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## Pathways to Ensure Affordable Hepatitis C treatment: A Case Study of Pakistan

**Dr. Saima Butt \***

Assistant Professor, The University of Faisalabad.

**Dr. Nadia Zafar**

Assistant Professor, The University of Faisalabad.

**Dr. Naseem Razi**

Associate Professor, The International Islamic University Islamabad.

**\*Corresponding Author**

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### ABSTRACT

The World Health Organization (WHO) has declared hepatitis as a public health threat and designed a Global Health Sector Strategy (GHSS) to eradicate hepatitis (up to 90% reduction in incidents and 65% reduction in mortality) till 2030. The introduction of Direct Acting Antiviral (DAAs) has revolutionized the treatment of Hepatitis C virus (HCV) with a cure rate of more than 95%. The availability of DAAs has increased in recent years. However, still, millions of patients in middle and upper-middle-income countries have not started treatment, and the reason, in most cases, is unaffordability. Pakistan is providing the lowest price of HCV treatment in the world. In 2019, the WHO surveyed 12 low- and appreciated the efforts of Pakistan to ensure affordable HCV treatment for its people. This research highlights the efforts and strategies adopted by Pakistan to control the price and to scale up the treatment for all. This research provides ways for countries still facing the affordability issue to access HCV treatment for their patients. The methodology applied for this research is primarily analytical and bears the qualitative aspect of the issue. This research recommends a need to ensure affordable treatment for all and the case study of Pakistan to control the prices of HCV treatment is a paradigm for other countries.

**Keywords:** affordable, medicines, Hepatitis C virus, Direct Acting Antiviral, Pakistan, right, health, patent, TRIPS, DRAP, medicines patent pool.

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## INTRODUCTION

Unaffordable treatment costs are a critical issue for developing countries worldwide.<sup>i</sup> Many factors, including internal and external, influence the medicine expenditure, including inappropriate health infrastructure, unavailability of medicines, high price of drugs, economic constraints, patent barriers, and weak regulatory system. There are different ways to control all these factors. Internal challenges can be addressed by promoting generic medicines,<sup>ii</sup> improving health infrastructure, strengthening the regulatory system, and supporting research and development activities in the country.<sup>iii</sup> External factors can be handled by appropriate policies<sup>iv</sup>, efficiently dealing with intellectual property rights<sup>v</sup>, promoting technology transfer, and using TRIPS flexibilities.<sup>vi</sup> It is the primary duty of the state to provide appropriate health facilities to its citizens. Availability and affordability of medicines are the key components of health facilities. It is the responsibility of the state to use all available means to protect public health.<sup>vii</sup> Availability of medicine is linked with affordability because the price of medicine determines its consumption. In low-income countries, the cost of medicine determines how many will die due to the unavailability and unaffordability of medicine in upcoming years.

Hepatitis is a viral disease that affects the liver. Chronic hepatitis C leads to liver cirrhosis, liver cancer, and other serious liver-related issues that cause many premature deaths.<sup>viii</sup> WHO revealed in its report issued in 2015 that 71 million people are suffering from HCV worldwide and 399,000 deaths are from liver cancer, liver cirrhosis, and hepatocellular carcinoma. The WHO declared hepatitis as a public health threat. The WHO estimates that if the member states take proper measures, including diagnosis at the proper time, vaccination, ensuring availability of medicines, and educating people, more than 4.5 million deaths can be avoided by 2030.<sup>ix</sup> Currently, 58 million people suffer from chronic HCV, and every year, 1.5 million new infections crop up. DAAs are the most effective and safe treatment to cure HCV and can be used for all people above the age of twelve years.<sup>x</sup>

The World Health Organization (WHO) adopted its first Global Health Sector Strategy for Viral Hepatitis 2016-2021. The WHO provides guidelines and assistance for the member countries to control and treat HCV. The number of people treated with DAAs from 2015 to 2021 increased dramatically, from 122,000 in 2015 to 2.6 million in 2018. There are many reasons for this increase, and the reduction in treatment costs is one of them.<sup>xi</sup> The availability of DAAs has increased in recent years, but still, millions of people who are diagnosed with HCV have not yet started treatment (38%), and the reason in most cases is affordability. Prices are very high for HCV treatment in upper-middle-income countries, e.g., China, Brazil, Colombia, Kazakhstan, Turkey, and Mexico. Approximately 14 million patients with HCV are living in these countries. These countries are not party to the voluntary license, and patents are also granted in most of the territories. For this reason, the entry of generic drugs is illegal and no competition leads toward high prices.<sup>xii</sup>

We divide this study into different sections. Section one of this study deals with the introduction of the topic. Section two defines the significance of the study and how this study is different from the other research conducted in this field. Section three deals with the data collection and sheds light on the means used to collect data for this study. Section four of this study elaborates the situation of hepatitis in Pakistan and declares HCV as a pandemic in a country with limited resources and a high burden of disease. Section five highlights the efforts of Pakistan towards achieving the WHO target of eliminating HCV by 2030. In this section, efforts of Pakistan to eliminate HCV were highlighted, including surveys conducted on the national and provincial levels, and national and provincial hepatitis strategic frameworks elaborated. This section highlights the efforts of Pakistan to scale up the treatment of HCV by lower the price of HCV medicines as there is high poverty rate with a huge disease burden, and the government has a limited health budget. In section six of this study, we discuss the ways used to control the price of HCV treatment in the country. It was the collective efforts of the Ministry of Health, DRAP, and the judiciary. Finally, section seven comes up with a conclusion that to scale the treatment of any disease is possible only through affordability which needs the collective efforts of all the departments of state.

#### **How this study is different from others**

We found different research works related to HCV prevalence in Pakistan. Some of the articles were related to the Patient Assistance Program, which provides financial assistance to patients who need HCV treatment in different regions of Pakistan.<sup>xiii</sup> Some of the research work highlights that the price of branded DAAs is much higher than the generic.<sup>xiv</sup> A review paper highlights the need to know about the exact data on HCV prevalence in Pakistan and suggests that only effective prophylactic vaccines will help to eradicate HCV till 2030. Some suggests that affordable prices and speedy regulatory approval can help to scale up treatment for HCV.<sup>xv</sup> We found an article that narrates the efficiency and safety of generic dectastavir and sofosbuvir available in Pakistan. It concludes that generics are cheap and safe to use, and they will help achieve the WHO goal of eradicating HCV.<sup>xvi</sup> Some of the research deals with HCV prevalence, causes to spread, and types of genotypes that are more common in Pakistan. It also highlights the importance of a new survey on the national level as there is a high risk of the prevalence of HCV in rural areas, which is ignored.<sup>xvii</sup> Some articles highlight the importance of affordable treatment through DAAs. They assert that HCV treatment is still unaffordable in many jurisdictions, and without affordable prices, countries are unable to increase the treatment ratio and minimize the burden of HCV.<sup>xviii</sup> Some studies narrate that the cost of DAAs is not adjusted as per the country's income, and the price is lower in some upper- and middle-income countries due to the battered negotiation power.<sup>xix</sup> The high price of DAAs to treat HCV is an issue not only for upper-middle-income countries but for all. Even in the USA, the price of HCV treatment is very high. Due to the high price of the HCV treatment, the medical board of insurance companies denied insurance coverage for the drug. Some insurance companies have

developed aggressive policies to authorize the expensive DAAs used to limit the cost spending of branded Sovaldi.<sup>xx</sup>

This study is different from others because we are highlighting the ways and strategies adopted by Pakistan to ensure affordable treatment in the country, as Pakistan provides the lowest treatment cost for HCV worldwide. It was indispensable to do so because there was a fatal combination of poverty, the high burden of existing HCV cases, and the continuous threat of adding new cases rapidly. The object of this research is to remind the concerned authorities to continue this practice for other medicines that are out of the reach of the patients in Pakistan and also to provide a way for other countries facing high pricing issues for HCV treatment in their jurisdiction. There is a motivation that if Pakistan can do this with its limited resources, economic constraints, and poor health indicators in the region, then other countries can also do this through commitment and collective efforts.

### **Data collection**

Data collection for this study was a challenging task as no research available which provide the reasons for the low price of HCV treatment in Pakistan. The WHO report appreciates the efforts of Pakistan to control the HCV treatment cost, but how this cost was controlled, as our question, remained unanswered. However, the WHO reports help a lot in this study. Pakistan conducted two surveys, one on the national level and the other in Punjab, to get accurate data about the prevalence of HCV in the country. This research gets data about these surveys from government official websites. Data about the National Hepatitis Strategic Framework (NHFS) was obtained from the Ministry of National Health Services of Pakistan. Data about the DRAP and registration of generic HCV medicines in the country get from the official notification of the Ministry of Information and Broadcasting Pakistan. The patent office of Pakistan provides a difficult and time-consuming procedure if anyone wants to know about the patent status of any medicine in the country, so for this study, we get Data about the patent status of different HCV medicines in Pakistan from the MedsPal, a database hosted by the World Intellectual Property Organization (WIPO). So, by searching scholarly work, WHO reports, official websites of the Government of Pakistan, and official notifications, we were able to conclude this study.

### **Hepatitis C and Pakistan**

Pakistan is a low-middle-income country with a GDP of 5110 USD per capita (2018). Health spending is USD International 160.6 per capita. The share of health spending made from out-of-pocket is 66.5 %, and it is the highest in the region. One doctor is available for 1000 people, and one nurse is available for 2000 people in Pakistan. Pakistan's health indicators are the worst among the other regional countries. The Global Human Development Index (HDI) report 2019 places Pakistan way behind India, Bangladesh, and even the average of South Asia. Pakistan stands at 152 positions among the 189 countries in providing insufficient health facilities.<sup>xxi</sup>

More than 40% of hepatitis C patients live in China, Egypt, India, and Pakistan. In Pakistan, more than 10 million people are infected with HCV (2020).

Pakistan has the highest HCV burden worldwide.<sup>xxii</sup> With a huge population and high exposure rate, the risk of more prevalence increased, and according to an estimate, 240,000 new infections are added annually, enlarging the disease burden.<sup>xxiii</sup> Pakistan has few diagnosis services, and people in rural areas suffer more from hepatitis C due to late diagnosis. Annual reporting of liver cancer and liver cirrhosis increased threefold.<sup>xxiv</sup> It was a great challenge for Pakistan to deal with hepatitis due to its limited resources, a huge number of cases, and economic constrain. Hepatitis was declared a public health threat globally, and it was like a pandemic in Pakistan.

In 2019, a survey was conducted by the WHO in 12 low- and middle-income countries to check the burden of HCV and other efforts taken by state authorities to control the disease. This survey provides very important information regarding strategies adopted by each country towards regulatory approval, price-controlling means, and patent status of HCV medicines. Pakistan is also one of these countries whose efforts in HCV treatment and elimination by 2030 are considered appreciable. WHO report also suggests that other countries with limited resources and high disease burdens should learn from the experiences of these countries.<sup>xxv</sup>

Medicines for HCV are very affordable in Pakistan, and this affordability led to the starting of treatment by many people. Price reduction through generic competition is a very important tool, and it is used very effectively in Pakistan. In 2018, the prices of HCV medicines jumped down more than 75%, and new prices fell from 80 USD to 15 USD. Now, the cost of HCV medicines for 28-day treatment is 7 to 10 USD in Pakistan.<sup>xxvi</sup> Pakistan enjoys the lowest prices for HCV treatment. However, this price reduction is not available in many other countries. There are price variations by the pharmaceutical companies in some countries that limit access, and in other countries, patent barriers limit access to affordable medicines. High prices of HCV are a main hurdle in scaling up the treatment.

#### **Efforts of Pakistan towards achieving the WHO target of eliminating HCV by 2030**

The only way to control the disease is to start a prevention and control program on a national level and to ensure the licensing and availability of affordable new DAA.<sup>xxvii</sup> In Pakistan, to control HCV, extraordinary efforts were needed to fight against the lethal combination of poverty and disease burden, as more than one-third of the population is living beyond the line of poverty.

Punjab is the most populated province in Pakistan. The increasing incidents of hepatitis forced the provincial government to initiate the prevention and control program for hepatitis in 2005. The federal government also recognized the seriousness of the issue, and the very next year, the federal government also launched the "Prime Minister Prevention and Control Program for Hepatitis" in 2006.<sup>xxviii</sup> Pakistan conducted a national survey in 2007 with the objective of evaluating the existence of hepatitis B and hepatitis C cases in the country. This survey concluded that 2.5% of the population was HBV positive, and 5% of the population was HCV positive. It was also estimated that these 5% of patients will be exposed to infection to approximately 8 million people. The survey validated the

efforts of the government to control HCV infection and highlighted that the issue of hepatitis needs to be addressed more seriously.<sup>xxix</sup> After the 18<sup>th</sup> constitutional amendment of the Constitution of Pakistan in 2010, health became a provincial subject, so the Prime Minister Prevention and Control Program for Hepatitis was handed over to the provinces. After this amendment, the program was titled "Chief Minister Hepatitis Prevention and Control Program" (HPCP) in 2011.<sup>xxx</sup> All provinces, including Punjab, Sind, Baluchistan, and KPK, have continued their prevention and control programs for hepatitis. The objectives of all HPCPs are almost the same with little modification, and these objectives include

- To prevent infection through vaccination
- Screening and treatment of chronic infections
- To create awareness in the general public regarding the prevention and control of hepatitis
- To promulgate and implement effective health policies
- To strengthen health care system by improving capacity building and infrastructure
- Ensure affordable treatment

Punjab, being the most populated province of Pakistan, has the highest burden of hepatitis C than other provinces. The government has taken the initiative to control and treat HCV infections, and for this purpose, it conducted a new survey in Punjab from 2017 to 2018. The survey concluded that despite all efforts, HCV infection rose from 6.7 to 8.9 from 2008 to 2018, respectively.<sup>xxxi</sup> The government realized that a stepped-up response is needed to control HCV and achieve the WHO's goal. To achieve these objectives, the government has introduced a National Hepatitis Strategic Framework (NHSF).<sup>xxxii</sup>

### **National Hepatitis Strategic Framework (NHSF)**

After the 18<sup>th</sup> amendment, health became a provincial subject; however, the federal government, after considering the seriousness of the issue, decided to develop the National Hepatitis Strategic Framework. The Ministry of Health assigned the duty to the Technical Advisory Group (TAG) to frame a policy for NHSF 2017-2021 which must be in line with the WHO strategy to eliminate hepatitis by 2030. TAG, with the coordination of different national and international bodies, i.e., national and provincial Technical Working Groups (TWGs), experts from the Centre for Disease Control and Prevention (CDC) USA, and WHO Eastern Mediterranean Regional Office's team, worked together and succeeded in formulating the strategy.<sup>xxxiii</sup> The government launched the National Hepatitis Strategic Framework (NHSF) on 8<sup>th</sup> October 2017, and Federal Minister Sara Afzal Tarar signed the affirmation. NHSF works through different partners, including federal and provincial health authorities, hepatitis programs of each province, and different non-government organizations. NHSF ensures the implementation of a provincial action plan for the elimination of hepatitis.<sup>xxxiv</sup>

NHSF has a vision: "In Pakistan, viral hepatitis transmission is halted, and everyone living with viral hepatitis has access to safe, affordable, and effective

prevention, care, and treatment." It set the goal to eliminate hepatitis by 2030 and aimed to achieve a 30% reduction in new viral hepatitis incidents and a 10% reduction in related deaths.<sup>xxxv</sup> Pakistan showed excellent commitment and made great progress in treating HCV patients annually. Number of patients who started treatment also increased from 65,000 to 160,000 respectively.<sup>xxxvi</sup>

### **Ways to control the price of HCV treatment in Pakistan**

Pakistan has started its prevention and control programs at the national and provincial levels with the cooperation of federal and provincial governments, as stated above. It was also the vision of these prevention and control programs to make the DAA more affordable to fight against the lethal combination of poverty and disease burden in Pakistan.

Before the introduction of DAA, interferon injections were used to treat HCV patients, and the treatment through interferon was very problematic as it had many side effects. After the introduction of DAA, the treatment of HCV became easier and more secure. In Pakistan, Gilead successfully registered its blockbuster drug, Sovaldi. DRAP (Drug Regulatory Authority of Pakistan) fixed the price of Sovaldi as RS. 1,940 for a single tablet, and the total cost for 28 days of treatment was RS. 55,000.<sup>xxxvii</sup> Ferozsons has been a partner with Gilead since the launch of HCV. Initially, Ferozsons started an innovative way of treatment on a "named-patient basis," and then by enlarging its access program in low-middle-income countries, Ferozsons became the authorized partner of Gilead to manufacture and distribute the generic drugs of HCV in Pakistan.<sup>xxxviii</sup> Due to this blockbuster drug, the sale of ferozsons rose from Rs. 2.5 billion to Rs. 9 billion, with a growth of 222% annually.<sup>xxxix</sup>

### **Patent status of different HCV medicines in Pakistan**

Ensuring access to affordable HCV treatment by the new DAA was not an easy task. The state authorities were determined to promote equitable access to HCV treatment in Pakistan, and they considered every aspect very carefully. As before adopting any strategy to deal with the affordability of medicines, it was very important to know the patent status of different DAA in the country because it helps to determine the different options available accordingly.

The patent status of different DAA in Pakistan is as follows: the primary patent for Sofosbuvir was not filed, and other patents, though filed, were not granted. The patent for the Declatasvir compound was withdrawn, and the Declatasvir crystalline form was not filed. The patent for the Ledipasvir compound is withdrawn, and the patent for the Ombitasvir compound is filed but not granted. The patent is granted for the glecaprevir compound, and the patent for pibrentasvir compound has been filed but not granted yet.<sup>xl</sup> So, the situation was much more favorable in Pakistan with regard to patents, as some of the patents were not filed, others were withdrawn, and some were not granted.

### **Role of the Drug Regulatory Authority of Pakistan (DRAP)**

DRAP and the Minister of State (Health) Saira Afzal Tarar should be praised for their efforts to make equitable and affordable access to HCV medicines in

Pakistan. Ferozsons had right to sell the HCV medicine at the rate of Rs. 55,000 per pack; however, this price was very high and unaffordable for many poor patients in Pakistan. It was estimated that the registration of more firms will increase competition and lower the price of treatment as one of the companies (Everest Pharmaceutical) offers a lesser price of HCV treatment at Rs. 11,000 per pack.<sup>xli</sup>

Saira Afzal Tarar encouraged, in her speech, the local manufacturers to complete the registration process quickly in terms of quality, safety, and effectiveness of their product (generic Sofosbuvir). As a response, 16 companies applied for the registration of their generic Sofosbuvir, and DRAP registered 11 generic companies to produce HCV drugs. To ensure quick availability of medicine, the DRAP completes the registration process in two weeks. According to the law (Drug Pricing Policy 2015), the price of the generic drug will be 30% less than the original branded drug, and accordingly, it should be 26,000. Keeping in view the high burden of disease, poor financial conditions of the people of Pakistan, and international trends about the reduction in Sofosbuvir price, the DRAP set the price of generic Sofosbuvir RS.5,868 for 28 tablets. For this purpose, DRAP modifies the provision of the Drug Pricing Policy 2015 with the endorsement of the Prime Minister.<sup>xlii</sup> However, the generic manufacturer challenged it in court.

#### **Getz Pharma V Federation of Pakistan<sup>xliii</sup>**

The case was brought before the Sind High Court, and a notification was challenged on the ground that the Drug Pricing Mechanism (DPM), which is created under the DRAP Act 2012 (7 (c)(viii)), requires that the price of generic substitute should be 30% less than the original brand. The petitioner applied for the registration of the generic drug with a trademark of Sofiget (Sofosbuvir 400mg). The price was fixed by the authorities at Rs. 5,868, which is not less than 30% of the original brand, but it is 15.4% of the original brand price. The council for the petitioner also contended that the FerozSons were allowed to sell the HCV drug at the rate of Rs. 114,000 for three months of treatment. The petitioner prayed that he would be permitted to sell Sofiget at the rate of Rs. 26,600 for 28 tablets as it is 70% of the originator brand. Representatives of the Federation explained to the court that from the period when the price of the originator was fixed till today, the prices of Sofosbuvir fell globally. The representative from the federation further explained to the court that Pakistan has the highest HCV burden globally, and it's increasing day by day. The objective of fixing this low cost is to ensure that the HCV treatment would be affordable for the poor people of Pakistan.<sup>xliv</sup>

When the council for the petitioner insisted again on the point that the price of generic would be 70% of the original brand, the court remarked: "That why not set the generic's price of Rs. 5,868/- as the baseline and let the respondent follow the formula of 30% increase in the originator's price, i.e., Rs. 7,628.4 being 30% more than the price of the generic,". The representative from the Ministry of Health explains to the court that the price, once set, cannot be decreased before four years or the entry of three generics.<sup>xlv</sup>

The court explained that though the Constitution of Pakistan did not provide the explicit provision for the right to health however, the right to life under Article 9 and the right to dignity of man under Article 14 in court opinion give birth to the "right to health" The court also gives reference to the International Convention on Economic Social and Cultural Rights (ICESCR), which puts an obligation on the state to provide health facilities and protect the right to health. The court reaffirmed that the state is not allowed to favor expensive medicines just to facilitate a few people. The court ordered that access to affordable treatment be ensured as a fundamental right. The price fixed for generic Sofosbuvir as Rs. 5,868 was declared legal, and the petition was dismissed.<sup>xlvi</sup>

### **Pakistan as a member of Medicine Patent Pool licenses and bilateral agreement**

In 2015, the Medicine Patent Pool entered into an agreement for dolutegravir with Bristol-Myers Squibb. Through this agreement, generic manufacturers are allowed to sell the drug in 112 countries, and Pakistan is one of these countries.<sup>xlvi</sup> In 2018, AbbVie entered into a royalty-free agreement with the Medicine Patent Pool for glecaprevir/pibrentasvir to treat chronic HCV infection. This agreement enables generic manufacturers to sell their generic drugs in 96 low- and middle-income countries, and Pakistan is also included in the list.<sup>xlvi</sup> To facilitate access to HCV treatment, Gilead took a very appreciative step and gave licenses to generic manufacturers for Sofosbuvir, Ledipasvir, velpatasvir, and voxilaprevir and their combinations. As per this agreement, the licensee is allowed to manufacture and sell in 112 low and middle-income countries; Pakistan is also included in the list.<sup>xlix</sup>

### **CONCLUSION**

Ensuring the right to health is the primary duty of the state, but it is the joint responsibility of different actors of state to ensure the availability and affordability of medicines to needy patients, and the state shares this joint responsibility with pharmaceutical companies, drug regulatory authorities of the country, NGOs, and courts. The countries that are still facing the problem of the high cost of HCV treatment should learn that the entry of generic medicine in the market can lower the price through competition. If the patent becomes a barrier to control the price, then state authorities should go for TRIPS flexibilities. Compulsory licensing and parallel importation are very important and useful tools for the entry of generic competition. Pakistan enabled the entry of generic medicines without using TRIPS flexibilities because the patent was not granted, but in the territories where patents are granted, generic competition is possible just by the use of TRIPS flexibilities.

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