Indian generic drugs debate heats up

India has strongly objected to the findings of new research that raises questions about the quality of drugs manufactured in the country and exported abroad. Sanjeet Bagcchi reports.

Findings from a new investigation have raised questions over the quality of generic drugs manufactured in India and distributed for selling in Africa. According to the study, generic drugs sold in Africa by some Indian drug manufacturers are of substandard quality compared with the same drugs that the companies distribute for selling in India and non-African countries. The paper hasn’t specified the name of any pharmaceutical company. The Indian Government, however, has strongly objected to the findings, calling the paper an “irresponsible report.”

Roger Bate from the American Enterprise Institute, Washington, DC, USA, and coworkers assessed 1470 samples of antibiotic and tuberculosis drugs claiming to be manufactured in India. The samples, as the researchers noted, were collected (and tested for quality) from five Indian cities and 17 low-to-middle-income countries. “We find that a significantly higher fraction of these Indian-made drugs are of poorer quality if they were purchased from India than from India or from non-African mid-income countries such as China, Brazil, Turkey, Thailand and Russia”, wrote the authors.

“Although this paper has focused on Indian produced medicines, India is by no means the only large exporter of drugs. Further research into the drug quality of Chinese and other export countries would be useful to understand how widespread the problem may be”, they continued.

“Developing countries, particularly African ones using Indian medicines, need to be more cautious”, said one of the researchers, Amir Attaran, University of Ottawa, Common Law Section, Ottawa, Canada. “Tests by several groups show that Indian medicines fail quality tests unacceptably often”, he told The Lancet. Attaran recommended that a wholesale replacement of drug laws and regulatory institutions must be done in India.

Concerns about the safety and quality of generic drugs manufactured in India—a major exporter of generic drugs to the USA and other countries—came into focus in June this year, when the US Food and Drug Administration (FDA) and UK Medicines and Healthcare Products Regulatory Agency (MHRA) issued two recalls of often used drugs—13560 bottles of antihypertensive metoprolol succinate were recalled by the FDA on June 19 (after a failed dissolution test), and batches of antibiotic clarithromycin were recalled by the MHRA (owing to possible impurities) on June 18. Last week, Health Canada moved to ban the import of all drugs and drug ingredients from three factories in India.

The research paper by Bate and coworkers, however, has sparked a backlash in India. The India Brand Equity Foundation (IBEF), a trust established by the Government of India’s Department of Commerce at the Ministry of Commerce and Industry, pointed out, “It seems that the effort is to tarnish the image of the Indian pharmaceutical industry, which it has painstakingly developed over the years and is often recognised as ‘Pharmacy of the World’”.

According to IBEF, “As the authors [of the research paper] themselves note, based on this study one cannot draw conclusions of the intention or practices of the Indian generic industry as a whole. One could reasonably conclude, however, that the quality of medicines available in the market in both India and the sampled countries in Africa... continue to be a concern and merit further attention and research.”

Attaran condemned the reaction: “Academics publish research that irks governments all the time, but no serious democracy ever sues them for it. Not even North Korea or Russia stoops to that sort of thing.”

D G Shah, secretary general of Indian Pharmaceutical Alliance, an industry body of 20 research-based Indian pharmaceutical companies, said, “[The research paper] tarnishes the image of the Indian pharmaceutical industry. It would be to the advantage of our adversaries as they can then sell more expensive drugs to the poor countries.”

According to Shah, the steps India should take to address any concerns include strengthening of regulatory infrastructure, regulatory capacity building, and initiatives to curb unauthorised or merchant exports to ensure stricter control of exported medicines.

Suerie Moon from the John F Kennedy School of Government, Harvard Kennedy School, MA, USA, told The Lancet, “As the authors [of the research paper] themselves note, based on this study one cannot draw conclusions of the intention or practices of the Indian generic industry as a whole. One could reasonably conclude, however, that the quality of medicines available in the market in both India and the sampled countries in Africa (which are not named [in the research paper]) continue to be a concern and merit further attention and research.”

Sanjeet Bagcchi