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Indian court stays DCGI's order on combination drugs

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New Delhi: The High Court of Indian state Himachal Pradesh granted an interim stay on the Drug Controller General of India's (DCGI) directive on combination drugs, while hearing the appeal by a member of the Himachal Drug Manufacturers' Association (HDMA).

In July 2013, the DCGI passed a directive that intended to tag all 'potentially unsafe' combination drugs as illegal. This directive was meant for drug makers that had not filed safety and efficacy data with the central drug regulator by September 30, 2013.

Mr S L Singla, general secretary, HMDA, questioned in his appeal that, "Some of these drugs are being marketed for over two decades with no adverse impact recorded in the country. Isn't that proof of safety? Why can't the government constitute an expert panel which can identify dubious combination drugs and study their safety and efficacy instead of going after all combination drugs?"

In January 2013, the DCGI asked the state drug controllers that drugmakers must submit safety and efficacy data for combination drugs to the central regulator within 18 months. The drug regulator also warned then that if drug companies failed to do this, the sale of their drugs would be forbidden in the country.

In July the central drug regulatory body preponed the deadline to August 30, later extending it by a month.Ã?Â The court has noted that the drug regulator has 'unilaterally altered' the deadline without citing any 'exceptional reasons' for doing so. Drugmakers asserted that such an approach to prohibit sale of combination drugs is unfair and would hurt their business.