PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Financial Express, Delhi
Wednesday 27th November 2013, Page: 2
Width: 20.55 cms, Height: 17.66 cms, a4r, Ref: pmin.2013-11-27.26.12

Several drugs banned abroad may face curbs in India as well

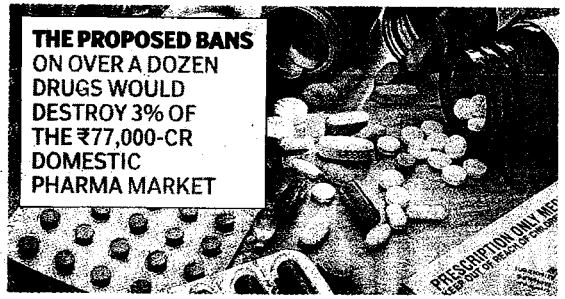
Jayati Ghose

New Delhi, Nov 26: Over a dozen drugs, including anti-allergic Buclizine and anti-asthma Doxofylline, that have been removed from two or more foreign countries on grounds of efficacy and safety could soon find their way into the Indian government's "banned-drug" list, denting turnovers of pharma giants such as Glenmark, Ranbaxy, Lupin, Mankind and Cipla.

Buclizine, prescribed in India as an appetite stimulant for children, is being marketed as Longifene by Mankind Pharma and this drug is also present in several combination formulations.

Doxofylline has over Rs 600 crore market in India and is being sold under various brand names such as Synasma (Ranbaxy), Doxovent (Glenmark) and Theobid-D (Cipla). In all, the proposed bans on over a dozen drugs would destroy 3% of the Rs 77,000-crore domestic pharma market, official sources said. The names of the other drugs that might be removed were not immediately available.

According to the sources, the government is also planning to set up a special expert committee to weed out irrational fixed dose combination (FDC) drugs that include muscle relaxants, painkillers, anti-depressants and antispasmodics from the market. FDC formulations account for around 45% of the domestic pharma market and are frequently prescribed by doctors.



A section of the FDC market is believed to be of drugs lacking any therapeutic efficacy.

"Drugs, which have been removed from two or more countries on grounds of efficacy and safety, will be considered for banning in India," said a health ministry note. The government is expected to formulate a stringent drug ban policy soon.

According to Ranjit Roy Chaudhury, chairman of the government committee on approval of new drugs, clinical trials and drug ban: "A list should be prepared of drugs not approved in the country of origin and those which have been banned or withdrawn in several countries. These should again be reviewed for withdrawal".

Recently, the government had to revoke its ban on anti-diabetic drug Pioglitazone, which has over Rs 800 crore domestic market, as the suspension had not been approved by the drug technical advisory board. Moreover, with the ban on antidepressant Deanxit being quashed by the Karnataka High Court in August, the drug may soon be allowed to be sold by prescription.

The issue of safety of drugs sold in the Indian market has hogged the limelight for long, with regulatory experts often citing instances of drugs banned in other countries continuing to be sold in India.

According to sources, both Buclizine and Doxofylline do not have the permission for sale in major developed countries such as US, Canada, Britain, Australia and are likely to be considered by the health ministry for suspension in India.

Sources added that even for Deanxit, which is banned in its country of origin Denmark, an expert committee would be constituted by the health ministry to make recommendations on its marketing in India.

India has banned over 91 drugs between July 1983 and June 2012.

Between between May and June this year, the health ministry banned four drugs — painkillers dextropropoxyphene and analgin, anti-diabetic pioglitazone and anti-depressant deanxit — which together garner sales of Rs 1,200 crore in the domestic pharma market.

On irrational FDCs, sources said that the committee "will review all the drug formulations and vaccines now in the market and prepare a list of drugs which should be removed".

The Ranjit Roy committee had noted with concern that in India there are an unacceptably large number of formulations in the market, somewhere between 60,000 and 85000, and many of these medicines should not have been allowed to reach the market in the first place.

Regulatory