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Tapan Ray
director general, Organisation of Pharmaceutical Producers of India (OPPI)

Several innovator companies feel that the generic pharma industry & drug regulators are not keen to effectively address and resolve the global public health issue of spurious drugs. This is because generic companies and drug regulators feel that the problem is not as acute as it is projected to be. Through their intense advocacy campaign, innovator global pharma companies are trying to exploit the situation to fight against generic medicines and parallel imports. Incidences of detention of in-transit export consignments as counterfeits drugs at the ports of the European Union are highlighted as examples.

Other groups, including a section of NGOs claim that R&D-based global pharma companies are using public health sentiments to extend intellectual property rights (IPR) to the patients' safety issue, allegedly for vested interest. These organisations have taken their arguments to various international platforms like Anti-Counterfeiting Trade Agreement (ACTA) and IMPACT of the WHO for the effective resolution of their grievances. The concern of IPR being extended to the definition of counterfeit medicines is misplaced. As even in India, though 'misbranding' is an integral part of IPR, it is considered as a public health issue and is an offence under Section 17 of the Drugs and Cosmetics Acts, 1940.

Currently, the magnitude of this problem is anybody's guess. Earlier, a study sponsored by the WHO and conducted by SEARPharm reported that only 0.3 per cent drugs were spurious, while 3 per cent drugs were counterfeits. To scientifically assess the magnitude of this problem, the DCGI, for the first time ever, has initiated a study with 61 popular brands from nine therapeutic categories for testing 24,000 samples. Expected to cost Rs 50 million, this study will be published soon. Since India is a part of IMPACT, the two decided to work together to combat the growing menace of counterfeit medicines. The DCGI was reported to have several discussions with the convenor of IMPACT to effectively address the issue.

A study carried out by IMPACT in 2006 indicates that in countries like the US, EU, Japan, Australia, Canada and New Zealand, the problem is less than 1 per cent. On the other hand, in developing nations like parts of Asia, Latin America and Africa, more than 30 per cent medicines are counterfeits. In South East Asia, an estimated prevalence of counterfeit artesunate – an anti-malarial drug – is 33-53 per cent. It appears that in all countries where access to modern medicines is poor, incidences of counterfeit medicines, ranging from anti-malarial, anti-hypertensive, anti-tubercular, anti-retroviral to cardiovascular and other life-saving & lifestyle drugs, are higher.