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No, the US FDA doesn't hate India

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STATISTALK

The US Food and Drug Administrator (FDA) has been going hammer and tongs at Indian drugmakers in recent times, showering warning letters on those shipping to the US.

It has also cited scary tales to support its ban on exports from certain Indian facilities – from 'black fibre that resembles human hair' in tablets to the lack of running water in toilets. So, is India being singled out by the FDA?

No, suggests an analysis of import alerts issued by the FDA in the past five years. In fact, the regulator has doled out the largest number of warning letters to home-grown pharma companies; 114 US-based pharma companies were served with warnings and censured for marketing-related offences and nine for faulty manufacturing processes.

For one, it has not taken too kindly to tall claims made by US pharma firms. It frowned upon J&J's advertisement for its blood thinner brand Xarelto claiming, falsely according to the FDA, it could prevent stroke in patients. Other US companies which have received warning letter for false promotion include Amgen Inc and Accorda Therapeutics.

Indian pharma companies do have the dubious distinction of receiving the second largest number of warning letters from the USFDA. But this is not surprising, given that India accounts for nearly 40 per cent of drug imports into the US. Indian companies were mainly found wanting in manufacturing and product quality compliance with 22 warning letters issued for manufacturing lapses while only 6 were for misleading promotions.

The US watchdog pulled up 17 UK-based pharma companies for false product claims. Chinese drug producers have also been hauled up for quality compliance issues, with twelve manufacturing facilities owned by Chinese pharma players receiving warning letters.

Germany closely followed China with ten of its manufacturing plants being subjected to regulatory action. In contrast, drug producers in countries such as Brazil, Australia and the Netherlands have had fewer issues with the FDA in the past five years.

If the warning letters are segregated according to offences, 187 letters were issued to marketing related misdoings with censures for manufacturing and quality compliance equalling only 90. Interestingly, 186 letters were issued to companies for wrongdoings such as irregularities in scientific investigations and online marketing of unapproved drugs.

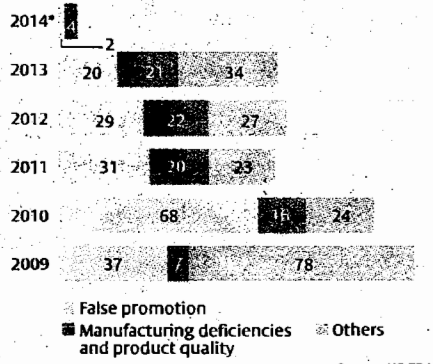
Medical bulletin

Number of warning letters issued by US FDA related to false promotion, manufacturing deficiencies and product quality

	US	India	China	Germany	UK	Others
2009	25	–	1	2	5	11
2010	37	9	5	–	10	23
2011	21	7	4	5	3	11
2012	22	1	3	4	2	19
2013	16	8	1	4	–	12
2014*	2	3	–	–	–	1

* Up to March 26, 2014

Manufacturers face the heat



Source: US FDA