

45 firms, including Strides Arcolab, Umedica, Marck Biosciences, fail quality tests

Vietnam declares war on Indian pharma companies

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Mumbai: Vietnam has banned at least 45 Indian pharmaceutical companies from supplying medicines to its markets.

Major players such as Strides Arcolab Ltd, Medley Pharmaceuticals Ltd, Marck Biosciences Ltd, Marksans Pharma Ltd and Umedica Laboratories Pvt Ltd are in the list.

Finding the drugs of these companies not of standard quality (NSQ), the Drug Administration of Vietnam (DAV) banned them. dna has with it a list of erring companies that failed DAV quality tests between January 1, 2011 and October 25, 2013.

Apart from the Indian companies, nine from Korea, two from Bangladesh, two from France, and one each from the US, Philippines, Pakistan, Russia, Indonesia, Germany, Cyprus, and Canada have been banned.

A health ministry source said India is one of the largest suppliers of medicines to South-East Asian countries like Vietnam and African countries like Kenya, Nigeria and Ghana.

Deepak Mittal, the Indian consul general in Vietnam, has written a strongly worded letter to the ministry of health and family welfare. Copies of the letter have been sent to the external affairs ministry, the department of commerce, the Indian embassy in Hanoi and to the office of the Drug Controller General of India (DCGI).

Mittal has said in his letter: "In view of the fact that a large number of Indian companies have been listed defaulters by Vietnamese authorities, it is requested that necessary background checks on these companies may kindly be undertaken in India to see if there are complaints against them from other countries and steps be initiated to penalise them for bringing bad name to the Indian pharma industries abroad."



In the dock

Korea: 9 firms

Bangladesh: 2

France: 2

1 each from the US, Philippines, Pakistan, Russia, Indonesia, Germany, Cyprus, and Canada

A drug can fail quality tests and be declared NSQ if the active pharmaceutical ingredient (API) in it is lesser than the declared amount. In such a case, the efficacy of the drug goes down. The other parameters that are checked are the quality of bonding agent, colouring agent, and the time taken for dissolution.

But this is not the first time Vietnam has banned Indian companies. About two years ago, it had banned 19 pharma companies on the same ground, the health ministry source said.

Some industry experts, however, feel this could be a Chinese ploy to malign Indian companies. "Vietnam depends on India for procuring drugs. In recent years, Chinese interference in the markets has been observed. But China is not yet at par with India in manufacturing finished drugs," TR Gopalakrishnan, advisor, Indian Drug Manufacturers' Association (IDMA), said. "It should be noted that Vietnam hasn't banned any Chinese company." Turn to p5

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But DG Shah, the president of the Indian Pharmaceutical Alliance (IPA), cautioned against jumping to such conclusions. "Vietnam sources drugs at the cheapest price. And quality is bound to suffer. But if big pharma companies are figuring in the list then regulatory authorities should inspect the quality of their injectibles, tablets, capsules and syrups."

Mahesh Zagade, commissioner of Maharashtra FDA, said state drug inspectors draw close to 6,000 samples from manufac-

turing plants, wholesalers and retail chemists for inspection in FDA drug laboratories. "These medicines could have come from other states as well. We have seen that up to 7% of all samples, on average, are not of standard quality or are contaminated."

The Central Drugs Standard Control Organisation (CDSCO) carries out routine checks across the country through its zonal offices. Every month, it issues a list of NSQ drugs. In March 2014, CDSCO issued an alert for 46 medicines on its website after assessing their quality.

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