Surveillance and Monitoring System for substandard and falsified medical products. Geneva: World Health Organization.*

[150] *WHO. (2020, March 31). Medical Product Alert. https://www.who.int/news-room/detail/31-03-2020-medical-product-alert-n-3-2020*

[151] *Walley T, Rawlins M, Stein K. Health technology assessment--the role of the pharmaceutical panel. Br J Clin Pharmacol. 1998;45(3):217-220. doi:10.1046/j.1365-2125.1998.00678.x*

[152] *Ibid.*

COVID-19 AND ACCESS TO POTENTIAL VACCINES

In their fight against COVID-19, governments have not only sought to contain the virus, but also pursued measures to ensure treatment. Medicines and vaccines are, undoubtedly, essential to minimising the impact of influenza pandemics, such as the one at hand, on populations.[153] On 11 August 2020, Russia claimed to have issued a registration certificate to the world's first COVID-19 vaccine.[154] Meanwhile, numerous countries continue to invest in diverse projects pertaining to the R&D of promising vaccines against COVID-19. Attention is also being paid to the issue of global availability of the vaccine, in particular, for developing countries. An examination of the 2009 H1N1 influenza pandemic reveals that wealthy countries, mostly belonging to the European Union (EU), were able to secure vaccines on a priority basis by entering into advance-purchase agreements with manufacturers.[155] A similar trend can be observed during the current pandemic. The European Commission (EC) has concluded talks with Sanofi-GSK, Johnson & Johnson, AstraZeneca and CureVac, envisaging contracts which would allow all member states in the EU to purchase a COVID-19 vaccine.[156] Ursula von der Leyen, President of the EC, observed that the EC would do everything to ensure that Europeans are able to gain prompt access to a coronavirus vaccine.[157]

[153] *Turner, M. (2016). 'Vaccine procurement during an influenza pandemic and the role of Advance Purchase Agreements: Lessons from 2009-H1N1', Global Public Health, 11:3, 322-335, DOI: 10.1080/17441692.2015.1043743*

[154] *Cohen, J. (2020, August 11). 'Russia's approval of a COVID-19 vaccine is less than meets the press release', American Association for the Advancement of Science. https://www.sciencemag.org/news/2020/08/russia-s-approval-covid-19-vaccine-less-meets-press-release*

[155] *FRANCE 24 English (2020, May 18). A universal patent for Covid-19 vaccine? [Video File]. Retrieved From: https://www.youtube.com/watch?v=o9OTJnAz3rc*

[156] *The European Union. (2020, August 20). Coronavirus: Commission continues expanding future vaccines portfolio with new talks. https://ec.europa.eu/commission/presscorner/detail/en/IP_20_1494*

[157] *Ibid.*

COVAX, the vaccine pillar of the Access to COVID-19 Tools (ACT) Accelerator, serves as a ray of hope in this regard as it promotes the idea of a people's vaccine for COVID-19 [158], attempts to speed up the search for an effective vaccine, and supports the development of manufacturing capacity[159]. However, the pillar admits that the supply of a safe and effective vaccine will far outstrip its demand initially, and a system of priority allocation will have to be introduced.[160]

In order for access to be equitable, vaccines or technology essential for their development must be readily available to nations which need them the most.[161] The WHO has estimated that about half a million children hailing from sub-Saharan Africa die annually from diseases that could be prevented with vaccines.[162] A lack of access to vaccines, thus, takes a huge toll upon human life, especially in the developing regions of the world. Related to this is the regime of intellectual property rights (IPRs) that runs the risk of effectively barring the poorer nations of the world from accessing health technology. It has been argued that despite the rhetoric on vaccines as public goods, public funders have not been able to guarantee that vaccine related IPRs are retained by public entities so as to be able to determine sufficient production and distribution.[163] Additionally, initiatives such as the ACT Accelerator will face competition in terms of price negotiations from richer countries who aim to procure the vaccine for themselves.[164] Thus, governments in developing countries must act swiftly to ensure access for their populations.

[158]MSF briefing document.(2020, June). COVID-19 Vaccine Global Access (COVAX) Facility: Key considerations for Gavi's new global financing mechanism. Access Campaign, 1-9. p. 1
[159]WHO. (n.d.). The Access to COVID-19 Tools Accelerator. https://www.who.int/initiatives/act-accelerator
[160]COVAX (n.d), the act- accelerator vaccines pillar. Insuring accelerated vaccine development and manufacture. https://www.gavi.org/sites/default/files/covid/COVAX-Pillar-background.pdf
[161]WHO. (2012). Report of the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative. Geneva: World Health Organization .
[162]UNCTAD. (2020, May 27). COVID-19 heightens need for pharmaceutical production in poor countries. https://unctad.org/en/pages/newsdetails.aspx?OriginalVersionID=2375
[163]MSF Briefing Document. (2020). COVID-19 Vaccine Global Access (COVAX) Facility: Key considerations for Gavi's new global financing mechanism. Access Campaign, 1-9. p. 2
[164]Ibid, p. 5

This section discusses the misalignment between trade and intellectual property regimes and human right objectives, with a particular focus on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) vis-a-vis the public right to health. It sheds light on the flexibilities afforded within the TRIPS agreement, and urges Pakistan to take steps for their maximum utilization so as to ensure the provision of a 'safe, effective, quality and affordable essential vaccine'[165] for its population in the context of the COVID-19 pandemic.

IPRs and their Significance

Intellectual Property (IP) is defined as creation that belongs to the mind, including, but not limited to, inventions and works of literature or art.[166] Like other property rights, IPRs allow the owners or creators to benefit from the fruit of their work by bestowing recognition and financial rewards upon them. IP can further be categorized into (i) industrial property which includes, amongst others, patents to protect inventions; and (ii) copyright for literary works.[167] Article 27(2) of the Universal Declaration of Human Rights (UDHR), 1948, and Article 15(1)(c) identify the right of all authors to enjoy the protection of the 'moral and material interests' arising out of the production of their works relating to science, literature or arts. The World Intellectual Property Organization (WIPO) affords a three-fold significance to these rights- firstly, the creation of new works is quintessential to the progress of humanity; secondly, a legal sanctuary for these works is crucial to promote commitment towards their development; and finally, their preservation acts as a catalyst for economic growth, thus, improving the standard of living as a whole.[168] Hence, effective IP regimes are essential for the creation of an environment that ensures a balance between the rights of the authors or innovators, and the welfare of the public at large.

[165] *Goal 3, Sustainable Development Goals 2030*

[166] *WIPO. (n.d.). What is Intellectual Property? World Intellectual Property Organization. p. 2 https://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf*

[167] *Ibid, p. 2*

[168] *Ibid, p. 3*

Pharmaceuticals and the TRIPS Agreement

A number of IPRs including copyrights, trademarks, trade secrets and patents afford protection to medicines, vaccines and related technologies.[169] While copyrights protect the materials and designs explaining the medicines, trademarks may be used to secure their brand name. Trade secrets preserve the knowledge relating to the manufacturing of the pharmaceuticals, and patents cover, amongst other, the formulation of the products themselves. Through patents, states grant authorization to the patent holders to exercise exclusive control over the use of the property invented for a certain amount of time.[170]

The World Trade Organization (WTO) TRIPS agreement grants protection to inventions, including both products and processes in all technological fields. Signed in 1994, the TRIPS agreement aimed to engender a global IPR regime that would allow the synchronization of legal standards across all states that were members of the WTO.[171] Prior to this agreement, various states refused to grant patent protection to pharmaceuticals. However, the TRIPS agreement, by virtue of Article 28(1)(a) allows the owner of pharmaceutical products to prevent third parties from developing, utilizing, selling or importing the patented product. Patents can also cover the devices used for administering the vaccines, such as injections or capsules.[172] Patent owners are further entitled to sell their invention rights to someone else, or enter into licensing agreements permitting others to use their product on agreed terms.[173] It is significant to highlight that a patent granted by a country on a particular product allows the owner to exercise patent rights in that country only.

[169] *Stevens H, Debackere K, Goldman M, Mahoney RT, Stevens P, Huys I. (n.d.). Vaccines: Accelerating Innovation and Access. London: World Intellectual Property Organization. p.19*

[170] *UNDP. (2016). Report of the United Nations Secretary General's High Level Panel on Access to Medicines . United Nations Development Programme. p. 21*

[171] *Wong, H. (2020, May 15). The case for compulsory licensing during COVID-19. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7242884/*

[172] *Stevens H, Debackere K, Goldman M, Mahoney RT, Stevens P, Huys I. (n.d.). Vaccines: Accelerating Innovation and Access. London: World Intellectual Property Organization. p.19*

[173] *WIPO. (n.d.). What is Intellectual Property? World Intellectual Property Organization. https://www.wipo.int/edocs/pubdocs/en/intproperty/450/wipo_pub_450.pdf p.6*

Nonetheless, ever since the promulgation of the TRIPS agreement, patent owners are likely to find similar IP protections in all WTO countries.[174] Patents, thus, effectively grant the owners of pharmaceutical products the right to choose who may or may not use their product till the patent expires.

IP Considerations for a COVID-19 Vaccine

A fundamental function of IPRs in relation to a COVID-19 vaccine is to encourage and promote the tremendous amounts of R&D investments necessary for the said innovation. Moreover, patents would allow for control to be exhibited over the development and distribution of the vaccine. This, in turn, can facilitate checks and balances over the quality, safety and effectiveness of the coronavirus vaccine. Such a system of quality assurance is mandatory to engender public trust in the vaccination program so as to enable compliance.[175]

The IP protections extending to COVID-19 vaccines will, however, put developing countries at a disadvantage. Since countries such as Pakistan are resource-limited, they are less likely to develop a homegrown COVID-19 vaccine. Reports have claimed that most of the frontrunners in the race to develop a coronavirus vaccine are developed nations, hailing mostly from the West.[176] It follows that those involved in the development process will patent their innovations. It is likely that patentees will seek to recoup their investments by charging exorbitant prices for their products, which third-world countries will be unable to pay. [177] Experts have hypothesized that while the prices of COVID-19 vaccines are likely to be high, their volume of production will be insufficient to meet the global needs.[178] Resultantly, once vaccines have been developed, richer nations will

[174] *Ooms G, Hanefeld J. (2019, May 28). Threat of compulsory licences could increase access to essential medicines. the BMJ, doi: https://doi.org/10.1136/bmj.l2098.*

[175] *Ibid.*

[176] *Peter, Z. (2020, July 23). Thailand Readies Human Trials of Homegrown Coronavirus Vaccine . https://www.voanews.com/covid-19-pandemic/thailand-readies-human-trials-homegrown-coronavirus-vaccine*

[177] *Penfold, E. (2015, August 6). Explainer: the problem drug patents pose for developing countries. https://theconversation.com/explainer-the-problem-drug-patents-pose-for-developing-countries-45667*

[178] *Acharya, A. (2020). Making a COVID-19 vaccine globally available once developed. Helsinki : United Nations University. p.1*

receive them on a priority basis, and it is unlikely for them to have the incentive to eliminate the disease in poorer countries.[179] A case in point is the Cambridge-based Moderna vaccine, which reports have claimed is expected to be sold at a price ranging between 32 USD and 37 USD per dose.[180] Pakistan's total population was estimated to be around 216.5 million in 2019.[181] Assuming that the vaccine is sold at the upper bound price, the cost of vaccinating the entire population would be over 8 billion USD which is significantly higher, to say the least, than the entire health budget of Pakistan for the year 2020-2021.

Contrary to the claim of the TRIPS agreement that intellectual property aims to promote societal well-being by encouraging innovation[182], patent holders of COVID-19 vaccines can exercise significant power over the products' accessibility, especially, in poorer regions of the world. Hence, the use of IPRs over a vaccine relating to COVID-19 has the potential to cause 'significant social harm'[183] for developing countries, such as Pakistan by making healthcare virtually unaffordable.

Intellectual Property, Human Rights, and the Right to Health

Human rights are entitlements that are inherent to people by virtue of their very existence. They are both universal and fundamental, and must be respected as such. Numerous international legal instruments recognize the right of all individuals to enjoy the highest possible 'standard of physical and mental health'[184], and deem health to be an undeniable human right necessary for the exercise of other rights[185]. This right includes the right to an adequate standard of living, which includes,

[179] *Ibid.*
[180] *Lupkin, S. (2020, August 6). Prices For COVID-19 Vaccines Are Starting To Come Into Focus. https://www.npr.org/sections/health-shots/2020/08/06/899869278/prices-for-covid-19-vaccines-are-starting-to-come-into-focus*
[181] *The World Bank. (2019). Population Total-Pakistan. https://data.worldbank.org/indicator/SP.POP.TOTL?locations=PK*
[182] *Article 7: TRIPS Agreement*
[183] *ANUCollegeofLaw. (2020, June 21). Patent law and a COVID-19 vaccine [Video file], Retrieved from https://www.youtube.com/watch?v=AMfGXApGOhA*
[184] *Article 12(1): United Nations International Covenant on Economic, Social and Cultural Rights,1966*
[185] *CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)*

amongst others, access to medical care to promote the health and well-being of individuals.[186] The UN Committee on Economic, Social and Cultural Rights, in General Comment No. 14, adopted on 11 August 2000, emphasised that availability and accessibility to health facilities, goods and services are essential components of the right to health. Further, this right imposes upon states, the three-fold obligation of respecting, protecting and fulfilling the right to health of their citizens.[187] In turn, the third obligation- fulfilling the right to health- entails the adoption of appropriate measures, including administrative and legislative measures, to realize this right.[188]

Even though the right to benefit from the fruit of one's scientific, literary or artistic work is enshrined in international human rights law, this right, the United Nations Sub-Commission on the Promotion of Human Rights has affirmed, is subject to limitations in the interest of the public at large.[189] Accordingly, the Sub-Commission in resolution 2000/7, observed that there exists a disharmony between the regimes of intellectual property rights and international human rights law because the latter seeks to protect the right of everyone to benefit from 'scientific progress and its applications'[190]. The TRIPS agreement, which has been referred to as the 'watershed'[191] in the development of the protection offered by the intellectual property regime previously, seemed to present a policy dilemma for states: the economic benefits of increased IP protection versus the negative impact on the right to health. However, negotiators of the TRIPS agreement allowed certain flexibilities to cater to these tensions which were further extended, as will be discussed below, by the WTO Ministerial Declaration on the TRIPS Agreement and Public Health, commonly referred to as the 'Doha Declaration'. In this manner, the TRIPS agreement was interpreted to promote and uphold the right to health and access to medicines, and harmony was

[186] *Article 25(1): Universal Declaration of Human Rights, 1948*

[187] *CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)*

[188] *CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)*

[189] *Sub-Commission on Human Rights Resolution 2000/7*

[190] *Article 15(1)(b): International Covenant on Economic, Social and Cultural Rights, 1966*

[191] *UNDP. (2016). Report of the United Nations Secretary General's High Level Panel on Access to Medicines. United Nations Development Programme. p. 17*

sought to be engendered between trade and intellectual property frameworks, on the one hand, and public health objectives, on the other.

The TRIPS Agreement and Compulsory Licensing

Though patent protections extended under the TRIPS have been referred to as a 'death warrant'[192] for populations based in poor countries, the agreement allows for certain flexibilities in the management of goods essential to public interest. The most prominent amongst these is the compulsory licensing regime enshrined in Article 31 of the agreement. Compulsory licensing envisages the issuance of a license by a government to a third party or a government authority to use a patent without the consent of the patentee. In return, remuneration is to be paid to the right holders to compensate them for the utilization of their patent rights.[193] Previously, with respect to pharmaceutical products in particular, compulsory licenses were construed to authorize governments to domestically manufacture generic versions of the products without having to obtain the consent of the patent holder[194], and sell them for prices lower than those set by the patentees. This flexibility, however, had its limitations for developing nations. While theoretically, these nations could issue compulsory licenses under the TRIPS agreement, practically, many of them did not have the capability to obtain the essential ingredients of, or manufacture the drugs sought.[195] Exports by countries possessing the said capacity were subject to the restriction imposed by Article 31(f), that of supplying the domestic market 'predominantly'.

Thereafter, in the context of the increasing AIDS pandemic, the TRIPS Council entered negotiations to determine the right of all WTO members to utilize the flexibilities afforded by the agreement.[196] Resultantly, the Doha Declaration was adopted which recognized the gravity of

[192] *Wong, H. (2020). 'The case for compulsory licensing during COVID-19'. Journal of Global Health.*
[193] *Abbas, M. Z. (2013). 'Pros and Cons of Compulsory Licensing: An Analysis of Arguments'. International Journal of Social Science and Humanity.*
[194] *Ibid.*
[195] *Reichman, J. H. (2009). 'Compulsory licensing of patented pharmaceutical inventions: evaluating the options'. J Law Med Ethics, pp. 247-263.*
[196] *Sihanya, B. (n.d.). 'Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya'. World Trade Organization https://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm*

public health concerns faced by developing nations as a result of epidemics, and reconfirmed not only the right of member states to issue compulsory licenses, but also to determine the conditions of the grant of such licenses[197], including national emergencies or 'other circumstances of extreme urgency'[198]. The Declaration, in paragraph 6, specifically addressed the constraints imposed by the TRIPS agreement on WTO members that lacked production capacities in the pharmaceutical sector, and provided the mandate for an expeditious solution to the problem in question. The WTO General Council, on 30 August 2003, took the 'Paragraph 6 decision' and temporarily waived the requirement of Article 31(f) of the TRIPS agreement to predominantly cater to the local market, thereby, allowing manufacturers to supply drugs to countries with insufficient production capacities.[199] Subsequently, this provision was afforded a permanent legal status in the TRIPS Agreement.

COVID-19 and the Authorization of Compulsory Licensing

In order to secure access to COVID-19 related pharmaceutical products, certain countries have passed laws and parliamentary resolutions allowing for the invocation of the compulsory licensing regime. On 25 March 2020, Canada passed the COVID-19 Emergency Response Act authorizing the issuance of a compulsory license by the government, while doing away with the requirement of first negotiating with the patentees, or demonstrating the country's own ability to supply the product. Further, the remuneration of the patentees is to be determined by the Commissioner of Patents.[200] Similarly, the parliament of Chile adopted a resolution to announce that the current pandemic generates valid grounds for the use of compulsory licensing to enhance access to COVID-19 medicines, vaccines, and diagnostics etc.[201] Israel, under its domestic patent law, allowed a local company, on behalf of the government, to import generic lopinavir/ritonavir

[197] *Paragraph 5(b), Doha Declaration on the TRIPS Agreement and Public Health, 2001.*
[198] *Ibid, Paragraph 5(c)*
[199] *UN. (n.d.). TRIPS Agreement: waiver from notification requirements for issuing compulsory licenses for exports of pharmaceutical products to LDCs. International Support Measures for Least Developed Countries. https://www.un.org/ldcportal/trips-agreement-paragraph-6-system/*
[200] *Syam, N. (2020). 'Intellectual Property, Innovation and Access to Health Products for COVID-19: A Review of Measures Taken by Different Countries'. South Centre.p. 2*
[201] *Ibid.*

combination from a company based in India.[202] Ecuador passed a resolution allowing the minister of health to grant compulsory licenses over all COVID-19 related technologies.[203] On 23 March 2020, France passed a law that went beyond the compulsory licensing policy, and allowed the Prime Minister to take all measures necessary for making available essential COVID-19 medicines.[204] On 28 March 2020, the Prevention and Control of Infectious Diseases in Humans Act was enacted by Germany. The legislation authorized the federal ministry of health to issue a compulsory license under the existing Patent Act for medical products and devices, contingent upon the Bundestag's declaration of a national epidemic.[205] It is essential to point out that, amidst the pandemic, two countries, Canada and Germany made effective use of their existing patent law provisions to promote the issuance of compulsory licenses.

In this context, it would be beneficial to review Pakistan's legal provisions pertaining to compulsory licenses. The Patents Ordinance, 2000, amends and consolidates the law pertaining to the protection of inventions. Section 58 prescribes that the federal government may allow a government agency or a third party to exploit a patent for the sake of promoting public interest, and in particular, among others, public health. Section 59 of the Ordinance empowers the Controller of Patents to issue, upon request, a compulsory license to prevent exploitations that may occur as a result of the exercise of rights bestowed by the patent. However, Section 59(1) specifies that such a request can only be made after the elapse of a period of four years from the date of filing of the patent, or an expiration of three years from the date of grant of the patent, whichever term expires last. Pakistan must enact legislation to expand the scope of compulsory licensing under the Patents Ordinance, 2000. The Controller of Patents must be authorized to grant compulsory licenses over all COVID-19 related therapeutic goods on a prompt basis.

[202] *Ibid.*

[203] *Abinader, L. G. (2020, March 20). 'Legislative Committee in Ecuador approves resolution on compulsory licensing of patents relating to the coronavirus'. Knowledge Ecology International. https://www.keionline.org/32429*

[204] *Houldsworth, A. (2020, April 2020). The key covid-19 compulsory licensing developments so far. https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far*

[205] *Ibid.*

Compulsory Licensing and Challenges for Pakistan

It is clear that the havoc wreaked by the COVID-19 pandemic offers justifiable grounds for the use of the compulsory licensing regime. Pakistan can make use of compulsory licensing by either producing or importing an affordable generic vaccine. The limitations that Pakistan faces in the shape of poor manufacturing and quality control practices have been discussed in detail in Section II of this paper. Consequently, with respect to generic vaccines, there are challenges associated with both their production and importation in Pakistan. With regards to producing generic vaccines, Pakistan lacks adequate quality assurance and the manufacturing capacity to meet the demand for a COVID-19 vaccine. Pakistan's pharmaceutical industry has seen steady growth, from 304 'active manufacturers' in 1999[206] to 759 in 2017[207]. As of 2019, there are 620[208] licensed drug manufacturing units in Pakistan[209], out of which 596 are licensed for formulation[210]. Out of these, the number of pharmaceutical Multinational Companies (MNCs) has shrunk from 40 in 2000 to 17 or 18 at present[211]. Most of these MNCs have shifted away from medicine production to consumer products. As a result, medicine shortages are common; with Pakistani companies producing only 10,000 of the 70,000 registered drugs[212]. Manufacturers in Pakistan face a number of barriers in development of new medicines, particularly from lack of access to new technology and government investment in R&D. Reliance on cheap imported raw materials has been a disincentive to increase Pakistan's internal capacity to produce its own medicines, including

[206] *Quintiles IMS Q1 2017 Report*
[207] *Association, P. P. (2017). Pakistan's Pharmaceutical Industry. Policy Research Institute of Market Economy.*
[208] *DRAP. (n.d.). List of Valid drug Manufacturing Units Operating in Pakistan. https://www.dra.gov.pk/docs/15112019_final_list_of_units.pdf*
[209] *DRAP. (2019). Press Release. https://www.facebook.com/OfficialDRAP/photos/pcb.599777147120351/599777007120365/?*
[210] *DRAP. List of Valid Drug Manufacturing Units Operating in Pakistan. https://www.dra.gov.pk/docs/15112019_final_list_of_units.pdf*
[211] *Pakistan Institute of Development Economics (PIDE). Time to get the Pharmaceutical Industry Policies Right. https://www.pide.org.pk/pdf/PIDE-COVID-Bulletin-8.pdf*
[212] *Ibid.*

commonly used drugs such as paracetamol and ibuprofen.[213] As such, Pakistan's capacity to produce a generic vaccine is compromised.

With regards to imported vaccines, quality checks are conducted through lab testing and are subject to national quality assurance mechanisms.[214] In spite of these checks, cases involving deaths from adverse effects of substandard imported drugs have brought to light gaps in their implementation.[215] The only reliable quality assurance mechanism at present is the WHO's test of safety and efficacy for purposes of prequalification[216], after which additional quality checks are not conducted by DRAP subsequent to importation. If, under the compulsory licensing scheme, substandard or falsified generic drugs or vaccines enter the market, the consequences for public health can be grave. Thus, it is essential to exercise adequate quality controls and improve the regulation of therapeutics goods in order to be able to benefit from the compulsory licensing flexibility afforded under the TRIPS agreement. The mere threat of invoking the compulsory licensing regime has also been used by states to achieve price reductions.[217] This is because certain patent holders prefer to be open to negotiations regarding the price, rather than receiving a royalty against the product invented.

Alternative Potential Measures

Measures that can be taken by developing countries to promote access to health products within the existing IP regime are not limited to compulsory licensing. Article 73 of the TRIPS agreements provides that nothing in the agreement can be interpreted to preclude a member state from taking decisions or actions "which it considers necessary for the protection of its essential security

[213] *Merchant, A., & Hussain, I. (2020, May 30). Why Pakistan cannot produce essential medicines. https://www.dawn.com/news/1560343*

[214] *Section 3, DRAP Act, 2012.*

[215] *APP. (2018, December 20). Tyno Syrup case: Arrest warrants against three doctors issued. https://www.pakistantoday.com.pk/2018/12/20/tyno-syrup-case-arrest-warrants-against-three-doctors-issued/*

[216] *WHO. (n.d.). A system for the prequalification of vaccines for UN supply. https://www.who.int/immunization_standards/vaccine_quality/pq_system/en/*

[217] *Reichman, J. H. (2009). 'Compulsory licensing of patented pharmaceutical inventions: evaluating the options'. J Law Med Ethics, pp. 247-263.*

interests...taken in time of war or other emergency in international relations". Since public health crises, according to the Doha Declaration, can be considered national emergencies, it follows that a pandemic can amount to an emergency in international terms.[218] Further, given the severity of the current situation, and considering the number of deaths caused, the provision of effective treatment options by a state for its citizens can safely be construed as a measure to further 'essential security interests.'[219] Accordingly, to uphold public health objectives and interests, the TRIPS agreement allows countries to take measures such as the grant of indemnity against enforcement of IPRs and infringement claims. This means that states can enact legislations to suspend the implementation of IPRs in the context of IP protected COVID-19 products.[220] Moreover, pursuant to Article 6 of the TRIPS agreement, states are allowed to carry out parallel importation of essential products.

National Coordination and Policy Coherence

The health related flexibilities offered by the TRIPS agreement must, in general, be incorporated in the domestic intellectual property regime. As observed above, the national law on patents in Pakistan contains provisions relating to the authorization of compulsory licensing which need to be expanded under the current circumstances. An implementation of the aims and objectives of these IP flexibilities requires consistent policymaking and coordination between various government ministries and divisions of Pakistan, including, but not limited to, health, commerce, finance, science and technology, law and justice, planning and development, and ministry of interprovincial coordination. Coherence on a national level, thus, requires collaboration between the federal and provincial governments, and cooperation on an inter-provincial level as well.

[218] *Ruse-Khan, H. G. (2020, April 15). Access to Covid-19 Treatment and International Intellectual Property Protection – Part II: National security exceptions and test data protection. https://www.ejiltalk.org/access-to-covid19-treatment-and-international-intellectual-property-protection-part-ii-national-security-exceptions-and-test-data-protection/*

[219] *Ibid.*

[220] *Ibid.*

CONCLUSION

Good governance practices, strong regulatory structures, improved oversight mechanisms, accountability and transparency in public service are crucial for the eradication of crimes in the health sector. These include unfair commercial practices of hoarding and excessive pricing, as well as acts of manufacturing, distribution or sale of S&F medical products. Victims of such offenses must be encouraged to come forward and actively report them. The existence of inter-agency, and federal and provincial cooperation can help prevent, detect, and respond to such crimes by ensuring that the costs associated with such offenses far outweigh the likely rewards.

Relevant legal and regulatory structures must be revised to ensure a clear demarcation of responsibility for the oversight of health-related items. Further, the CCP must be called upon to assist existing authorities in eliminating consumer exploitation in the pharmaceutical industry. The CCP must engage in advocacy pushing for consumer protection measures while also ensuring that the incentive for necessary products to enter the market remains intact. In accordance with Section 29 of the Competition Act 2010, it must create awareness about competition issues occurring in the pharmaceutical sector, especially, in the context of disasters, such as the one at hand.

Access to safe, efficacious and quality therapeutic goods is a key component of the right to health. The circulation of S&F medical products is a menace to the enforcement of this right, and must be curbed by way of strengthening quality assurance mechanisms. This can be done through an increase in the budget and capacity-building of DRAP as well as an enhancement of inter-government and inter-agency coordination. DRAP must work with relevant departments in the provincial governments to define SOPs for cooperation and knowledge-sharing to enhance the enforcement of GMPs. This entails collaborations with provincial health departments, law-enforcement agencies and legislators. The capacity of DRAP to enforce GMPs must be increased through additional training programs which can be achieved through collaborations with experts from the private sector and foreign regulatory authorities. This will increase DRAP's internal capacity, and make it eligible for international certification schemes. Furthermore, DRAP must enter into Memorandums of Understanding (MOUs) with international law enforcement agencies,

such as Interpol, to facilitate information-sharing to prevent trafficking of S&F medical products. This will not only result in increased vigilance, but also serve to incentivise local manufacturers to invest in good-quality drugs to meet public demand.

Clinical trials are key to advancing medical knowledge and ascertaining the safety and efficacy of new drugs. In order to increase Pakistan's capacity to conduct clinical trials, a thorough system of oversight must be implemented. Any new health technology or essential drug must be evaluated for its effectiveness, side effects and public health consequences in the final stages and subsequent to completion of the clinical trial. In addition, a national public registry must be established for clinical trials taking place in Pakistan, based on WHO guidelines. This will enhance the overall quality of health research in Pakistan by making medical data available, and ultimately aid in policy decisions. Furthermore, the research capacity, resources, and quality of both public and private hospitals must be assessed. Models from hospitals with high standards of pharmacovigilance should be used to train researchers and improve clinical study capacity across Pakistan.

Public-Private partnerships between institutes of medical education and hospitals should be enabled to enhance the quality and growth of the R&D sector. Through these partnerships, researchers can pool resources and be more likely to produce research that meets international standards. This will also allow researchers in public institutions to access a variety of resources unavailable to them due to a lack of funding in the public sector.[221] In order to build the capacity of local researchers, in both the public and private domain, collaborations with international researchers must be enabled. This must include information-sharing agreements with reputed foreign institutions for medical research, funding for local researchers to be trained by international experts and clear targets for collaborative research enhancement. In order to produce drug testing data, investment in R&D must be accompanied by a database on the quality and public health impact of all imported and locally-produced drugs.

[221] *Shoaib, A. U. (2020, July 29). Post-Budget HEC. https://nation.com.pk/29-Jul-2020/post-budget-hec*

Interviews with policy experts revealed that DRAP is commonly perceived as a dysfunctional institution that has failed to play its role as an efficacious regulatory authority. However, a gap between the views of policy experts and DRAP officials was noted, whereby, the latter claimed to have been limited in their ability to effectively check the prices and quality of drugs owing to the availability of insufficient financial and human resources, as well as a lack of political will. The function of regulation must not be left on an 'autopilot mode'. The government must make efforts to activate the pharmaceutical regulatory structure, harmonize standards at the federal and provincial levels, and ensure sufficient budgetary allocations.

Despite repeated announcements of the introduction of the National Medicine Policy aimed at reforming the pharmaceutical industry of Pakistan, the government has failed to launch it. In this context, the untimely resignation of Dr. Zafar Mirza, who strongly advocated for the introduction of the National Medicine Policy, is deeply regretted. The federal government is urged to issue the policy and then move towards its implementation on a prompt basis.

In accordance with the prescription of the Alma Ata Declaration, it is vital to recognize that gross inequalities exist between the healthcare facilities available to the people of developing and developed countries, and these differences are 'politically, socially, and economically unacceptable'. They are, therefore, a matter of common concern for all nations, and signify the critical role of international cooperation in realizing the right to health. Since a crucial element of the global COVID-19 response is the treatment of the disease itself, it is necessary to analyze the measures that can be adopted within the existing intellectual property regime to ensure the provision of quick and affordable access to therapeutic goods. In this context, a reliance on compulsory licensing can prove to be advantageous, especially, for developing countries. Pakistan, being a signatory to the TRIPS agreement, must pursue with vigour the implementation of the flexibilities afforded within the agreement, and compulsory licensing must be viewed as a significant tool to advance access to essential pharmaceutical innovations.

Interlinked, is the idea of ensuring coherence between future trade agreements and public health priorities for national governments. Future trade agreements must be drafted in a manner that is supportive of universal human rights, and strike a balance between the promotion of health technology and pharmaceutical innovation, and the right of individuals to access essential medicines.

Health, a fundamental human right, is intrinsically linked with the right to enjoy a dignified existence. Therapeutic goods are crucial for the fulfillment of healthcare needs of the population, and for the attainment of sustainable development. Obstacles in accessing high quality, affordable therapeutic goods pose a challenge to human dignity, development and health objectives. Pakistan must view health as a fundamental goal of its policies and programmes, and strive to eradicate existing barriers so as to strengthen its national health system.

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