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How deep runs 'The Rot' in the pharma sector?

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While weeding out corruption is a tall order, especially in the pharma industry, there needs to be a will to implement the 'checks and balances' already in place. Corruption in the pharma industry is nothing new and the recent reportage of unethical, illegal and fraudulent activities in India have, in effect, tarnished the image of the industry in the global sphere. Let's pick up a few recent threads of corruption and find out what industry insiders have to say.



Public health is in limbo and the ‘Pharmacy of the World’ tag for India is in real distress with the latest happenings in India’s pharma sector. Things unfolded recently with the Central Bureau of Investigation (CBI) arresting a top executive of Biocon Biologics, a drugs inspector and a joint drug controller for alleged corruption. According to media reports, several people have been booked over alleged bribes to get approval for insulin injections for diabetes patients developed by Biocon.

Biocon, however, came up with clarifications to protect itself and tried to come out clean. The National Stock Exchange (NSE) has sought clarification from Biocon concerning the firm's subsidiary being caught by the CBI for allegedly offering bribes to waive-off a trial of a new drug, according to media reports.

Recently, Micro Labs’ offices were raided by the Income Tax Department for tax evasion. It is notable that it is the same company which provided life-saving Dolo-650 during the COVID-19 pandemic. In this case, however, there was no reaction from the company.

All these happenings have put to question how the regulatory body works and the in-depth corruption that is happening across the pharma sector.

Corruption in the pharma sector is nothing new and the recent episode has opened a can of worms where pharma regulatory agencies are hand in glove with pharma companies on various occasions.

It may be noted that nine years ago, in 2013, the Parliamentary Standing Committee on Health in its 118-page report found lapses in the way Central Drugs Standard Control Organisation (CDSCO) functions and blamed the department citing incidences of lapses, irregularities, and opaqueness. According to the committee, it is of the firm opinion that most of the ills besetting the system of drug regulation in India are mainly due to the skewed priorities and perceptions of CDSCO.

Dinesh Thakur, Founder, Thakur Family Foundation, a pharma crusader and a whistleblower, who worked with Ranbaxy and eventually exposed frauds within the company, says, “Regulatory capture, when it comes to the pharma industry, is not a new phenomenon. It exists both in India and worldwide. However, the level of capture is by far an order of magnitude worse in India compared to elsewhere.”

Some pharma companies indulge in giving gifts, cash, and paying for trips to attend medical conferences. This is done to potentially influence a doctor to be favourably inclined to prescribe the company's products.

Says **Girdhar Balwani, Professional Mentor & Independent Director, Cadila Pharmaceuticals** said, “All companies and doctors have to operate within the legal domain of the country. While various laws and codes exist, it is important to look at the best way to ensure compliance. The Prevention of Corruption Act prescribes that corporate entities have compliance procedures in place to prevent their employees from engaging in any act which may be categorised as corruption or bribery. Subsidiaries of foreign companies have to also adhere to the applicable laws of the jurisdiction where the parent company is located.”

Instances

Recently the Supreme Court has asked the Centre to file an affidavit on a plea alleging unethical marketing practices by pharmaceutical companies in their dealings with healthcare professionals resulting in the prescription of excessive or irrational drugs and a push for high-cost or over-priced brands. The plea was filed by the Federation of Medical & Sales Representatives Association of India (FMRAI) seeking a Uniform Code of Pharmaceutical Marketing Practices (UCPMP) and making it effective by providing a monitoring mechanism, transparency, accountability as well as consequences of violations.

The Hisar vigilance department recently arrested the deputy President of the Haryana State Pharmacy Council (HSPC) for bribing officials related to some registration-related activities.

An article published in *Frontiers in Research Metrics and Analytics talks about* ghost-management of medical research, a process by which industry representatives craft and publish research in the names of doctors and psychiatrists. There have been instances where the pharma industry's sponsorship of clinical trials have influenced the results, putting a question mark on evidence-based medicine.

The Pharma City in Telangana was also in the news when a Member of Parliament from the state met the Prime Minister of India regarding the cancellation of the permission granted for setting up of Pharma City due to some corruption.

Take for instance Ranbaxy. A few years back, the company, a pioneer in India’s generic medicines revolution, had to pay damages to the tune of $500 million to settle corporate fraud related to unethical production of medicines that compromised on quality.

Global corruption in pharma

A few years back US-based China focussed SciClone Pharma had to cough out more than $12 million in fines, penalised by US prosecutors after violating the Foreign Corrupt Practices Act. Many years back, US-based Purdue Pharma was fined $600 million for misbranding its blockbuster painkiller drug, OxyContin. The recent one is the corruption charges against GlaxoSmithKline in China. The UK-based pharma giant was prosecuted by local authorities and was found guilty of bribing physicians and hospitals to promote products and subsequently the company paid $490 million in fines.

The recent opioid crisis in the US where over 50,000 people died due to overdose of drugs like oxycodone, fentanyl etc. as these were often overprescribed by giving inducement to doctors, is a classic example. Off-label promotion of a drug for an indication not approved by the US FDA is also another form of corruption.

Similarly in the UK, the National Health Service (NHS) which is often touted as a model healthcare system in Europe, reported losses due to frauds in 2016-17 to the tune of £ 1.25 billion per annum.

The way out

Technology can play a huge role in preventing corruption in the pharma sector. Technologies such as Artificial Intelligence (AI) and blockchain, can help eliminate the loopholes which can lead to bribery/corruption and improve transparency and accountability within the industry. The faster AI and blockchain are implemented across the industry the more we can prevent certain corruption in the sector.

Says **Dr Ajit Dangi, President & CEO, Danssen Consulting**, "Elimination of intermediaries by extensive use of digitisation is one way to reduce corruption as we have seen in the success of the centre's ‘Direct Benefit Transfer scheme. The Right to Information Act and Whistleblower policy are also other tools to reduce corruption. If the new drug approval process was fully digitised there would have been fewer chances of the recent example of approval of a new drug of Biocon by allegedly waving phase three trial by the Deputy DCGI (Drugs Controller General of India) for consideration, may not have happened.”

The UCPMP guidelines and newly enacted the National Medical Commission Act 2019 may usher into a new era to clean up the rot in the healthcare industry.

According to Gunjan Bhardwaj, Founder and CEO, Innoplexus, blockchain integration in the pharma industry will lead to lower drug development costs, efficient clinical trials and an effective and efficient system of secure spending, transparent data and more medicines for patients and consumers throughout the world.

Need for clampdown

There is much more to this menace and only strict regulations by the government will help to weed out the corruption. As it is known that officials from CDSCO, DCGI and some members of the pharma fraternity are well involved in these activities, more stringent laws may help in the long run. Putting the culprits behind bars will send a strong message to those who plan to indulge in such activities.

The Union Health Ministry is learnt to have been taking steps to improve compliance and crack down on corruption. There is news that the Centre has decided to introduce QR codes for ensuring authenticity and traceability for 300 common drug brands including analgesics, vitamins, diabetes and hypertension medicines etc. This step is aimed at preventing spurious drugs from getting into circulation. The health ministry has made necessary amendments to the Drugs Rules, 1945, to implement the rule.

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