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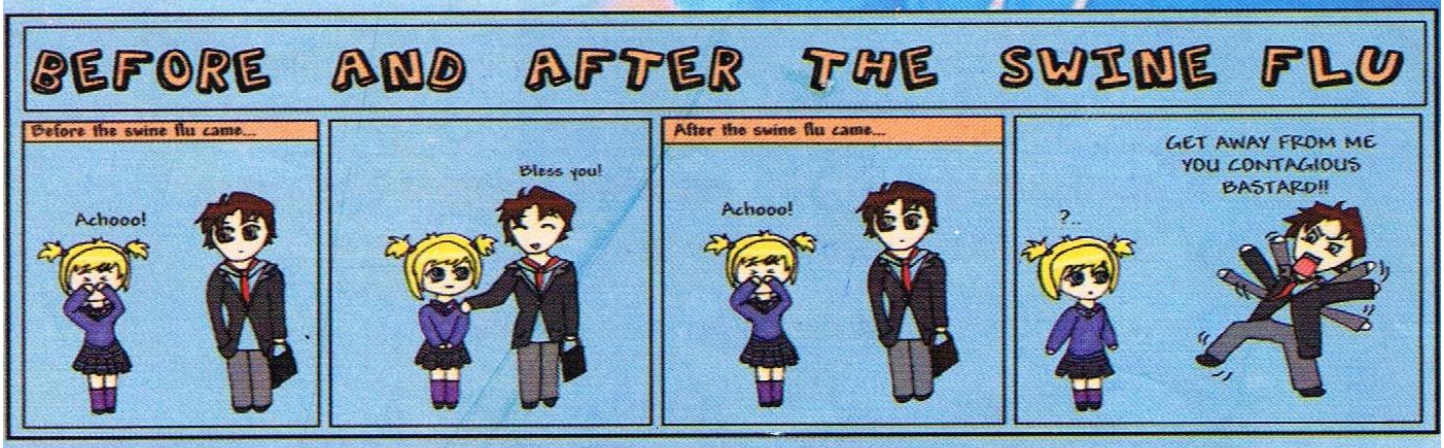
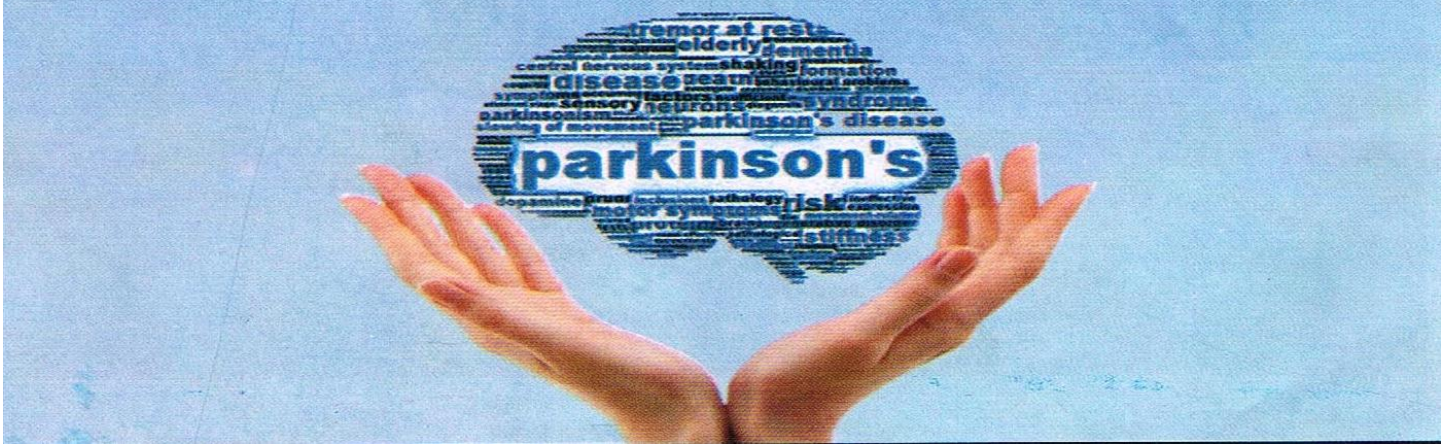
HIV

Symptoms & Treatment





Ban of FDCs may lead to weaken pharma sector

SANJAY AGRAWAL

The Drugs Controller General of India's recent act of banning of 344 FDC (Foxed Dose Combination) drugs under Rule 26-A of D&C Act with immediate effect, without allowing the pharmaceutical companies for getting a chance to sell the already manufactured drug products which are already in the market for many years, is injudicious and unfair, reports many Associations representing pharma sector.

Union Health Ministry vide notification dated 10th March 2016, banned 344 FDCs. Over 2000 branded drug products involving these 344 FDCs will be now out of sale due to the ban by the government, and that also all at once. These 2000 branded FDCs are used widely by diabetic, cardiac, psychiatric, asthmatic and other patients suffering from chronic diseases. All these patients are medically stabilised by these combo drugs for several years. Sudden overnight ban and discontinuation of these drug products will definitely undermine millions of patients on these medications.

Several of these FDC drugs are licensed officially by the State Licensing Authorities under the D&C Act and also by the office of the DCGI and these drug products are prescribed to the patients by the qualified doctors, and no adverse reaction has been reported on efficacy and safety side of these banned FDCs, say experts.

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The government not only have given any chance to the pharmaceutical industries and their trade associations for personal hearing, but also not responded to the several issues raised by the drug makers. When the UPA government had banned about 94 FDC drug products, the whole exercise was carried out in a systematic, careful and judicious manner so as to avoid hardship to all concerned. Advanced nations including USA are moving towards FDCs to reduce medicinal product costs for the benefit of the common people, but in India, it is going in the opposite direction. Main negative point is that this immediate ban will help question the credibility of the Indian pharmaceutical sector and it will adversely affect the image of the country, according to experts.

The ban will have a negative impact on growth of Indian pharma sector and it will not only affect revenues, turnover and profitability of the drug companies but also weaken their R&D capability. Approximately 5000 drug makers including MNCs like Pfizer and Abbott, and domestic pharma companies such as Lupin, Sun Pharma, Glenmark, Wockhardt, Aristo, Intas, Alkem, Ipca Labs, Wockhardt, MacLeods, and many SMEs and tiny units will be affected, according to pharma industry associations.

The ban including widely used and sold pain-killers, anti-diabetics and respiratory therapies could affect a minimum 7 per cent of domestic drug market resulting in losses of approximately Rs.7,000 crore to pharmaceutical companies, and about 90 per cent of those which have been affected by the ban are domestic drug units, according to pharma market experts.

Any way, 344 FDCs ban continues, many drug makers are approaching Delhi High Court and they are getting stay orders on the ban, and this has created a lot of questions and confusions in the pharmaceutical market about how does one interpret the stay orders; can the chemists start dispensing the brands, and if yes, which specific ones; or the chemists cannot dispense the products at all; what is the authenticity of the orders; and can doctors start prescribing these brands, and is there an assurance that these brands will be available.

The government has banned these drugs without citing any serious side effects or any global health regulatory prohibition order. The govt authorities should have adopted phase by phase approach for banning these drugs by giving enough time to stop manufacturing first, and then to put a deadline to fold up the products from the market. Now the value of these banned drugs is approximately Rs.4,000 crore which means crores of patients would be currently consuming it. By withdrawing various categories of drugs by overnight ban will create lot of problems to the patients also, besides, the patients will have a feel of insecurity and threat in their mind about their doctors who prescribe these drugs and may worry about their health since they are taking it for long time, say experts.

Another factor is that the doctors may not have any idea about the ban and they normally do not follow the DCGI notification in the gazette. They will continue to prescribe the same drugs. More than 50 different cough formulae have been banned by the government with the notification now. The doctors will have to write minimum four different drugs to cure cough and cold for a child instead of writing one FDC cough syrup.

When the Government is promoting 'Make in India' programme concept the current situation will be against the Indian pharmaceutical companies especially for SMEs, and small and medium pharmaceutical companies would be so badly hit by the prohibition of that they will be forced to shut down their business. Indian drug makers have been consistently outperforming and providing the best quality of medicines at affordable prices for the healthcare of the people of India and also across the globe at large number.

This sudden decision of overnight by the Ministry of Health and Family Welfare through CDSCO – the Office of the DCGI for prohibition of 344 FDCs has questioned the credibility of the Indian pharmaceutical industry and will adversely impact the image of the country.

In 1950, Ahrens and colleagues defined primary biliary cirrhosis in a compilation of 25 cases of diagnosed chronic intrahepatic biliary obstruction with xanthomatosis, reported between 1851 and 1950. The first case of primary biliary cirrhosis had been described almost 100 years earlier by Addison and Gull. Ahrens and colleagues noted the female preponderance, hyperpigmentation, jaundice, pruritus, hepatomegaly, hyperlipidaemia, and xanthomatosis that are now known to be characteristic of the disease.

Primary biliary cirrhosis is deemed a model autoimmune disease because of the serological findings, detection of antimitochondrial antibody (AMA), and specific bile duct pathological changes that occur in the disorder. Primary biliary cirrhosis is most often diagnosed when routine laboratory studies reveal an increase in alkaline phosphatase. AMA, the serological hallmark of primary biliary cirrhosis, is present in about 95% of patients with the disorder.

High alkaline phosphatase in conjunction with presence of AMA is sufficient to diagnose the disorder. Liver biopsy is not necessary for diagnosis but can be useful in the absence of AMA or in the presence of overlap syndromes. Primary biliary cirrhosis predominantly affects women, and usually presents in the fifth or sixth decade of life.

Fatigue and pruritus are the most common symptoms of primary biliary cirrhosis, and both can be debilitating in some patients. The only accepted therapy is ursodeoxycholic acid (UDCA), which has been shown to extend transplant-free survival, especially when started early in the course of disease. However, UDCA does not Cure the disease and about 40% of patients with primary biliary cirrhosis do not have a biochemical response to UDCA. **The Lancet**

Inflammasomes are tightly controlled intracellular immune sensors which assemble upon stimuli from tissue damage, infection or metabolic disturbances. Activation of inflammasomes results in production of the pro-inflammatory cytokines interleukin (IL)-1 β and IL-18, and also pyroptotic cell death. The NLR containing a pyrin domain 3 (NLRP3) inflammasome gets activated in following 2-step manner:

- 1st step: A priming signal is required to increase the expression of NLRP 3 and pro-IL-1 β which can be initiated by activation of PRRs or cytokine receptors on the cell surface or by post-translational mechanisms.
- 2nd step: Inflammasome gets assembled upon stimuli such as reactive oxygen species (ROS), ion changes and crystalline structures. **Jubilant CVD Times The treasure of knowledge**