

THE HINDU BUSINESS LINE  
**Business Line**

## Pfizer's smoking-cessation drug cautions behavioural changes

**After red flag raised by the US regulator on parallel drug**

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Mumbai, Sept. 5

Pfizer has updated the label on its smoking-cessation product Champix, to alert health professionals of behavioural changes, including depressed moods and suicidal thoughts, reportedly associated with such products.

The update has been submitted to the regulatory Drug Controller General of India, a Pfizer spokesperson told *Business Line*.

Pfizer's move follows the red flag raised by the US regulator recently, when it mandated "boxed warnings" on Chantix (varenicline) and Zyban (bupropion hydrochloride), two prescription medicines used as part of smoking cessation programmes.

Chantix is sold by Pfizer in India as Champix and it was launched in 2008. Zyban is GlaxoSmithKline's product, launched locally in 2001, but shelved two years later.

The use of Chantix or Zyban have been associated with reports of changes in behaviour such as hostility, agitation, depressed mood, and suicidal thoughts or actions, the US Food and Drug Administration observed. And the boxed warnings caution



healthcare workers of the new safety related information.

Smokers looking to quit and their families are kept fully informed of the risks, says Dr Sandeep Budhiraja, Chief of Internal Medicine, Max Healthcare.

There is also a psychiatrist on board to explain the implications, he says.

### NICOTINE WITHDRAWAL

The FDA too observes that since Chantix and Zyban do not contain nicotine, people who use these drugs to help them stop smoking may still experience symptoms of nicotine withdrawal.

"It is common for people who are attempting to break their nicotine habit to expe-

rience unpleasant symptoms like depressed mood, irritability, restlessness, anxiety and trouble sleeping," the FDA said.

Nevertheless, smokers undergoing the cessation programme are asked to report untoward incidents to their doctors, Dr Budhiraja said.

But no such incident had been seen in the 150 people undertaking the therapy at the three cessation clinics jointly run by Max and Pfizer in Delhi, he added.

### BENEFITS OUTWEIGH RISKS

While there are reports of behavioural changes associated with cessation products, the consensus is that benefits of the product outweigh its risks, observes Dr P.C. Gupta, Director of Healis Sekhsaria Institute for Public Health.

With smoking known to cause "serious and potentially fatal health consequences" including lung cancer, heart attacks and stroke, among others, the FDA points out, "The risks that are known to be associated with smoking must be balanced against the small, but real risk of serious adverse effects associated with medicines that can help patients quit smoking."