

Panel to Vet Drug Combos for Safety

SOMA DAS
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Flooded with over 5,000 combination drug applications awaiting clearance, the central drug regulator has set up an expert panel under president of the Pharmacy Council of India, B Suresh, to fix standard parameters, which would be used to isolate unsafe combination drugs from the safe ones.

This committee would be a sub-committee under the Drug Technical Advisory Board, the apex body for regulation for technical matters on drug safety.

Combination drugs constitute 46% of the country's ₹70,000-crore drug market but many of these have not been tested for

safety and efficacy and are termed 'irrational' by drug experts. Also, a large chunk of this is being sold with the state drug controllers' consent, but the central drug regulator is kept out of the loop.

Thousands of applications for combination drugs have piled up before the central drug regulator since January, after it asked state drug controllers to ensure that drugmakers must submit safety and efficacy data for combination drugs they are marketing in the country to the Drug Controller General of India (DCGI) within 18 months. If pharma companies fail to do so, the sale of these drugs would be forbidden in the country, it said. "Many of these drug applica-

tions were referred to New Drug Advisory committees, the therapy specific expert groups en-

trusted with the task of vetting new drugs in the country. Many experts questioned the rationale of some of these drugs and shot down the permission to market them," an official said.

Many of these drugs, however, continue to be available in the market, the government official noted. Considering the huge number of combination drug applications, the need for a comprehensive set of

guidelines was felt, which can be used to filter safe and rational drugs from the unsafe and irrational drugs, he added.

The government renewed its efforts to phase out 'irrational' combination drugs this year after a parliamentary panel last year criticised the regulator for not acting on such potentially 'unsafe' drugs flooding the market.

Drugmakers are arguing that such an approach to prohibit sale of combination drugs is unfair and would hurt their business. "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?" SL Singla of Himachal Drug Manufacturers' Association, had told ET recently.

Regulatory.