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A study of price regulation for patented medicines in India

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Abstract
In the realm of healthcare, the pricing of patented medicines has become a subject of intense scrutiny and debate. As India strives to ensure access to essential medicines while fostering an environment conducive to innovation, the regulation of drug prices, especially for patented medicines, takes centre stage. To grasp the current scenario, it is crucial to traverse the historical trajectory of pharmaceutical patenting in India. Since the early years of a product patent regime, India has undergone transformative changes in its approach, adopting measures that seek to strike a delicate balance between rewarding innovation and safeguarding public health. The introduction of a stringent product patent regime for pharmaceuticals is indeed a very controversial aspect of the TRIPS. Nevertheless, after the completion of the transition period of ten years, India introduced product patents on January 1, 2005, by making the necessary amendments to the Patents Act of 1970. But the most significant impact of TRIPS on India is the reintroduction of the product patent regime in pharmaceuticals. Although during the British era product patents were available in India, after independence, keeping in view the public health concerns, product patents for pharmaceuticals were made prohibited; only process patents were permitted under the Patents Act 1970. As India reintroduced product patents in pharmaceuticals, the main concern was how the introduction of a product patent regime might affect initiatives to strengthen public health and technical advancement, notably whether it would enhance the price of pharmaceutical products. However, measures like price regulation and compulsory licensing may be able to keep pharmaceutical prices in check. Even the threat of compulsory licensing could keep the price of patented drugs under control. In view of the above, this article undertakes a comprehensive exploration of the intricate landscape surrounding the price regulation of patented medicines in India, shedding light on the challenges, implications, and delicate equilibrium between innovation and affordability.

Keywords: NLEM, healthcare, territories, frameworks

Introduction

Affordability of medicine is always a concern for all developing countries; India is not exceptional. India's progress in healthcare and quality of life seems unsatisfactory. In the Human Development Index 2021/22, India ranks 132 out of 191 countries and territories [1]. Though India has been the world's top generic cheap medicines producer, with a considerable percentage of its exports (including low-cost HIV triple medications) made to the least developing nations, the affordability of medicine remains a great challenge in India, which has become more crucial in the new patent system. The cost of medicines in India is approximately 90 percent of the total amount that the vast majority of people spend on health care. Out of the total amount spend on healthcare, 72% in rural areas and 68% in urban areas spend towards the purchase of drugs for non-hospitalised. Spending money directly out of one's pocket continues to account for the majority (90%) of all healthcare expenses [2]. As in India, there was no product patent in medicine before 2005; only process patents were allowed. Indian pharmaceutical companies were in a good position as it allowed them to produce generic medicines using a new process that is both less expensive and sometimes more effective. But, under the new product patent regime, this will no longer be possible. As a result, it is a matter of concern for a country like India regarding the accessibility of patented medicine at an affordable price, particularly when a vast number of India's population live below the poverty line. However, measures such as price regulation of patented medicines, expanding healthcare coverage, strengthening regulatory frameworks, and promoting generic medicines may be adopted to keep pharmaceutical pricing within range.

National List of Essential Medicines (NLEM)

Indian NLEM is based on the Essential Medicines List (EML) published by the WHO, which serves as the foundation for medicine price control in India. For all patients (regardless of insurance status), NLEM medicine is subject to a price ceiling. NLEM medicines are generally comprised of treatments for diseases that have a substantial public health concern and are subject to a price ceiling. Any pharmaceuticals that meet prescribed conditions are included in the NLEM, according to the principles of inclusion [3]. It has undergone multiple updates and modifications since its introduction, with the most recent edition, NLEM 2022. When medicine is included in the NLEM, it guarantees that the medicines will always be available in sufficient quantity, at a price that is reasonable, and of high quality with a consistent standard. Essential medicines are chosen by following one of the fundamental concepts that guide the formulation of the National Medicine Policy (NMP), which seeks to assure access to, high-quality and reasonable price of, pharmaceuticals. In 1996, the government of India published the first NEML but unfortunately the list was neither implemented for procuring drugs nor treatment guidelines drawn up. Thereafter NLEM, was published and revised many times till date in 1996, 2003, 2011, 2015, and 2021, 2022. The NLEM 2021 has been released by the Union minister of health and family welfare on September 2, 2021 [4]. Subsequently, the Standing National Committee on Medicines (SNCM) was

constituted to review and revise the National List of Essential Medicines. The committee was headed by Secretary, DHR/DG, ICMR. The SNCM has submitted its final report on 10.09.2022 and after examination of the report; the Government of India has accepted the recommendations of the Committee in toto and adopted the National List of Essential Medicines (NLEM), 2022 as recommended by the SNCM along with other recommendations as contained in the report.

National List of Essential Medicines (NLEM) and National Pharmaceutical Pricing Policy

In addition to the NLEM, the government launched the National Pharmaceutical Pricing Policy (NPPP) in 2011 to boost the supply of essential medicines. The NPPP was later updated in 2012 with 652 drugs to further enhance access to critical medicines [5]. To make drugs cheaper, the NPPP, 2012, placed all drugs with the prescribed dose and strength listed in the NLEM under a price control regime. Accordingly, Drugs Prices Control Order, 2013 was issued by the Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers to establish the ceiling price of medications listed in the NLEM, 2011. Accordingly, all NLEM listed medicines are included in Schedule I of the DPCO 2013. All NLEM-listed medicines are referred to as "scheduled formulations," while those that are not are referred to as "non-scheduled formulations." Manufacturers are prohibited from selling their scheduled formulations for more than the ceiling price fixed by the NPPA, and non-scheduled formulations' pricing can never be raised by more than 10% in a single year. Medicines designated "essential" by the Director-General of Health Services (DGHS) are made available to consumers at reasonable rates as part of the NLEM, which is prepared by an expert committee appointed by the DGHS. LEM-listed medicines are referred to as "scheduled formulations," while those that are not are referred to as "non-scheduled formulations." Manufacturers are prohibited from selling their scheduled formulations for more than the ceiling price fixed by the NPPA, and non-scheduled formulations' pricing can never be raised by more than 10% in a single year. Medicines designated "essential" by the Director-General of Health Services (DGHS) are made available to consumers at reasonable rates as part of the NLEM, which is prepared by an expert committee appointed by the DGHS.

Drugs (Prices Control) Order

As per the current setup of price control mechanism in India, there is a list of essential medicine called NLEM the price of the medicine included in the list is regulated by NPPP through an authority NPPA [6] which is governed according to DPCO. In India, drug prices are fully controlled by the DPCO, issued by the government in line with Section 3 of the Essential Commodities Act of 1955. Due to the lack of pricing control regulations in place before 1962, India was badly affected by a severe shortage of life-saving medicines during the Chinese attack in 1962. As to serve national demands initiatives such as the promulgation of Drugs (Display of Prices) Order, 1962 and in 1963 the first order for price regulation was issued under the Defence of India Act, 1962 to fight the problem of price rise. However, the government realized eventually over time that such actions proved insufficient. Meantime, the Drugs Prices (Control) Order of 1966 was issued which made mandatory makers of drugs to get particular approval of the administration if the cost of such compositions as of 30th June 1966 had to be increased. Following the Chinese invasion of India in 1962, prices of all drugs and compositions were made frozen on and from April 1963 by Government order. These prices remained frozen for some important medicines until 1968, despite a subsequent increase in demand. But the pharmaceutical sector could not comply with this; the complaints and concerns were that raw material prices and manufacturing costs were not frozen and that rates continued to increase. As a result, in August 1968, the Government Order of Prices for Drugs (Control) was amended. This amendment exempted price approval of medicine mentioned in the prescribed list. After assessing the market structure and justification of the demand raised by manufacturers, the prices of new formulations were increased based on case to case basis. On16th May 1970 Drugs (Prices Control) Order was adopted and medicines were brought under the Essential Commodities Act, 1955. The main purpose of this order was to rationalize the prices of the indigenous pharmaceutical formulations. In this evolving process, Government then agreed to make further amendments to its DPCO-1970 policies. In February 1974 a committee had been set up under the leadership of Mr. Jaisukhlal Hathi, then MP. Some other MPs and experts were appointed as members. The Committee discussed the condition and development of the pharmacy sector, the positions of the public sectors, the development of indigenous manufacturs, and their capacities, particularly small-scale producer, product prices, the adequacy of and quality assurance initiatives, etc. The Hathi Committee submitted its report with 224 suggestions to the government in April 1975. The recommendations again stressed that government-owned enterprises would play a leading role in producing cost-effective medicine in bulk. Throughout the 1970s the government even adopted the Patent Act, under which " process patents’" were accepted. Though was not a straightforward policy for price regulation, but it had an immense influence on lowering costs for medicines in India, helping the nation to establish a major leader in the market for generic drugs. The Drug Policy-1978 and DPCO-1979 were formulated largely by the government based on the Hathi Committee's recommendations. The Drugs Policy - 1978 targeted at optimizing the production of bulk drugs domestically, offering leadership to the PSUs, decline in imports in bulk drugs, and support for the growth of the local industry. The fundamental form of the DPCOs stayed virtually unchanged between 1979 and 2013.

In 1997, the Indian government set up National Pharmaceutical Pricing Authority (NPPA) to control the prices of scheduled and Non-scheduled drugs and in 2002 the Pharmaceutical Policy was announced. The policy was not appealing to a wide segment of the Indian general public. The policy was considered to be more market-friendly and going to affect a dramatic price rise in drugs that the ordinary citizen requires. In Karnataka High Court a Public Interest Litigation was filed against the policy praying to quash, the same because the policy was structured like a business policy, and it would remove life-saving and critical medicines, from the scope of the Drugs Price Control Order which would greatly detrimental to the public interest. The High Court in Karnataka issued a stay order on pharmaceutical policies, the Central Government opposed the stay order and moved an appeal to the Supreme

Court on 10.03.2003. The Supreme Court lifted the stay and directed the Indian Government to create a mechanism to prevent price regulation for essential life-saving drugs. Since the Karnataka High Court orders backed by the order of the Supreme Court, the Government of India did not enforce the pharmaceutical policy of 2002 and The Drug Policy 1994 and DPCO1995 continued till a new policy was formulated according to the directives of the Supreme Court Order. The Indian government created its new drug policy in 2012 and the DPCO in 2013, which increased the number of medicine that come under the essential medicines category from 74 to 348 pharmaceuticals. The price control order issued by the department of pharmaceuticals has resulted in a 22 percent drop in the average cost of around 250 medications; but, according to recent research, the order only covers 17 percent of India's total pharmaceutical market [7]. To put the 2012 policy into effect, the government established the DPCO in 2013. The following are the most significant clauses of the DPCO, 2013:

1. The cap price for the 348 medications (only formulations) listed in the NLEM, will be fixed by the government.
2. The ceiling price will be set on the basis of market-based data given by IMS Health, a private-sector market research firm. The market share will be estimated based on yearly turnover.

Essential medicines and patents in India

Like in WHO MLEM, few patented medicines should be included in Indian NLEM as they are new with high therapeutic value and effective for the treatment of some lethal diseases like Cancer and HIV AIDS, so that they may be treated as essential medicines. If a pharmaceutical meets the basic requirements for inclusion in NLEM due to its effectiveness in treating a specific disease, it should not be exempted from inclusion due to the fact that it is protected by a patent. Every patient has the right to access such medicines, and the government and the pharmaceutical industry should work together to fulfil the purpose of NLEM and guarantee that even patented drugs should also be considered for inclusion in the NLEM. If a medicine is placed in the NLEM, that particular medicine cannot be sold above the price fixed by the government. But as per rule in case a particular medicine is not listed in NLEM, then also the importers/manufacturers cannot increase their price more than 10 percent within one year time. Whereas this policy will not be applicable to patented new drugs for a period five-year from the date of its launch in India as per a new amendment to the DPCO in January 2019 by the Department of Pharmaceuticals. Though it can be said that this amendment is only applicable for patented medicines that are marketed newly not for the existing patented medicines but the fact is that to date no patented medicine has been included in the NLEM. The government has also deleted 16 drugs from the existing list and the final NLEM 2021 now contains 399 essential medicines [8].

Impact of product patent on the price of patented medicine in India

As India brought back product patent rights in pharmaceutical, there were serious concerns that patented drugs would become inaccessible due to high prices. Nevertheless, the controversy over drug patents and prices in the post TRIPS situation was emphasized by many experts, and sometimes conflicting views on the impact of TRIPS on the price of medicine has been put forward by many studies and report conducted on the issue by many organizations. Some claimed that product patent of medicines would result in higher costs, some suggested that the costs of patented items would not automatically be high because costs vary according to the way companies set prices as well as depending on other regulatory frameworks. Prices of medicines can also be put under control by enforcement of price control mechanisms and compulsory licensing which are allowed under TRIPS. It might also happen that even if patents are enforced the average market price of medicine may not be high because of many factors such as demand factors, availability of alternative medicine, and other factors [9]. But with the controversy created by TRIPS, especially with regard to pharmaceuticals prices, it is surprising that some systematic empirical study on this issue supports the notion of the negligible effect and some other study confirms concerns about high prices and non-accessibility [10]. The market structure and the prices of generics do not vary widely because of TRIPS. Generic medicines can, according to the number of sellers, be sold like before and can be reasonably priced. Nonetheless, some study on medicine reveals that in practice those companies have proceeded to demand high prices on certain drugs since TRIPS [11]. The total market share of high-price medicine is small, thus TRIPS may appear to have little impact. In many classes of diseases especially Cancer, the ratio of high-priced drugs is significant. Though Cancer is still now not reported as a pandemic like HIV/AIDS. But is considered one of the most important public health issues in the world and certain drugs for cancer treatments are much more expensive than others.

Prices regulation of patented drugs in India

In 2006, it was planned to formulate a new National Pharmaceutical Policy, and a proposed National Pharmaceutical Policy, 2006 was drafted [12]. The most important aspect of the said policy was that patent drugs that would be introduced in India after the first day of January 2005 would be subjected to price negotiations before being granted marketing approval. Following the announcement of the policy, an expert committee will be constituted to conduct price negotiations for patented medicine.

Committee on price negotiations for patented drugs

As mentioned above, a committee was established by a memorandum in February 2007, which consisted of seven members, along with the chairperson [13]. The committee was entrusted with investigating the issue of the exorbitant price of patented medicines in the country and proposing a framework to keep them under control. The committee was supposed to submit its recommendations within three months of being formed, but it ended up taking nearly six years and ultimately submitted the report in 2013. Some of the most notable recommendations were as follows:

Table 1: Notable Recommendations of Committee on Price Negotiations for Patented Drugs

Patented Drug Pricing	Comparing the patented drug price prevailing in the developed countries such as USA, UK, France and then adjusting the same by considering India's purchasing power in relation to those countries
Patented Drug Pricing and Gross National Income	The committee found that the rates of patented medications are extremely high and even when the prices are calculated using Gross National Income with purchasing power, the price are still far beyond reach of the general population of the country
Fixation of price by the government	In case the prices are fixed unilaterally by the Government for open market it may result in the non availability of the medicine.
Expand the coverage of Healthcare	The government should expand the coverage of healthcare and insurance scheme at least for the best prescription medicine for all the citizens who are not covered under insurance or any other reimbursement scheme.

However, various groups have questioned the seriousness and dedication of the committee because of the massive delay in submitting the report. Though the government, on the other hand, rejected the recommendation, citing changes in market and pharmaceutical company market shares as reasons for abolishing the committee and its report. Following the dissolution, a new inter-ministerial committee was formed [14] to re-examine the issue [15].

Exemption of patented medicines from price control

In January 2019 amendments have been made to the DPCO 2013, which exempted producers of new patented drugs from price regulation for five years from the date of commercial marketing in India [16]. Though in the National Pharmaceutical Policy of 2002 there was a provision for exemption of patented drugs that are not manufactured abroad, from price regulation for 15 years from the beginning of commercial production in the nation. While the Department of Pharmaceuticals (DoP) claims the decision is in the best interests of Indian patients, civil rights advocates term it a "pro-pharma" action with "no element of public interest". It leaves people vulnerable to giant pharmaceutical companies that demand high rates for monopoly drugs. However, DoP claims the strategy will lead to more orphan medicine development. Due to the small patient number, few companies invest in rare disease medications. The action was taken to encourage firms to create drugs for rare diseases. The pharmaceutical sector hailed the move as it will make the Indian market more appealing to multinational pharmaceutical corporations and boost new medicines launches in India.

Conclusion

In regard to the affordability of patent medicines, product patents have a serious impact. To dilute this negative impact of product patents, pharmaceutical price control of patented medicines is an effective measure but is subject to government policy. The Indian government has developed a sophisticated drug pricing system, but it is only applied to generic medicines because the government has resolved not to implement any price control mechanisms for patented drugs. Price control is permitted under various agreements of the WTO, including TRIPS. The government's current pharmaceutical policy does not cover patented drugs and instead plans to regulate them through a separate mechanism. Committees have been assigned to conduct a comprehensive examination of the issues surrounding the price regulation of patented drugs. Reports have been generated, but no concrete action has been taken till now.

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