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DCGI associates with commerce ministry to re-examine spurious drugs definition

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Drugs Controller General of India in association with Union Ministry of Commerce & Industry has started an exercise to re-examine the definition of spurious drugs in the wake of recent seizures of Indian generic drugs by the EU authorities.

The decision came in after the 58th meeting of the Drugs Technical Advisory Board (DTAB). During the meeting, a proposal from the commerce ministry was considered to re-examine the definition of spurious, adulterated and mis-branded drugs provided under Section 17 of the Drugs & Cosmetics Act. The re-definition needs to be in the context of current scenario and trade practices followed in the national and international markets, according to a DCGI circular.

The circular issued to the pharma industry and its associations through a government order No. 18-3-2010-DC dated February 2010 has sought formation of an expert committee to examine the definitions of the spurious, misbranded and adulterated drugs under the Drugs & Cosmetics Act and suggest amendments.

The expert committee includes director of Ministry of Commerce, Dr K Satyanarayana, scientist, 'G' and head P&P, Indian Council of Medical Research, HG Koshia, commissioner, FDCA, Gujarat, Dr BR Jagashetty, Karnataka Drugs Controller, DG Shah, secretary general, Indian Pharmaceutical Alliance and Presidents of Indian Drug Manufacturers Association and Organization of Pharmaceutical Producers of India.

The Ministry of Commerce and Industry pointed out in its strategy document 2008 that Indian pharma industry had on occasions failed to adhere to the regulatory framework, including compliance and enforcement. Further, it viewed that there are different definitions for counterfeit and spurious drugs by regulated markets which had led to seizure and award of punitive damages against many Indian pharma exporters. "Especially in European Union the definition covers even generic versions of innovator drugs without authorization even if they meet quality standards and also trademarks and copyrights leading to monopolistic practices. Even exports of such drugs to a country where patents are not granted to them and fully legal are liable for seizure if such products touch European ports during transit. Products from some of the Indian SMEs were reported to have been seized in various European ports because of IPR (Intellectual Property Rights) violation.

In consultation with the Expert Committee, DCGI is expected to take a re-look at the definition of 'spurious' and 'misbranded' drugs in the Drugs & Cosmetics Act and preferably de-link IP related issues which will benefit the pharma manufacturers, stated sources.