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Pharma Industry Trade Platform

Experts condemn blanket ban on combination drugs at second edition of Vantage Point

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Panelists highlight the need for proper guidelines and processes to weed out harmful FDCs from the market and ensure better safety and efficacy of medicines

The second edition of Vantage Point, Express Pharma's platform to discuss and deliberate on Indian Pharma's most pressing and controversial topics, was recently held at SciTech Centre in Mumbai. This time the debate was on 'Combination Drugs: Is Banning the Real Answer?'

The eminent panel at the second Vantage Point, comprising Dr Jayesh Lele, President, IMA Maharashtra state; Dr Milind Antani, Head, Pharma and Life Sciences, Nishith Desai Associate; Dr Vasant V Joshi, General Manager- Clinical Research, USV; Susan Josi, Managing Partner, Sorento Healthcare; Ashish Babtiwale, Marketing Director, Virchow Pharma Group; and Ashish Prasad, Partner – Legal, Economic Laws Practice, discussed and shared their views on the various aspects of this issue and their implications. It was moderated by industry veteran, Dr RK Sanghavi, Chairman – Medical Committee & Nutraceutical Committee, IDMA.

Dr Lele said that FDCs should be both, compliant with the regulations and effective in treatment. Answering Dr Sanghavi's query on the different criteria to judge an FDC, he answered that the foremost criteria is the need for it. The other aspects to be looked into are the compatibility of the combination drugs, the dosage of each drug and the effect the FDC seeks to achieve. He also pointed out that one issue with FDCs is that in case of adverse drug effects, it becomes difficult to identify which of the combination drugs caused the problem. However, he also counterbalanced it by stating that some combination drugs have given very good results in treatment, in fact certain combinations have nullified the side effects of the individual drugs. So, a blanket ban on FDCs was definitely not justified.

Antani, who practiced as an ENT surgeon for 14 years before becoming a lawyer, offered very valuable insights on this issue. He said that FDCs offer comfort and convenience to the patients and the healthcare practitioners, however ensuring the safety and efficacy of these FDCs are equally important. He highlighted how essential it was for the combination drugs to be rational. He also raised concerns over the judicial delays in settling this issue. He also felt that better documentation by the industry would help them prove that their FDCs is safe and effective and at the same time make their case stronger.

Babtiwale highlighted that India has the ability to offer rational combination drugs to the world and he was of the opinion that safety was not being compromised in their production. He also pointed out that the banned drugs were earlier given approvals by the government after studies about their side/ adverse effects were conducted and analysed. He also raised a query that when there were very elaborate steps to be taken before approval was granted to manufacture combination drugs why was the ban enforced without any process and research? He also said that the role of a regulator was to regulate, however, an extreme stance has been taken by the regulator in this issue.

Prasad spoke on the existing regulations for drugs and their efficacy. He said that the current regime covers several points but also needs amendments and clarity in certain areas. He also emphasised that that there is a

need to analyse and learn from the regulatory guidelines globally. He felt that the ban was very skewed. He opined that it was important to weed out the wrong doers however, it is equally important to ensure that ethical, effective, safe and efficacious FDCs get a chance to thrive.

Representing the pharma industry, Joshi elaborated on the process of formulating the combination drugs and steps taken to ensure their safety and efficacy. The panelists also pointed out that if there was sufficient evidence about the adverse effects of a drug then the doctors themselves would stop prescribing it.

Josi, speaking on behalf of the patients, said that the consumers remain woefully misinformed about the whole issue. She also felt that the government's move has caused panic among the public because many of these drugs have been in use for quite some time. The other panelists agreed with this view.

Dr Sanghavi also steered the panelists to discuss various points like, is safety really compromised in FDCs, loopholes in the current regulatory system for drugs, is eligibility of the current regulatory committee which passed the ban to take this step, and so on. He also drew parallels between the current issue and the case of Pioglitazone, a popular diabetic drug which was banned by the government citing concerns over safety. Later the ban was revoked due to lack of sufficient evidence.

Thus, the panelists were unanimous in their view that the sudden ban on 344 FDCs by the government was an irrational and hasty decision. They also pointed out that as many diseases today were multi-factorial, FDCs served a very pertinent need. They were of the opinion that the government had no conclusive evidence proving that all the banned FDCs are harmful to human health. However, there was a consensus over the need for proper guidelines and processes to weed out harmful FDCs from the market and ensure better safety and efficacy of medicines.

The panelists stressed on the need for regulatory authorities to put better processes in place so that what's good stays while what's bad gets taken out of the system. The experts also recommended some measures such as:

Mandatory patient information leaflet about the drug, its usage and warnings about side effects
Improved pharmacovigilance
Better reporting of adverse drug effects
Improved synergy between stakeholders to ensure safety, compliance, and efficacy of drugs
Formation of an ethical committee with proper guidelines to judge and analyse these cases
The event ended with a Q&A session between the panelists and the audience.