PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Financial Chronicle, Delhi
Wednesday 8th July 2015, Page: 4
Width: 8.70 cms, Height: 16.94 cms, a4, Ref: pmin.2015-07-08.33.32

Lupin takes a knock as Brazil suspends drug

PRESS TRUST OF INDIA
New Delhi

BRAZILIAN drug regulator ANVISA has suspended import of active ingredients produced by pharma major Lupin used to make antibiotics, citing "unsatisfactory inputs" and deviation from good manufacturing practices (GMP).

In a statement posted on its website, ANVISA said it has suspended imports of "all beta-lactam cephalosporin pharmaceutical ingredients and all imported drugs using these inputs, which are manufactured by Indian company Lupin".

"The analysis considered unsatisfactory inputs. Furthermore, irregularities were detected during the inspection for verification of Good Manufacturing Practices," the statement said. A Lupin spokesperson told PTI that the company exports only one beta-lactam API to Brazil.

"A few months ago, ANVISA, the Brazilian regulatory authority had inspected our cephalosporin facility near Bhopal and had certain observations, which have since been addressed," the spokesperson said.

One observation related to the plant manufacturing a beta-lactam API for veterinary use for supply to Europe, he added.

"While we don't see this as a GMP concern, Lupin has confirmed to ANVISA not to manufacture API for Brazil in the plant referred above. ANVISA did not have concerns with Lupin using another plant at the same location to continue supply. We expect clearance from ANVISA to resume supply by September," the spokesperson said.

In May this year, Lupin had announced acquisition of Brazil's Medquimica Industria Farmaceutica, marking its foray into the Latin American nation.

Lupin is a transnational pharmaceutical company based in Mumbai.

It is the seventh-largest company by market capitalization; and the 10th-largest generic pharmaceutical company by revenue globally

Regulatory