Jus Corpus Law Journal
Open Access Law Journal – Copyright © 2023 – ISSN 2582-7820
Editor-in-Chief – Prof. (Dr.) Rhishikesh Dave; Publisher – Ayush Pandey

Book Review: The Truth Pill: The Myth of Drug Regulation in India

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Received 16 May 2023; *Accepted* 19 June 2023; *Published* 23 June 2023

INTRODUCTION

India's pharmaceutical industry is a significant contributor to the country's economy, as it is one of the largest manufacturing industries and a major source of exports. [1]However, the industry has faced international criticism for engaging in unscrupulous and unethical manufacturing practices, resulting in multiple disasters. The Truth Pill: The Myth of Drug Regulation in India, authored by Dinesh S Thakur and Prashant Reddy T, provides an investigative approach to India's drug regulatory landscape, using historical and contemporary insights to address the regulatory, political, and financial challenges that affect the regulatory body. Mr. Thakur, a chemical engineer with expertise in drug manufacturing processes, and Mr. Reddy, a lawyer who has studied India's drug manufacturing laws, have together combined the science of drug manufacturing with government initiatives necessary to strengthen the regulatory framework. The book draws upon primary sources of information, including government reports, judicial decisions, and government data.

[1] 'Pharmaceutical companies in India' (*India Brand Equity Foundation*, February 2023) <https://www.ibef.org/industry/pharmaceutical-india> accessed 04 May 2023

REGULATORY GAPS AND FAILURES SURROUNDING NSQ DRUGS

The book offers a comprehensive overview of India's drug regulatory landscape in eleven chapters. It begins by examining the historical context that led to systematic drug regulation globally and in India. [2]The book further delves into the significant regulatory gaps and failures surrounding NSQ drugs, safety and efficacy requirements for new drugs, generic medicines, and regulatory violations. [3]Sadly, the Indian market has been riddled with the widespread sale of NSQ drugs, posing serious health risks, including aseptic shock and even death. The book draws attention to the concerning trend where, even after identifying such drugs, judges tend to disregard the minimum mandatory punishments stipulated in the Drugs and Cosmetics Act 1940 and has continued to impose minimum fines. This tendency incentivizes guilty pleas and exacerbates the problem.

GENERIC MEDICINES AND REGULATORY VIOLATIONS

Furthermore, the authors present a provocative title, "Can 'Made in India' Generic Medicine be Trusted?" and delves into a discussion on essential aspects of drug manufacturing, such as bioequivalence and drug stability, while highlighting the significance of adhering to regulatory requirements in India.[4] Although the authors do not explicitly answer the question posed in the title, the book highlights a significant concern in the generic drug industry in India, concerns about variations in formulations and potential adverse reactions in patients, and this has resulted in the hesitancy of doctors to prescribe generic drugs even after indication to do so.[5] This chapter raises pertinent questions about the regulation and quality control of generic drugs in India, providing a comprehensive understanding of the challenges and opportunities in the generic drug industry in India.

EVALUATION OF THE AYUSH SECTOR IN INDIA

The book offers a meticulous evaluation of the AYUSH sector in India, delving into the historical and political factors that have shaped its development and the regulatory mishaps that have

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[2] Dinesh Singh Thakur and Prashant Reddy Thikkavarapu, *Truth Pill: The myth of drug regulation in India* (Simon & Schuster 2022)
[3] *Ibid*
[4] *Ibid*
[5] George Thomas, 'The Truth About Drug Regulation in India' (*The India Forum*, 05 January 2023) <https://www.theindiaforum.in/health/truth-about-drug-regulation-india> accessed 04 May 2023

allowed for its proliferation.[6] By exposing the double standards of Indian politicians who advocate for the "scientific aspect" of traditional medicine while simultaneously dismissing the need for proof of efficacy, the book highlights the inherent contradictions in the government's approach to AYUSH. The authors also explore the various risks associated with the sector, not only from the practitioners and manufacturers but also from the Indian government itself, which has invested public funds into research establishments for traditional medicine without adequate testing or regulation. Through a series of case studies, the book uncovers instances of government-endorsed products that have been found to be adulterated and have caused adverse reactions, further highlighting the need for a critical and evidence-based approach to traditional medicine in India. These drugs also make wild claims while advertising and have been supported by the government in their advertisements which has further promoted their usage. Despite calling for a re-evaluation of the current approach and emphasising the need for scientific valuation of remedies, the authors understandably hold a pessimistic view on making any meaningful regulatory reforms due to the powerful lobbying efforts of the Ayurvedic industry and cultural propaganda. The industry's net worth of 16 billion dollars underscores the significant challenges to instituting meaningful changes that could safeguard public health.[7]

ECONOMIC GROWTH VS PUBLIC HEALTH

The author's analysis sheds light on a concerning trend in the pharmaceutical industry, where economic growth is often prioritised over public health. This problem is not unique to India but is prevalent in many countries, and it can have severe consequences in the pharmaceutical sector, where prioritising profit over patient safety can have devastating effects. The situation is particularly concerning in India, where the government's regulatory approach often prioritises the growth of the pharmaceutical industry over the protection of public health. The example of the CDSCO's first mission statement, which prioritised the interests of the pharmaceutical industry over public health, is a clear illustration of this trend.

[6] Dinesh Singh Thakur (n 2)
[7] Vinay Umarji, 'Traditional medicines sector ayush gets funds worth rs 6000 CR at summit' (*Business Standard News*, 22 April 2022) <https://www.business-standard.com/article/current-affairs/traditional-medicines-sector-ayush-gets-funds-worth-rs-6000-cr-at-summit-122042101265_1.html> accessed 05 May 2023

The author also mentions the stand of the Indian government has also been known to take a defensive stance and dismiss any criticism, often labeling it as propaganda. This was exemplified in the Ranbaxy scandal, where the company was penalised by the US government, but the Indian media, doctors, and government dismissed the allegations as Western propaganda aimed at damaging the Indian pharmaceutical industry. To address this issue, governments and regulatory bodies must prioritise the protection of public health in the pharmaceutical industry and hold companies accountable for any wrongdoing. This will ensure that patients receive safe, effective, and affordable medications that meet their healthcare needs.

NEED FOR GOVERNMENTAL REGULATIONS

In the final chapter of 'The Politics and Levers of Reforming India's Drug Regulatory Framework', the authors attempt to address the crucial question of how to reform India's drug regulatory system. However, the chapter lacks the clarity and precision found in earlier chapters. The authors seem to favour a strong centralised regulator over the current multiple state regulators with the necessary resources and powers to ensure that drug manufacturers in India comply with recognised quality standards and have uniform standards. However, even if the regulatory body were to be centralised, the question remains whether the government would accept the deep-seated problems in the regulations and address them, such as setting up mandatory trials for the creation of traditional medicine. The authors suggest that middle-class activism could play a crucial role in driving reform. The authors highlight how the glorification of the Indian pharmaceutical industry and the tendency to attribute any criticism to anti-Western propaganda have contributed to the collaboration between these parties, which could impede reform efforts.

CONCLUSION

In conclusion, The Truth Pill is a highly relevant and compelling book based on years of deep research. The book, through multiple case studies and examples, shows you the frightening reality of the consequences of a dysfunctional regulatory system in India and the impact this can have on patients globally. The book raises pertinent questions about the regulation and quality control of generic drugs in India, the proliferation of the AYUSH sector, and the need for the scientific evaluation of remedies. It further highlights the challenges and opportunities in the

generic drug industry in India, revealing the concerning trend where economic growth is prioritised over public health. As readers, we are challenged to consider how we can contribute to creating a better future for global public health. We must demand better regulation and quality control of generic drugs, advocate for more scientific evaluation of remedies and hold politicians and corporations accountable for their actions. The book reminds us that 'India can only truly be considered the 'pharmacy of the world' if it upholds the highest standards in drug manufacturing and is recognized for doing so. It is up to us to ensure that this vision becomes a reality.'[8]

[8] George Thomas (n 5)