

MNCs play proxy war against Indian generics

Five Indian drug companies received FDA's warning letters in 2014, but the number doubled last year.

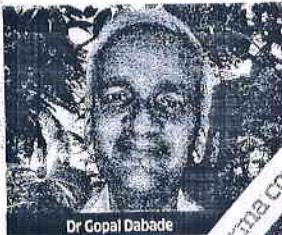
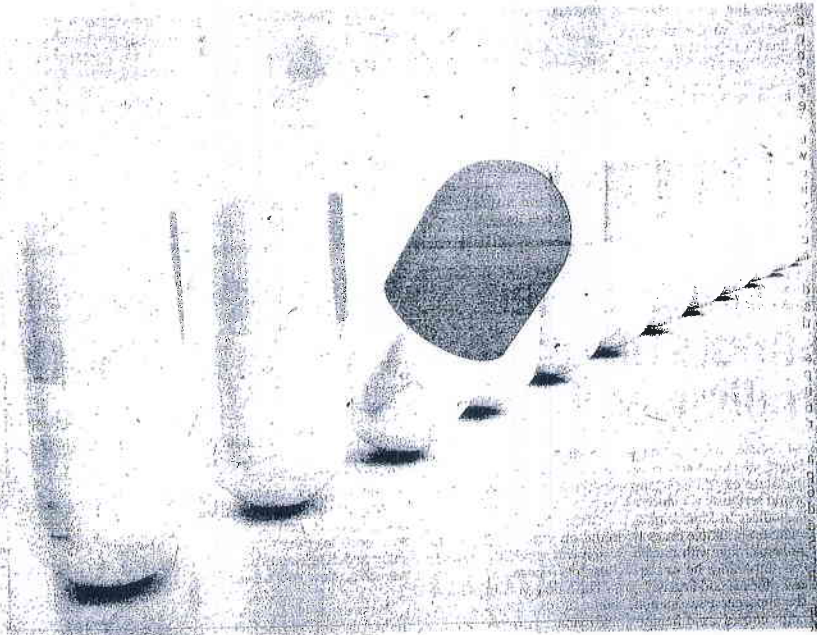
Dr Gopal Dabade

Recently, a spate of accusations against Indian drug manufacturing companies by Food and Drug Administration (FDA), the drug regulatory authorities of the US have been noted. During last year December, Sun Pharma's two plants and Dr Reddy's three plants had received warning letters from the FDA drug authorities for quality issues. In addition, Ranbaxy, now part of Sun Pharma, and Wockhardt are under the FDA scanner for the past few years.

All these have raised many eyebrows and definitely caught the attention of global media. Also, a complaint had been lodged in October 2015, against Cipla—a well-known and large Indian generic drug manufacturing company—that its standard and quality in manufacturing at the site was not up to the mark. Not just Cipla, a dozen Indian drug manufacturing units just in 2015. Some of these include smaller companies like Mylan Laboratories' acquired facility, Agila Specialties' units in Bengaluru, Hyderabad-based contract testing laboratory, Sipra Labs, Ahmedabad-based active pharmaceutical ingredients maker Mahendra Chemicals, Ahmedabad-based Cadila Pharmaceuticals, Bengaluru-based Micro Labs and Apotex Research Lab's facility in Bengaluru.

What is furthermore worrying and annoying is the fact that the number of complaints received in 2015, has almost doubled from that in the previous year. In 2014, only five Indian drug companies had received such warning letters, of the total 19 issued by the FDA authorities.

The violations of Indian generic drug companies, noted by FDA, are not so serious and are mostly related to lack of proper data maintenance or issues with manufacturing processes at the plant level. Usually the FDA gives warning letters and suggests guidelines for corrections as well within a stipulated period of time. Most Indian generic drug companies are exuding confidence that they will overcome the hurdles set by FDA. But what is glaring is the media attention that it has been receiving, and this has created a false image



about the Indian generic industry.

Pharmacy of the developing world

To understand this knee-jerk response of the USFDA, one needs to understand the contribution of the Indian generic drug industry towards making medicines available at affordable prices to several parts of the world. It needs to be highlighted that the Indian generic drug industry is a major exporter of medicines to around 200 countries all over the world. The Indian drug industry has registered a spectacular growth over the last two decades, and currently occupies the third position in the world in terms of volume and tenth in value. So much so that India is often referred to as the 'Pharmacy of the Developing World'. The pharmaceuticals are valued at over \$14 billion. The Indian Pharmaceutical industry has been a dominant player in manufacturing generic drugs.

Doctors Without Borders / Médecins Sans Frontières (MSF), winner of Nobel Prize in 1999, which has relief medical units in conflict areas, is not only at the forefront in utilising medicines manufactured by Indian generics, but also campaigning for it. MSF acknowledges that India is an important manufacturer and

supplier of quality generic medicines for millions of people around the world. MSF is highly dependent on the availability of affordable high-quality medicines to provide medical care, as are many of the Ministries of Health with whom it works. As many as 98 per cent of PEPFAR's (The United States President's Emergency Plan for AIDS Relief) HIV drug purchases are generic medicines from India.

Threats to Indian generics
 All these achievements of the Indian generic drug industry have no doubt created a threat for the multinational drug companies of the US and Europe. These drug companies not only rule the world but also dictate terms to their governments. The powerful MNC lobby has been

consistently trying to hit hard at the Indian generic industry. Earlier in 2005, it has done these anti-trust strategies through the World Trade Organisation (WTO) and now it is through the FDA. The MNC lobby seems to want no stones unturned in efforts to weaken the Indian generics.

To recapitulate, in 2005, India and other developing countries began granting pharmaceutical patents in accordance with TRIPS. India granted more than 2,000 pharmaceutical patents between 2005 and 2008, and the country continues to grant patents.

But as India prepared to change its legislation in order to introduce patenting for pharmaceuticals, the World Health Organisation and UNAIDS wrote to the Indian government to ask the country to safeguard its role as the main supplier of affordable quality antiretroviral and other medicines used in the developing world, and to urge the country to use the existing international legal regulations to ensure that the harm to access to affordable medicines would be limited.

In addition, a huge MNC lobby has been trying to prevent India from utilising Compulsory Licensing (CL). The only drug to which India granted CL was Nexavar, which created huge debates in the western media. And the MNCs were at the forefront in striking at the Indian generic companies.

Way forward

The USFDA's warning letters are no doubt the handwork of the MNC. This is more a political battle than just the quality of few medicines and so it needs a political stand and solution. The Indian government should acknowledge the unique contribution and should not bend to the forces and strategies of the MNCs. This is not the first time that this lobby has tried this. Eternal vigilance and lobbying against such vested threats are the only way out.

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Source: Gov, Corporate Catalyst India (CCI)