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GUEST EDITORIAL

Affordable healthcare threatened! Concern for all stakeholders

The outrageous price rise of the 62-year-old drug, Daraprim (Pyrimethamine) has sent the United States medical fraternity into a dizzy. The price of the drug was raised from USD 13.50 to USD 750 per pill in just over a month. This obnoxious price rise of over 5,000% came after the New York-based pharmaceutical company Turing Pharmaceuticals acquired the patent for the drug from Impax Laboratories[1].

Daraprim is one of the widely used drugs while treating toxoplasmosis commonly as an antimalarial drug and more routinely for HIV when used with a combination of sulphadiazine; it is one of the WHO List of Essential Medicines, and is a drug whose affordability needs to be absolutely ensured. Such a massive price rise adversely affects patients who are not compensated by insurance in the United States. There are various medical associations that are rallying against this price rise and presently to no avail. The Infectious Disease Society of America (IDSA) and HIV Medicine Association (HIVMA) have written '*Under the current pricing structure, it is estimated that the annual cost of treatment for toxoplasmosis, for the pyrimethamine component alone, will be $336,000 for patients who weigh less than 60 kg and $634,500 for patients who weigh more than 60 kg.*'[2] threatening thousands of patients to look for alternative treatments, which may not have the same impact as Daraprim. Viciously, the move deprives a patient of an essential treatment.

Daraprim is not the stand-alone case of such abrupt price rise. Cycloserine, which is a critical second-line drug used in the treatment of a rare form of multi-drug resistant tuberculosis, was raised by Rodelis Therapeutics, from USD 500 (for 30 pills) to USD 10,800 (for 30 pills)[3]. It has been just over a month since the Chao Center transferred the Cycloserine rights to Rodelis Therapeutics. The immediate decision of Rodelis to hike the price of Cycloserine by over 2000% again raised the question of who regulates affordability in healthcare?

The above-mentioned two scenarios are not the only cases that threaten affordable healthcare. The business model currently used by smaller pharmaceutical companies is that they acquire the rights to drugs whose patents have expired and then reintroduce them at a higher price, thereby allowing these companies to enter the league of the high-stakes pharmaceutical industry. The sustainability and viability of such a business model need to be understood. The alarming situation is that the big-pharma did not blink an eyelid at these situations. The calm acceptance of the raising prices of essential drugs by the dominating forces of the industry sends out the message that companies are comfortable with subjecting patients to the financial trauma, which accompanies their treatment. As quoted by renowned big pharma veteran Bernard Munos, '*The recent stories about cycloserine and pyrimethamine (Daraprim) came from small rogue companies that are using regulatory loopholes to turn the drug business into a racket. Yet the meek reaction of big pharma, and especially PhRMA, is problematic. It suggests a reluctance to seriously confront practices that are now widely rejected.*'

This alarming situation could soon be a reality in India as well! The exploitation of patent expiry allows pharmaceutical companies to position the price of essential drugs according to their profit purviews. As big pharmaceutical companies come knocking on the doors for acquiring Indian generic companies, it is now more important than ever that stakeholders, national and state governments, the Indian Pharma Association (IPA) and patient rights advocacy groups, who play a key role in ensuring that the prices of essential medicines are always kept in check should show major concern and ask for stricter policies for acquisition of home-grown generic companies by foreign pharmaceutical companies.

Looking through the Indian market lens, there are over 40 generic companies that manufacture nearly 70 generic brands of Daraprim (pyrimethamine + sulphadoxine). Similarly, over 8 generic companies manufacture cycloserine, leading to 11 brands of cycloserine generics in India. Among these are front-runner companies of the Indian market such as Lupin Laboratories, Samarth Pharma, Panacea Biotech, Torrent Pharmaceutical, etc. The price of pyrimethamine is as low as USD 0.03 per tablet and cycloserine is USD 0.6 per tablet. This pricing mechanism has been made possible by enforcing strict price-cap on essential medicines. This is the only way to ensure that 270 million people who live below USD 1.25 per day can afford these essential medicines[4].

Currently the Govt of India allows 100% Foreign Direct Investment (FDI) in Greenfield projects and

Brownfield projects (through government route). This distinction in the FDI policies was laid down to protect the domestic generic industry from acquisitions thereby leading to a steep rise in drug prices. If companies such as Turing Pharmaceutical and Rodelis Therapeutics were allowed to acquire Indian generic companies, the government's vision to provide affordable health care for all would be totally lost. Hence it has become absolutely essential to revisit the 100% FDI in pharmaceuticals, especially for brownfield projects. The prices of essential drugs are always subject to external threats such as patent expiry and such patent exchanging hands. Transforming profit-making to profiteering at the cost of patients needs immediate global attention. On the other hand, the California-based pharmaceutical giant Gilead reduced the price of Sovaldi, a life-saving drug used in the treatment of Hepatitis-C, from over USD 94,500 (for a 12-week treatment) in the United States to about USD 900 for distribution in developing countries including India[5]. Gilead had entered into a voluntary licensing agreement with 11 Indian generic firms[6] which will market the drug in 91 countries at 1% of its cost in the United States. This partnership can be seen as a move by Gilead to ensure that patients, in the developing world, with acute Hepatitis-C have accessibility to this miracle drug at an affordable price.

Indian public sector companies (Bengal Chemicals and Pharmaceuticals Ltd, Bharat Immunologicals and Biologicals Corporation Ltd, Hindustan Antibiotics Ltd, Indian Drugs and Pharmaceuticals Ltd, Indian Medicines and Pharmaceutical Corporation Ltd, Karnataka Antibiotics and Pharmaceuticals Ltd, Orissa Drugs and Chemicals Ltd, Rajasthan Drugs and Pharmaceuticals Ltd) have to be re-strategized and encouraged so as to generate intellectual property in collaboration with national laboratories, especially for essential medicines. Investments for capacity building in public sector companies need to be promoted so that the government is well equipped to tackle sudden price effect on life-saving medicines in India.

In the light of healthcare becoming a matter of profit transaction, it is essential to look at alternate initiatives as well. It is at this stage that international bodies, national governments of India and many other developing countries should steadfastly support initiatives such as the Open Source Drug Discovery (OSDD)[5]. Initiatives such as OSDD that spearhead the commitment towards making healthcare affordable for all[7]. Since its inception, OSDD has vehemently voiced its concerns over the price rise of essential drugs as well as rising costs of drug discovery. The vision of OSDD redirects to the principle that only when a drug is affordable to the patient it creates the need for availability, when the needs of affordability and availability are met does it ensure thorough accessibility to the patient. Having expressed similar concerns recently in a meeting in Marburg, Germany, an Open Source Pharma (OSP)[8] initiative was launched with the global participation of various eminent researchers and leading organizations such as the Tata Trust (India), Médecins Sans Frontièrs (MSF), OSDD, Drugs for Neglected Diseases Initiative (DNDi), Medicines for Malaria Venture (MMV), Open Societies Foundation (OSF), the European and Developing Countries Clinical Trial Partnership, etc. Such intense global collaborations are a testament that stringent actions are needed to ensure that millions of people have access to affordable healthcare.

In conclusion, though the Govt of India currently has in place a strict regulatory policy for acquisitions of Indian generic companies by pharmaceutical giants, they should continue having a firm stand on the matter, especially in the light of 100% FDI policy. The public sector companies need to be strengthened so as to play a more active role in the generic industry and thus ensuring that the case similar to Daraprim and Cycloserine does not occur in India. Such a situation would only threaten the lives of millions of patients suffering from the burden of diseases such as tuberculosis and malaria. Affordability to quality healthcare should be the cornerstone of the decision-making strategies; in doing so the role and commitment of major initiatives such as OSDD, in strengthening affordability, accessibility, and availability, should be promoted.

1. Pollack, A., Ex-hedge funder buys Rights to AIDS drugs, increases prices by 5,500%, 2015; http://tribune.com.pk/story/961393/ex-hedge-funder-buys-rights-to-aids-drugs-increases-prices-by-5500/
2. RT, Pharma firm hikes life saving drug price by 5,500%, 2015; https://http://www.rt.com/usa/316046-pharma-daraprim-price-hike/
3. Strong, B., Some drug prices are shooting up overnight. Why? 2015; http://www.youthhealthmag.com/articles/23733/20150922/drug-prices-pharmaceutical-industry-daraprim.htm
4. UN-ESCAP, Economic and social survey of Asia and the Pacific 2015: making growth more inclusive for sustainable development, 2015.
5. Harris, G., Maker of costly hepatitis C drug Sovaldi strikes deal on generics for poor countries, 2014; http://www.nytimes.com/2014/09/16/business/international/maker-of-hepatitis-c-drug-strikes-deal-on-generics-for-poor-countries.html
6. Babu, G., IPA, Natco withdraw opposition to Gilead's drug. In *Business Standard*, 2015.
7. Bhardwaj, A. *et al.*, Open source drug discovery – a new paradigm of collaborative research in tuberculosis drug development. *Tuberculosis [Edinb]*, 2011, **91**(5), 479–486.
8. Open Source Pharma; http://www.opensourcepharma.net

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