DEVELOPING AN AGENDA FOR INCULCATING A 'TRUST-BASED' REGULATORY REGIME IN THE INDIAN PHARMACEUTICAL SECTOR

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Abstract

While it is a trite statement that regulation and bureaucratic red-tape stifles industry functioning and innovation, it is equally trite that regulation of various sectors of the economy are quintessential and there cannot be lowered regulation or complete deregulation. One such sector is the pharmaceutical sector. The rationale for regulation within pharmaceutical sectors across the world is one of public interest- these sectors are regulated stringently to protect public health and access to medicines. India's pharmaceutical industry has been hailed to be the "pharmacy of the world" due to the fact that it supplies numerous developing countries, and has a strong supply of generic medicines which are cost effective and increase access to medication in many of these countries. However numerous tragedies involving Indian pharmaceuticals have harmed the repute of the Indian pharmaceutical sector, both globally and domestically. If India is to truly become the "pharmacy of the world", it will have to rebuild these burnt bridges. To this end, this paper proposes an agenda for a 'trust-based' regulatory regime adopted by the Indian pharmaceutical regulator. The paper will begin by outlining the theoretical justifications for regulation, highlight the importance of trust as a value in regulatory regimes, the failures of the Indian pharmaceutical sector, and highlight the prescriptions for a 'trust-based' regime.

Keywords: Pharmaceutical Sector, Regulatory, Trust-Based, public interest

Introduction

India has the distinction of being hailed as the "pharmacy of the world" as a result of its ability to efficiently produce and export medicines at very affordable rates to many countries.[1] A perusal of the top 25 countries where Indian pharmaceuticals are exported reveals that many of the countries which do import Indian pharmaceuticals are all low-income countries which

[1] Rakhi Bose, *India Takes Pride in Being the 'Pharmacy of the World' But Cough Syrup, Eye Drops Tell a Different Story*, OUTLOOK (Feb. 13, 2023, 7:30 AM) https://www.outlookindia.com/national/india-takes-pride-in-being-pharmacy-of-the-world-but-concerns-over-eye-drops-and-syrups-risk-denting-the-image-news-261679; Guest Author, *Why is India the Pharmacy of the World*, FINANCIAL EXPRESS (Sept. 25, 2021, 15:37 PM) https://www.financialexpress.com/lifestyle/health/why-is-india-the-pharmacy-of-the-world/2337554/ .

cannot afford high-priced pharmaceuticals that 'big pharma' companies sell. As a result, they turn to cheaper alternatives (known in pharmaceutical parlance as 'generic medicine') in order to shore up their supply of necessary medication. India's pharmaceutical industry has become adept at supplying generic medication due to the prevalence of skilled labour along with its patent regime that allows for the creation of such generic medicine.[2]

However, in recent times, these exported medicines have become the subject of much public scrutiny. Exported Indian cough syrup has been the cause for a spate of deaths in Uzbekistan and Gambia.[3] Investigations conducted by the World Health Organization ('WHO') have revealed the Gambian deaths were a result of a toxic contaminant Diethylene Glycol ('DEG') being found in the impugned cough syrups.[4] Similar findings were also reported with the Uzbekistan deaths.[5]

The logical question to ask would be how the 'pharmacy of the world' could allow such incidents to take place? The answer to this question is nuanced. Firstly, it has to be stated that many of the countries that India does export pharmaceuticals to are developing countries which do not have such stringent regulatory regimes as a result of financial constraints. Due to this, numerous substandard products can pass through and lead to outcomes such as the ones outlined above. The more uncomfortable reality (and one which needs to be faced), is that India does not have a very robust and stringent pharmaceutical regulatory regime and it results in substandard products being produced.

The deaths due to exported pharmaceuticals are unfortunately the tip of the iceberg. Numerous other lapses in the industry have gone under the radar. Such incidents damage the reputation and legitimacy of the Indian drug regulators- the Central Drug Standards Control Organisation (CDSCO) and the state regulators, both domestically and internationally. In order to win back that reputation, the regulator will have to rebuild these burnt bridges and show it is an

[2] Sajid Sheikh and Gunjan Deshpande, *What You Need to Know About Generic Drugs and Why They Matter*, THE WIRE SCIENCE, (Mar. 11, 2021) https://science.thewire.in/health/what-you-need-to-know-about-generic-drugs-and-why-they-matter/#:~:text=The%20Government%20of%20India%20launched,generic%20drugs%20at%20affordable%20prices.

[3] Safina Nabi, *Death by Cough Mixture: Global Scandal Exposes India's Weak Drug Regulations*, HEALTH POLICY WATCH, (Feb. 20, 2023) https://healthpolicy-watch.news/india-death-by-cough-mixture/#:~:text=The%20cough%20mixture%20had%20been,of%2070%20children%20in%20Gambia.

[4] World Health Organisation, Medical Product Alert No. 6/2022: Substandard (Contaminated) Paediatric Medicines, (Oct. 05, 2022)https://www.who.int/news/item/05-10-2022-medical-product-alert-n-6-2022-substandard-(contaminated)-paediatric-medicines .

[5] World Health Organisation, Medical Product Alert No. 1/2023: Substandard (Contaminated) Liquid Dosage Medicines, (Nov. 11, 2023)https://www.who.int/news/item/11-01-2023-medical-product-alert-n-1-2023-substandard-(contaminated)-liquid-dosage-medicines .

organisation which isn't just a toothless tiger. Effectively, this would mean that more regulation and regulatory activities are required. To this end, the paper proposes the move to a 'trust-based' regulatory regime. Through the journey that this paper takes, it will be established that having a 'trust-based' regime will be more effective in the regulatory outcomes it seeks to achieve compared to the current fragmented regulatory scheme.

I wish to make two crucial contributions through this paper. The first is to increase the nascent scholarship on regulation and regulatory governance in India. The second is to provide a theoretical understanding to prescriptions of regulatory reform. It is hoped that the theoretical justification will present a clearer vision of why these prescriptions are necessary and might be effective.

The paper proceeds in the following manner- firstly, it outlines the theoretical justifications for regulation. Secondly, it explores the contours of trust and its importance in a regulatory regime. Thirdly, it outlines the failures of the CDSCO in going about its regulatory functions. Finally, it lays out the prescriptions that a trust-based regime might espouse, before concluding.

Understanding Regulation

It can often be fallacious to suggest that regulation can be cumbersome and stifles innovation, and less regulation would be beneficial to the market.[6] There are two issues with such claims. The first is that such claims often do not define regulation nor does it reflect an adequate understanding of the regulatory space and regulatory processes. It is often given a broad generalized understanding as some form of state intervention under this paradigm. The second issue is that such reasoning assumes that regulation is a thoughtless and arbitrary imposition by the State onto firms within the market, and ignores the rationales for regulation. It would thus be imperative to understand regulation, and study the rationales for regulation. This helps provide a better appreciation for the regulatory process and need for regulation, and would help to assess any merits of such statements that argue against having regulation.

The starting point of this analysis is the understanding of the regulatory space. The regulatory space, as conceptualized by Hancher and Moran, is an 'analytical construct'.[7] Essentially, it is envisioned as a boundary within which the activity of economic regulation takes place, and is

[6] Phillip Aghion et al., *Does Regulation Affect Innovation? Study Shows it Does, But There is a Way Out,* THE PRINT (Feb. 03, 2021, 14:27 PM) https://theprint.in/opinion/does-regulation-affect-innovation-study-shows-it-does-but-there-is-a-way-out/597700/ .

[7] Leigh Hancher & Michael Moran, *Organizing Regulatory Space, in* CAPITALISM, CULTURE, AND REGULATION 272, 277 (Leigh Hancher & Michael Moran eds., 1989).

comprised of various stakeholders in the regulatory process- consumers, regulated firms, and the regulator. Within this boundary, each of the actors are seen as being involved in a struggle for power and an analysis of this would require an investigation into the relational dynamics between the actors.[8] It is in light of this relational analysis that the element of 'trust' will be examined in the subsequent section of the paper.

Once this understanding of the regulatory space has been established, it is imperative to understand what the activity of economic regulation entails. Regulation is the process of exercising public and popular control by a sovereign authority over the workings of private power in the market place.[9] A control of the market has always been deemed necessary to prevent 'capitalism by its own greed, fear, avarice and myopia destroy itself.'[10] The 'market-failure' rationale of regulation would involve attempting to ensure the efficient functioning of the market by preventing monopolies, curbing externalities, ensuring the continuity of services, and creating parity in information available to consumers.[11] The other dimension to regulation is a social rationale for regulation. Under this paradigm, even when markets are being regulated, the rationale for regulating markets moves towards broader social and political goals of justice rather than mere economic logic.[12] This would involve mandates such as improving public health, and having universal access to basic utilities such as water and electricity. In either case, we can see that regulation is premised to be done in the public interest.[13]

With a sector such as pharmaceuticals, we might be able to see that this distinction between market and social justifications for regulation is blurred. Pharmaceutical regulators are concerned with safety and pricing of medicines, which would fall into the silo of a social justification; while their standards for information presented on the packaging would be a strategy falling into the market justification due to it attempting to curb informational asymmetry.

With this understanding of how regulation is a democratic control mechanism of private markets with the aim of furthering public interest, particularly in the case of the pharmaceutical sector, it becomes difficult to suggest lowered regulation. Particularly in India, where there has

[8] *Id.*
[9] *Id.* at 273.
[10] WILLIAM O. DOUGLAS, DEMOCRACY AND FINANCE: THE ADDRESSES AND PUBLIC STATEMENTS OF WILLIAM O. DOUGLAS, (J. Allen ed., Yale University Press 1940) 244.
[11] ROBERT BALDWIN et al., UNDERSTANDING REGULATION 15-22 (2011).
[12] *Id.;* see also Tony Prosser, *Regulation and Social Solidarity*, 33 JOURNAL OF LAW AND SOCIETY 364, 364-387 (2006).
[13] BALDWIN, *supra* note 11, at 22.

been a large history of malpractices within the industry, it would in fact require more stringent regulation. While there are some aspects of the industry which seem to be overregulated with very little thought presented (such as advertisements that present cures for certain ailments and diseases), the needle tends to point towards the industry needing stricter regulation. It becomes all the more necessary when one looks at how numerous scandals have eroded the trust in regulators. Trust is a crucial value in regulation and regulatory theory, and the following section will outline the importance of trust in regulation.

Understanding Trust in Regulation

To begin with, one has to understand how trust is defined. Adopting the characterization of Russel Hardin and Bart Nooteboom, trust is conceptualized as a 'relational concept'.[14] Essentially, one actor trusts another actor with certain future activities or behaviours. Essentially, at a very basic level, this conception is a relationship between two parties premised on predictability in a party's actions and outcomes. In the context of regulation, it is a complex measurement of interaction between various actors- citizens, regulators, and regulated firms or organizations (at its most basic level).[15] Even this relational concept contains many dynamics and assumptions that will be crucial to our understanding of regulatory reform in the later part of the paper.

Trust is always a selective relationship-it is not always justified, but one cannot always assume distrust in an actor. The latter part of this premise assumes that there is some amount of leeway that actors can be afforded to make errors, and if they cross those boundaries, only then can distrust manifest itself. It would be uncharitable to always assume distrust in an actor. For example, a regulator might not be able to perform its duties well at a particular time due to changes in the parent governmental authority, despite the regulator being an efficient body in other situations. Similarly, a small company might try hard to comply with regulations, but it might not be able to achieve complete compliance due to its lack of financial capacity.

It is important to understand that dropping levels of trust need not mean automatic distrust.[16] Distrust can't be seen as a logical conclusion when trust withers away; rather it is an extreme outcome of repeated lapses in either regulatory functioning or compliance which is likely to

[14] RUSSEL HARDIN, TRUST AND TRUSTWORTHINESS (2002); BART NOOTEBOOM, TRUST: FORMS, FOUNDATIONS, FUNCTIONS, FAILURES AND FIGURES (2002).
[15] Frédérique Six & Koen Voerhoest, *Trust in Regulatory Regimes: Scoping the Field*, *in* TRUST IN REGULATORY REGIMES 1, 3 (Frédérique Six & Koen Voerhoest eds., 2017).
[16] *Id*., at 15.

lead to distrust.

In high-risk industries like the pharmaceutical industry, the activity of trust building is ever more crucial.[17] These sectors have high amounts of informational asymmetry between consumers and firms, and if the goals of public health and efficiency are to be met, then it requires a stringent regulator which can be trusted by the public. Trust needs to be examined in the context of different actors, and the role trust plays also varies according to the context.

If the starting point is the consumer, then the trust placed in the regulator and the regulatory regime provides consumers with a level of confidence and certainty that the products within the industry are up to specific standards and are fit to be consumed with little risk posed. This position would shift when looking at the regulator as the baseline for analysis. In such a case, if the regulator enjoys the public's trust and confidence, it provides it with legitimacy and empowers the regulator. This deters firms from non-compliance, as firms know that a regulator which enjoys public legitimacy can impose harsh sanctions for any non-compliance. Any act of non-compliance would also mean that consumers avoid such firms within the market, and this is an additional deterring factor for non-compliance. The regulator could also trust the firm enough to the point that there need not be micromanaging by the regulator. In such a scenario, the firm is trusted enough to comply, and the regulator need only remain broadly cognizant of the functioning of the firm and step in periodically. Lastly, from the point of view of regulated firms, they trust that the regulator will afford them requisite autonomy to operate without excessive interference, in exchange for guaranteed compliance.

It is also important that trust is not blindly placed by regulators in firms they are regulating. Blindly trusting firms leads overconfidence in the regulators ability to detect deception.[18] In order to avoid this, any mechanism where the regulator remains at a distance from the firm must also contain enforcement mechanisms such as fines or other punitive measures that actively deter non-compliance.[19]

[17] Russel W. Mills & Rubenstein Reiss, *The Role of Trust in the Regulation of Complex and High-risk Industries: The Case of the US Federal Aviation Administration's Voluntary Disclosure Program, in* TRUST IN REGULATORY REGIMES 37, 37 (Frédérique Six & Koen Voerhoest eds., 2017).

[18] Guido Möllering, *Inviting or Avoiding Deception through Trust*, MPlfG Working Paper 08/1, Max Planck Institute for the Study of Societies.

[19] Peter J. May, *Regulation and Compliance Motivations: Examining Different Approaches*, 65(1) PUBLIC ADMINISTRATION REVIEW 31, 31-44 (2005); Jodi L. Short and Michael W. Toffel, *Coerced Confessions: Self-Policing in the Shadow of the Regulator*, 24(1) JOURNAL OF LAW, ECONOMICS AND ORGANIZATIONS 45, 45-71 (2008).

Thus, we can see how crucial it is, particularly for regulators, to actively foster trust by being proactive in their regulatory activities, and not allowing for lapses that would lead to that trust being weakened. Unfortunately, this has not been the case in India, and the following section of the paper will outline the numerous instances where regulatory failures have occurred. The sheer number of instances are difficult to recount, but the severity of these instances ensures that the extreme outcome of distrust, and not merely withering trust, takes place.

Regulatory Failures in the Indian Pharmaceutical Sector

Beyond the deaths due to contaminated cough syrup in Uzbekistan and Gambia, there have been a series of DEG related deaths in India as well. Dinesh Thakur and Prashant Reddy point out that the high frequency of deaths occur due to the fact that Indian pharmaceutical companies are in blatant violation of legally prescribed Good Manufacturing Practices ('GMP').[20] If these GMPs were followed and strictly enforced by the regulators, such occurrences would not be a common sight.

There are instances where the regulator seldomly performs inspection into manufacturing facilities, instead largely relying only on the manufacturer's records being submitted to the regulator.[21] These records are not particularly helpful in relaying information to the regulator as it won't reflect the manufacturing standards and conditions being employed. Similarly, when it comes to dealing with infractions, there are two possible punishments that can be levied-criminal sanctions as categorized by Section 27 of the Drugs and Cosmetics Act, along with administrative sanctions as delegated. The administrative route involves the suspension or cancellation of manufacturing licenses, and this route is often preferred over criminal sanctions. It is again rare that the cancellation of licenses is the employed punishment, with suspensions being the more frequently used tactic. As suspensions last between 10 and 180 days, the regulators are effectively weakening their own reputation by being perceived as lax organizations.[22]

When criminal sanctions are employed and cases are prosecuted, the regulatory scheme and prosecutorial network again show how helpless the regime appears. Prior to the 2008 Amendment of the Act, most penalties under Section 27 were imprisonment for a term no less

[20] DINESH THAKUR AND PRASHANTH REDDY, THE TRUTH PILL: THE MYTH OF DRUG REGULATION IN INDIA 7 (2022); *See also* Drugs and Cosmetics Act, 1940, No. 23, Acts of Parliament, Schedule II.
[21] Thakur and Reddy, *id*. at 68.
[22] Thakur and Reddy, *id*. at 87.

than 5 years and fines that extended till 10,000 rupees.[23] It is utterly shocking that the cost for playing around with human life and public health can be let off with such slaps on the wrists. It is compounded by the fact that judges have pronounced ludicrous decisions such as "imprisonment till the rising of the court"- effectively meaning that the offender is only imprisoned till the court remains in session.[24]

The perception that stems out of these regulatory failures is that the regulator is unable to fulfill its mandate in promoting and protecting public health and this is a worrying scenario for the regulator, as it goes towards weakening its legitimacy in the eyes of the public. Secondly, firms also know that they will not get stringent punishments and this would mean that compliance is greatly reduced as there is no deterrence. In order to turnaround this image, the regulator has an uphill task in building trust and showing that it is a body which will not be a pushover.

The Way Forward- A Trust-Building Exercise

While the outlined instances are only a few due to the constraints of space within this paper, they are indicative symptoms of the broader malaise plaguing the regulation of the industry.[25] An overhaul of the regulatory regime in the industry is the need of the hour. The framework of analysis that will be utilized here is the consumer, and the regulator as the starting point. Consumers can't trust the regulator to keep them safe, and as a result the legitimacy of the regulator begins to decline. Beginning with safeguarding the interests of public health will create a positive feedback loop that ends up increasing the legitimacy of the regulator.

To begin with, institutional reform of the regulator is required. The CDSCO is not an independent regulator created by the Act, unlike regulators in other sectors such as telecommunications (TRAI Act) and electricity regulators (Electricity Act).[26] As a result, the body is subjected to political pressures from the nodal ministry that it is a part of, along with constraints on finances, staffing and mandates. This means that the regulator is not able to efficiently carry out its duties. In order to combat this, the CDSCO must be made an independent regulatory body under the statute. This would now mean that it would have the

[23] Drugs and Cosmetics Act, 1940, No. 23, Acts of Parliament, §27.
[24] Thakur and Reddy, *supra* note 18, at 26.
[25] Priyanka Pulla, *The Dangerous Irrationalities of How India Regulators Classify Substandard Drugs*, THE WIRE SCIENCE (Oct. 13, 2021) https://science.thewire.in/health/dangerous-irrationality-indian-regulators-classify-substandard-drugs/ ; *see also* Priyanka Pulla, *The Zydus Cadilla Remdesivir Fiasco Wasn't an Isolated Incident*, THE WIRE SCIENCE (Jan. 06, 2021) https://science.thewire.in/health/cadila-remdesivir-endotoxins-hetero-healthcare-state-drug-regulators-impurity-testing/ .
[26] Shreya Shrivastava et al., *Comments on the Drugs, Medical Devices, and Cosmetics Bill 2022*, Vidhi Centre for Legal Policy 8 (2022).

requisite autonomy to better carry out its mandate, and with separate budgeting and staffing, can do so more efficiently.

In addition to now being an independent body, the regulator must not miss this opportunity to bolster its own powers. The regulator must adopt an approach embodying 'responsive regulation'.[27] According to Ian Ayres and John Braithwaite, this means that a regulator's direction must have a strong sanction behind that command. If this is there, regulated subjects are cautious about breaching regulations as they fear the repercussions. Having strict sanctions and penalties is another way the regulator can boost its own legitimacy and reputation in the eyes of the public. To the credit of the regulatory scheme, post the 2008 Amendment, the Act has more stringent penal punishments with the fines extending to 10 lakhs. However, now the regulator and prosecution must seek the highest quantum of punishment when the law provides for it (of course in proportion to the severity of the offence), while prosecuting cases. No longer can leniency be doled out while punishing offenders, if the regulator is to now seek a rebrand. Additionally, the regulator must now be more proactive with surprise inspections, and must not shy away from cancelling licenses of offending manufacturers. This will portray the regulator as a strong body which will not cower in the face of malpractice, and will only help raise its stock in the eyes of the public.

Lastly, in order to improve accessibility and foster awareness about public health, the regulator must take steps to improve public relations. While the CDSCO currently does put up many circulars and alerts on its website concerning banned drugs, there is a high degree of asymmetry involved. Members of the public are not aware that such notices are frequently being uploaded on the website, and the content of these notices are couched in scientific terms. The regulator must produce this information in plain-language understandable to general consumers, as well as upload this information in forums such as newspapers, over television announcements, and social media. This would increase the circulation of this information and ensure consumers are better informed. Doing this would boost the confidence of consumers in the regulator, as they see the proactive nature of the regulator in actively protecting consumer interests.

Concluding Remarks

Trust is a crucial, yet underexplored dynamic in the regulatory space in India. It is ever more important when one considers that very little literature exists on regulation in India, and one looks at the numerous instances of regulatory failure. It is not a good look for regulatory

[27] JOHN BRAITHWAITE AND IAN AYRES, RESPONSIVE REGULATION 19 (1992).

governance in India for the repeated instances of harm being caused. If a turnaround is required, then the regulator must engage in actively rebuilding that trust, lest it loses its own legitimacy and becomes a toothless tiger. It is hoped the prescriptions in this paper provide some roadmap and clarity for this journey. While it is an uphill climb, it is a necessary journey to embark on if India is to truly become a "pharmacy of the world".