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QUALITY CONCERNS AND ACCESSIBILITY ISSUES: GENERIC MEDICINES AND COMPULSORY LICENSING IN INDIA

Prof. Shiv Shankar Singh
Faculty of law, C.M.P. Degree College, University of Allahabad
Mrs. Shreya
Research Scholar, Faculty of law, C.M.P. Degree College, University of Allahabad

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Abstract

Despite India's reputation as the global manufacturer of generic drugs, a huge quality concern persists in India and generic medicines are assumed as low quality drugs compared to the branded options. Due to high prices, many citizens in India are deprived from various essential and life saving drugs. This deprivation has also been enhancing due to quality concerns and accessibility issues in the generic alternatives of the branded drugs. The authors have tried to find out whether there are enough legal standards and experts' backing in India to confirm that generic medicines are as effective as the branded drugs and lower prices of the generic medicines are not associated with poor drug quality or do not indicate that there is lack of essential ingredients in the manufacturing of generic drugs to make them affordable. Essentially, the authors have analysed whether low cost generic medicines are really an affordable option of the costly branded drugs or not. At the end various suggestions have also been given to eradicate the quality concerns in the generic medicines and to enhance their accessibility.

Keywords: *Generic medicines, compulsory licensing, Patents Act 1970, The Drugs and Cosmetics Act 1940, Jan Aushadhi*

1- Introduction

In this globalised world, the role of India has evolved as the "Pharmacy of the World" and a destination of affordable medicines. This paper analyses the legal landscape concerning generic medicines, compulsory licensing in India and the current shift towards quality enhancement. Regarding medicines a perception has been established that the high cost of medicines gives more effectiveness. This perception has gone against generic medicines and created trust issues. Low trust (because generic medicines are quite cheaper compared to branded patented medicines) and lack of awareness among the public have worked as hindrances to promote preference of generic medicines over branded medicines.

As the world's pharmacy India not only produces over 20% of global generic medicines but exports these to 200+ countries. In this way there is a big contribution of India in making healthcare affordable worldwide. But lack of trust and doubt over the quality of generic medicines still persists among Indian citizens. Recently a non-profit Mission for Ethics and Science in Healthcare in Kerala under Citizens Generic vs Branded Drugs Quality Project tested a total 131 samples from 22 medicines popularly used for heart disease, liver disorders, diabetes, infections, acidity, allergies, pain and thyroid conditions. Compared to the branded medicines, no difference in quality of generic medicine was found in this study,[1] which proves that Indian citizens should not hesitate in preferring generic medicines over branded drugs. Government schemes like Pradhan Mantri Bhartiya Janaushadhi Pariyojana along with various apps and online platforms have started providing easy mediums to purchase generic medicines but still lack of trust exists and accessibility issues persist.

2- Generic Medicines & Compulsory Licensing

Low-cost generic medicines can be manufactured after the expiry of patents of the branded drugs. The patent in the branded drugs lapses after 20 years, during this period manufacturers sell it at a high price which can make many needy people skip the much needed doses. These branded drugs can not be afforded by lower middle class and poor people which makes it necessary to bring some alternative drugs with the same effect after expiry of patent or the government to intervene to immediately allow other manufactures to bring the same drug in the market. In the first case other manufacturers can bring the alternative drugs after the lapse of patent period but in the second case other manufacturers by seeking Compulsory Licence can bring alternative drugs even during the enjoyment of patents rights by branded manufacturers. In this way, both ways are quite impactful in solving the high prices of needy medicines but the legal mechanism of compulsory licensing is much more effective during public health emergencies.

It requires solid hard work, long time research and continuous funding to manufacture various important & life saving drugs.[2] These reasons justify the high prices and the innovators should be allowed to recover their spendings but at the same time saving the life of needy people is also important. In India patents in drugs expire after a period of 20 years which gives manufactures genuine time to recover their spendings or make profits but after this period the government should take effective steps to make these life saving drugs accessible to all at the affordable prices.[3]

In a country like India where many patients are deprived of life saving drugs due to high prices, the government should continuously remain active to eradicate accessibility concerns by granting compulsory licensing against an active, valid patent and by giving justified compensation to the patent

[1] Anuja Jaiswal, "Quality of generic drugs as good as that of costlier branded cousins: Study", *The Times of India,* January 5, 2026, *available at* <https://timesofindia.indiatimes.com/india/quality-of-generic-drugs-as-good-as-that-of-costlier-branded-cousins-study/articleshow/126346200.cms#ampshare=https%3A%2F%2Ftimesofindia.indiatimes.com%2Findia%2Fquality-of-generic-drugs-as-good-as-that-of-costlier-branded-cousins-study%2Farticleshow%2F126346200.cms> (last visited on February 25, 2026).

[2] Prathiba M. Singh, *Patent Law (In 2 Volumes)*, 1st ed., Eastern Book Company, Lucknow, 2019.

[3] Bryan Mercurio & Daria Kim (eds.), *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options*, Routledge, London, 2021.

owners.[4] The Patents Act, 1970,[5] legally regulates Compulsory Licensing (CL) in India. Its section 84 has allowed a person to apply for a compulsory license after 3 years of a patent grant but based on following conditions:

1. if the reasonable public requirements are not met,
2. if due to high price the patented invention is not affordable,
3. if the invention is not available or manufactured in India.

Due to these reasons the first case of CL happened in 2012 when Nexavar (the generic version of Bayer's cancer drug), prepared by Natco Pharma, received CL. This historical and successful move with the aim of enhancing public health decreased this cancer drug's price by over 90%. In future, similar steps are also expected to make affordable medications available to all.

2- Quality Assessment of Generic Medicines

Due to lack of awareness, many patients fail to take the benefits of generic medicines. Medicines form 62% to 69% of the total healthcare expenditure of Indians. Many Indians deliberately don't purchase various important medicines just because of the fear of high prices which results in missed doses, treatment discontinuation, worsening health conditions and in many cases loss of life.[6] Under Pradhan Mantri Bhartiya Janaushadhi Pariyojana the government has taken initiative to supply generic medicines at a very low price compared to the branded medicines but with the same quality.

Recently, the Citizens Generic vs Branded Drugs Quality Project tested a total 131 samples from 22 medicines popularly used for various serious health issues. Compared to the branded medicines, no difference in quality of generic medicine was found in this study. At the same time it was also found that there was a huge price gap of 5 to 14 times in the branded medicines compared to the generic medicines. This landmark study has helped a lot in strengthening the trust in generic medicines.

A lot of people consider cheaper products as low quality products. There are many companies which produce both branded as well as generic medicines but with a huge price gap which creates confusion among people with improper knowledge about generic medications. They can't afford the branded medicines but at the same time ignore the cheapest versions as well due to lack of trust and quality concerns.

The Drugs and Cosmetics Act, 1940,[7] has mandated uniform standards for all drugs whether domestic or imported, which ensures that generic drugs are not less effective and in reality contain the same active ingredients in equivalent dosages as branded ones. It shows that the Indian laws are in favour of generic drugs, hence effective steps should be taken to prevent inconsistent manufacturing of generic drugs. Continuous production, hassle free supply and adequate awareness among people are must to eradicate the accessibility concerns.

3- Effectiveness & Accessibility Concerns

Generic medicines are as effective as branded drugs but lack of awareness, wrong perception among people related to cheaper products, association of lower prices with bad quality, non-recommendation by the physicians/doctors and inadequate supply, along with many other reasons are responsible to generate trust issues and make needy people remain inaccessible to generic options.

Many Senior clinicians have affirmed that generic medicines, including Jan Aushadhi drugs, are effective and comply with Indian Pharmacopoeia Standards. They have claimed that the many generic drugs are even 14 times lower in costs compared to branded ones but perform as equal as the branded drugs. They have recommended continuous monitoring and quality assessment of the generic drugs to enhance the trust

[4] Tanusree Debnath, *Compulsory Licensing of Pharmaceutical Patents and Access to Medicine*, Satyam Law International, New Delhi, 2017.

[5] (Act 39 of 1970).

[6] Anuja Jaiswal, "Quality of generic drugs as good as that of costlier branded cousins: Study", *The Times of India,* January 5, 2026, *available at* <https://timesofindia.indiatimes.com/india/quality-of-generic-drugs-as-good-as-that-of-costlier-branded-cousins-study/articleshow/126346200.cms#ampshare=https%3A%2F%2Ftimesofindia.indiatimes.com%2Findia%2Fquality-of-generic-drugs-as-good-as-that-of-costlier-branded-cousins-study%2Farticleshow%2F126346200.cms> (last visited on February 25, 2026).

[7] (Act 23 of 1940).

among people. Continuous lab testing should be actively done and any generic medicine with quality lapses (5-10% substandard) should be removed from the market to maintain the trust among people.

Adulteration or supply of spurious drugs should be dealt strictly with harsh penalties on the wrongdoers along with punishment up to life imprisonment. Inconsistent manufacturing and inadequate supply aggravate accessibility issues. Domestic Active Pharmaceutical Ingredients (API) production has to be enhanced to streamline drug manufacturing and to reduce India's dependence on China. Physicians/Doctors also have to play an important role to make patients aware about affordable options by recommending them generic medicines. Some credits and rewards should also be given to them for recommending such drugs to patients. Evergreening Strategies by the branded drug manufacturers should be strictly prevented. Branded drug manufacturers should be promoted and encouraged to bring generic options of their drugs or not to restrict the supply of generic options of their branded drugs.[8]

9- Conclusion & Suggestions

The authors found that there are enough legal standards and experts' backing in India to confirm that generic medicines are as effective as the branded drugs and lower prices of the generic medicines are not associated with poor drug quality or do not indicate that there is lack of essential ingredients in the manufacturing of generic drugs to make them affordable. Hence the authors conclude that generic medicines are genuine medicine with low prices and following suggestion are given to eradicate quality concerns and enhance accessibility:

- Fast-track approvals should happen for all the applications for manufacturing generic drugs or requests for compulsory licensing.
- Continuous lab testing should be actively done and any generic medicine with quality lapses (5-10% substandard) should be removed from the market to maintain the trust among people.
- The issue of shortage of labs should be resolved immediately. Their capacity has to be enhanced via public-private partnerships,
- Implementing AI-driven risk-based inspections, continuous monitoring and real-time batch tracking are much needed steps in this technologically advanced world.
- A dedicated IP bench should actively work to quickly resolve Compulsory licensing related issues or disputes.
- Domestic API production has to be enhanced to streamline drug manufacturing and to reduce India's dependence on China.
- Steps should be taken to prevent inconsistent manufacturing of generic drugs. Continuous production, hassle free supply and adequate awareness among people are must to eradicate the accessibility concerns.
- Some credits and rewards should also be given to Physicians/Doctors for recommending generic drugs to patients.
- Evergreening Strategies by the branded drug manufacturers should be strictly prevented.
- Branded drug manufacturers should be promoted and encouraged to bring generic options of their drugs or not to restrict the supply of generic options of their branded drugs.

Generic mediation should also be made available for low-risk categories.

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[8] Van Anh Le, *Compulsory Patent Licensing and Access to Medicines: A Silver Bullet Approach to Public Health?*, Palgrave Macmillan, Cham, 2021.