

Media Coverage

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Pharma Companies play guardian angel for orphan drugs

For some pharma companies, profit motive takes a back seat. Rising above margins concerns, these companies are venturing into orphan drugs – a category that is not frequented by their colleagues in the industry. Orphan drugs were long neglected by the Indian pharmaceutical companies who are keen on producing those drugs which are sold like hot cakes. However, of late, some brave hearts in the sector have taken up the manufacture of these drugs. Orphan drugs are those drugs that are used for the treatment of diseases which are so rare that the pharmaceutical industry is reluctant to develop medicinal products under usual marketing conditions. The drugs which are intended to treat diseases affecting a small number of patients suffering from rare disease or a more common disease where manufacturer can not expect to make profits. But a few companies have come up with range of orphan drugs in their kitty. Take the example of Ahmedabad-based Troikaa Pharmaceuticals Limited that produces five orphan drugs – Aprotinin injectables, Naloxone Hydrochloride, Pralidoxime Hydrochloride, Adenosine and Cyanide antidote kit. MD of Troikaa Pharma, Ketan Patel, told ET that his company produces orphan drugs basically to serve the society as it provided medicine for those diseases where the biggies of the pharma industry are reluctant to enter. Giving an example of one his orphan drugs- Cyanide antidote kit, Mr. Patel said that the drug is vital for those in the defence forces involved in chemical warfare. The drug is also useful in saving lives in case of major chemical industry mishap – something similar to the Bhopal Gas Tragedy. The other drugs like Apportioning that the company produces is a protein, used in reduce bleeding and decreased need for blood transfusions following heart and liver surgery. It acts mainly by preventing the breakdown of clots. Naloxone is a drug used to counter the effects of overdosing with opioids such as heroin and morphine. Another Gujarat-based pharma company, Cadila Pharmaceuticals Ltd produces drug for leprosy patients under the brand name of Immuvac. Dr. Bakulesh Khamar, ED of Cadila Pharma, says that leprosy patients are now largely taken care by the government. US – based non-profit drug company The Institute for One World Health recently collaborated with Gland Pharma Ltd, a Hyderabad based pharma company for the production of Paromomycin IM Injection. Drug Controller General of India (DCGI) has approved Paromomycin Intramuscular (IM) Injection for the treatment of Visceral Leishmaniasis (VL) (kala-azar), the second most deadly parasitic disease in the world following malaria. One World Health is a San Francisco based non profit pharmaceutical company that develops drugs for people with infectious diseases in the developing world. It is also working with the Indian Council for Medical Research and four kala-azar centers of excellence in Bihar, India.

Similarly, Cipla is one of those companies that produces 'Orphan drugs' for the treatment of thalassemia disease.

Dr. Dinesh Badyal, associate professor, Department of pharmacology, Christian Medical College and Hospital, Ludhiana and an expert in orphan drugs, told ET that out of 30,000 known diseases, 5,000 occur rarely and 5 new rare diseases are described every week in the medical literature. While as per his knowledge, there are approximately 3-5 companies in India, who are manufacturing orphan drugs, usually in collaboration with other International agencies. He drew to the fact that the cost of manufacturing is too much high. Dr. Badyal further says that country like United States where nearly 25 years ago, former President Ronald Regan signed into law the Orphan Drug Act (ODA) of 1983, to promote the development of medicines to treat diseases that affect less than 2,00,000 people in the country had become one of the most important piece of health care legislation today. He says that this law provided orphan drug developer certain financial benefits and incentives from the US government in exchange for researching, developing and getting a drug approved for a rare disease or condition.

Interestingly, India is way behind in creating conducive environment for the development of research in orphan drugs, as there is no such regulation in India. Dr. Badyal informs that a group of pharmacologists requested the Indian government to institute Orphan Drug Act at a conference held by the Indian Drug Manufacturing Association in November 2001, but nothing concrete has materialized so far till now, says Badyal. However, ODA exists in various countries like Japan, Singapore, Australia, Canada, France, Sweden and UK.
