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Drug regulator bans raw material import from 10 Chinese firms

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<http://economictimes.indiatimes.com/news/news-by-industry/healthcare/biotech/pharmaceuticals/Drug-regulator-bans-raw-material-import-from-10-Chinese-firms/articleshow/6048536.cms>

NEW DELHI: The country's drug regulator has banned import of raw material from 10 Chinese drug companies for supplying products without having the mandatory drug manufacturing standards, people familiar with the matter said. The move could lead to shortage of a few drugs which are manufactured from inputs largely supplied by these companies, industry officials said asking not to be named. The Drug Controller General of India (DCGI) cancelled the registration of the Chinese firms last week, which effectively stops any import of products manufactured by them into India.

These raw materials include clotrimazole, mefenamic acid and sulphadoxine that are used to make anti-infective and painkillers. "A limited number of Chinese companies supply some of the active pharmaceutical ingredients (APIs) so there can be shortage for that particular lot," an industry executive said. "This will give a chance to local API companies to increase sales," Lalit Kumar Jain, chairman at SMPIC, an association of small drugmakers said.

Indian drug companies largely depend on imports from China for APIs, the basic chemical used to make medicines and intermediates. Local drug makers use these API and intermediates to make finished products which are sold in India and overseas markets. There are concerns among Indian companies that a single lapse in manufacturing standard can be blown up by foreign drugmakers to question the standards of drugs made in India.

At present, India exports medicines worth Rs 42,000 crore every year while another Rs 58,000 crore are sold here. "We have to ensure that drugs made here are of top quality, if we are to become the pharmacy of the world in the next decade or so," a senior health ministry official said.

As per an industry official, DCGI found during scrutiny that the Chinese companies had not submitted proper good manufacturing practices (GMP) certificates. "The drug regulator cancelled registration of around half dozen Chinese companies and a few others themselves surrendered their licence to supply products into India as they also did not submit proper certificates that are mandatory." This is probably the first time the DCGI has taken action against Chinese companies.