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Indian drug firms lobby against EU's new directive

Vidya Krishnan, Mint

July 24, 2012: Indian drug companies are lobbying against a move by the European Commission to check the import of counterfeit drugs through a directive that comes into effect in about a year from now.

According to the Pharmaceuticals Export Promotion Council of India (Pharmexcil) lobby group, the country's drug exports to the European Union (EU) were worth $1.93 billion (around Rs.10,769 crore) in 2010-11. If India fails to get an EU equivalence certificate by 2 July 2013, when the rule is set to go into effect, 30% of this could be affected, the lobby group said.

Industry and government officials say they don't have the manpower or the resources to be able to comply with the new directive.

Under the EU falsified medicines directive, each shipment of active pharmaceutical ingredient (API) or drug raw materials from India should be accompanied with a written confirmation, vouching that the quality of the exports conforms to EU standards. The legislation was adopted by the EU Council in May 2011 with the objective of preventing the entry of fake drugs.

Failure to provide this "equivalence certificate" would mean loss of business for India, said D.G. Shah, secretary general of the Indian Pharmaceutical Alliance (IPA) lobby group.

"The EU initiative is protectionist and while they are citing safety and public health as reasons, it is clear that they want to protect their domestic pharmaceutical companies from competition," he said. "We can only hope that the Indian government will respond appropriately, keeping this in mind."

The EU and the Indian drug companies have been in conflict before. In 2008, the Netherlands seized Indian drug consignments on the ground of patent infringement, triggering a trade dispute between India and the EU. The incident had prompted the Indian government to approach the World Trade Organization (WTO).

The term "falsified medicinal product" in the European Commission's directive is of particular concern in India.

"While the directive is pertaining to API, the word 'falsified' could be used broadly to apply to generic drugs made in India," said C.M. Gulati, editor of the *Monthly Index of Medical Specialities*, a journal on prescription drugs available in India. "If an Indian company makes a generic version of a drug patented by a multinational pharma company, it could come under this directive and be treated as a 'falsified' or spurious drug and be confiscated."

At a meeting with industry representatives on Monday, the department of pharmaceuticals (DoP) sought a response from the Drug Controller General of India (DCGI) about the feasibility of training Indian drug inspectors on EU standards.

"We have sought DCGI's position on the matter and we are concerned by the use of 'falsified'. We have also proposed a meeting with representatives from the commerce and health ministries on the matter. We do not want to delay this any further as our exports will be adversely affected," said Raja Sekhar Vundru, joint secretary, DoP.

The government appears to be convinced that the Indian drug companies have a case. "We are looking at various alternatives, including approaching WTO...," said a commerce ministry official who didn't want

to be named. A questionnaire sent by *Mint* to the European Commission did not elicit a response at the time of going to press.

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India, China plan to jointly oppose EU regulation on API at WTO forum

Joseph Alexander, Pharmabiz.com

New Delhi, August 6, 2012: India and China may together move the World Trade Organisation (WTO) against the European Union (EU) regulation on bulk drugs which may affect the current exports of Active Pharmaceutical Ingredients (APIs) from both the countries to Europe.

EU has changed the rules for importing active substances into EU for medicinal products for human use and the amended regulation would come into effect fully by July 2013. It would make mandatory the current good manufacturing practices (cGMP) certificate from the local authority for all bulk drugs exports.

Sources said the Commerce Ministry had already taken up the matter with the EU authorities as the directive is expected to pose serious challenge to the API exports and is meant to secure the EU pharma supply chain.

Under the technical barrier to trade (TBT) provisions, India can raise the issue at the WTO forum and it is learnt that India would possibly make a joint statement with China at the next meeting of the WTO. China Chamber of Commerce had already written to Pharmaceutical Export Promotion Council of India (Pharmexcil) on the possibility of making joint representation, it is learnt.

China's share in EU's API imports is 12 per cent while India commands only two percent share in the API imports into the EU. Hence, China is going to be affected more than India.

The Commerce Ministry has also sought the opinion of the Bulk Drug Manufacturers Association over the issue.

Meanwhile, the industry representatives are also trying to take up the issue with Drugs Controller General of India (DCGI). Industry had pointed out that the DCGI was not authorized or conversant enough with EU GMP standards to issue certification. The companies will have to produce such certificates even after their manufacturing facilities and products (meant for exports) get all regulatory clearances directly from the EU drug regulatory authorities in that case.

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US, EU oppose India's proposed quality regulations for imported toys

Amiti Sen, Economic Times

New Delhi, September 8, 2012: The US and EU have opposed India's proposed quality regulations for imported toys, saying the legislation requires disclosure of extensive information by manufacturers.

The draft legislation, called Toys and Toy Products Compulsory Registration order, makes it mandatory for imported toys to be tested for toxic chemicals and registered in India before being sold to consumers.

Both the US and the EU have demanded that India should incorporate their suggestions and make the legislation framing process more transparent so that all concerns are addressed.

India, however, maintains that extensive bilateral consultations have already been held on the issue and the draft legislation, once framed, would be placed before the World Trade Organisation.

"Most countries frame laws to protect consumers on their own. We, too, are aware of our sovereign rights," an official told ET, adding, "At the same time, we do not want to keep the world guessing. So, we would definitely put up the draft legislation before the WTO."

The legislation is being prepared by the Bureau of Indian Standards (BIS), which is under the consumer affairs ministry, in consultation with the Department of Industrial Policy and Promotion, the nodal body for FDI policy.

"The BIS is continuously carrying out tests on the toxins that contaminate our toys and is upgrading the quality norms. The proposed order on registration of toys is to ensure that all our imports, too, strictly adhere to domestic standards," the official said.

Imports account for almost half of India's toy market, estimated at about $1.5 billion. It is expected to touch $2.6 billion by 2015, according to a recent study by industry body Assocham.

In 2009, India had banned import of toys from China over fears that the country was being flooding with cheap products that contained harmful chemicals. India, however, was forced to withdraw the ban after China complained to the WTO of being singled out.

In response to growing pressure from consumer activists, the BIS revised its toy safety standards last year, building in requirements for phthalate, a harmful chemical used for softening toys. The new compulsory registration order will ensure that imported toys are regulated on the same lines as domestic ones, the official said.

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Shrimp Export: India protests unscientific, unjustified standards

Amiti Sen, Economic Times

4 December 2012: India has raised with the World Trade Organisation what it calls "unscientific and unjustified" health standards imposed by Japan on its shrimp exports.

The move comes as more than 140 containers of frozen Indian shrimps await clearance at Japanese ports. Japan, which has recently lowered the acceptable level of ethoxyquin in shrimps, has since August rejected seven Indian consignments of the seafood. Ethoxyquin is an anti-oxidant widely used in shrimp feed.

"We have raised the issue with the sanitary & phytosanitary committee of the WTO. We believe the new standards that have been imposed are unscientific and unjustified," a commerce department official told ET.

According to industry estimates, export of shrimps from Odisha and West Bengal has fallen by up to 50% in the last four to five months due to the Japanese restrictions. In 2011-12, shrimps accounted for half of India's total seafood export of $3.5 billion.

While India is not immediately filing a case against Japan at the WTO, it hopes that discussing it at the SPS committee will generate pressure on Japan to respond positively.

"There are other countries like Vietnam that are facing similar entry barriers in Japan for their shrimps. We hope to generate enough pressure at the WTO forum to force Japan to reconsider," the official said. "If this doesn't work, we could consider a formal case against this restrictive measure."

The commerce department has also sought a clarification on why the testing procedures were institutionalised selectively only in 2012, despite the notification being made in 2005.

Japanese authorities rejected shrimps from India in August after the level of ethoxyquin, an anti-oxidant, in some shrimps was found to be in the 0.02-0.04 ppm range. Japan's newly introduced health standards tolerate ethoxyquin levels up to 0.01 ppm.

"Figures supplied to us unofficially by the marine products export development authority reveal that more than 140 containers that have reached the Japanese port face the risk of rejection," the official said. New Delhi's primary concern is that Japan has not carried out a risk assessment for setting the tolerance limit for the chemical and the extremely low default level of 0.01 ppm has been set without any scientific justification.

"Most of the countries, including the US and the EU, and international bodies like Codex have not prescribed any limit for ethoxyquin in fish and shrimp. So far, there is no evidence to prove that ethoxyquin at a level above 1ppm is injurious to health," MPEDA chairman Leena Nair said.

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To shield groundnut exports, govt to make certification mandatory

Sandip Das, The Financial Express

New Delhi, 5 February 2013: With reports of Indian groundnuts (peanuts) consignments being detained at countries in the European Union (EU) and Southeast Asia getting frequent, due to presence of a high level of aflatoxins, the government has decided to make certification of exporting units mandatory under the globally approved Hazard Analysis Critical Control Point (HACCP).

Along with the HACCP certification, the government would try to see to it that farmers follow norms under good agricultural practices (GAP), which will improve the quality of groundnuts shipped from the country. To start with, Agricultural and Processed Food Products Export Development Authority (APEDA), the commerce ministry's arm, has asked the Indian Oilseeds and Produce Export Promotion Council to compile a list of potential units having high export turnovers so that the HACCP certification process can be initiated.

"By June 2013, we expect the exporting units to have the HACCP certification, which will boost the export potential for groundnut products," Asit Tripathy, chairperson, APEDA told FE.

India mostly exports groundnuts to Southeast Asian countriesm such as Malaysia, Japan, Indonesia, Korea, China, Philippines and Thailand. Besides, a small quantity is exported to countries in the EU and Russia.

India exported more than 3.7 lakh tonne of groundnut worth more than R2,808 crore during April-November 2012. Commerce ministry officials say that during the last five years, out of approximately 750 official rejections of groundnut products, over 365 were reported due to excess levels of aflatoxins in peanuts, which is about 50% of all the rejections.

The official admit that most rejected consignments also do not meet the domestic aflatoxins levels. There have been inspection visits to India by food regulators from the EU, Japan and Russia.

The main purpose of launching a mandatory certification process was to ensure that groundnuts products exported from India do not test for aflatoxin in excess of the prescribed levels. Besides, APEDA wants to facilitate web-based traceability through PeanutNet with the objective of tracing and tracking the product for better compliance.

HACCP is a management system wherein food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

India is one of the major exporters of groundnuts after China. Andhra Pradesh, Bihar, Gujarat, Haryana, UP, Maharashtra, Tamil Nadu and MP are the key producers.

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New bulk drug export norms to comply with EU standards

The Hindu

New Delhi, 23 May 2013: The Commerce and Industry Ministry, on Thursday, issued new guidelines for pharmaceutical makers to comply with the European Union (EU) Good Manufacturing Practice (GMP) standards. In a statement issued here, the Ministry says such a move will give a boost to pharma exports from India. □\India has demonstrated its keenness to meet international requirements for exports of pharmaceutical products yet again by taking timely action for complying with the new procedural requirements of the EU for import of Active Pharmaceutical Ingredients (API) into the EU,. the statement adds. Active Pharmaceutical Ingredients, commonly referred to as bulk drugs in the industry, are used in making medicines. The new legislation, which will come into force from July 2, requires a written confirmation by a competent authority nominated by the government that the API has been manufactured in accordance with the EU GMP standards, the Ministry says in the statement. The authority will also give a written confirmation that the manufacturing facility, where the API is produced, is subject to control and enforcement of GMP standards and is equivalent to those in the EU countries. EU Directive

The EU had issued a new directive on June 8, 2011, to lay down a community code relating to medicinal products for human use and to ensure that the defective products do not reach consumers. The directive lays down a system of control over the entire supply chain for pharmaceuticals. □\Various EU industry members have been expressing their concern over the ability of India to comply with the new procedure by the July 2 deadline. However, India is optimistic that its pharma industry will be able to meet regulatory requirements within the given timeframe. This landmark achievement underlines the seriousness of India towards pharma exports. Compliance by pharma industry with the EU directive is expected to have a positive impact on the companies as many of them are aspiring to export to developed countries, the statement adds.

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Rules for 'Sensitive' Electronic Goods Import Likely Soon

Kalyan Parbat & Joji Thomas Philip, The Economic Times

Kolkata/New Delhi, 24 May 2013: The home ministry will shortly unveil comprehensive guidelines to screen imported electronics, IT and telecom gear deemed 'security sensitive' in its bid to secure India's core information infrastructure. It has identified eight categories of electronics, including cameras, radars, routers, base stations, devices used for data storage/transmission, general computers and biometric/access control devices, that will be subject to a stringent security drill if procured from overseas markets, according to internal ministerial documents reviewed by ET. The home ministry has evolved a template to assess whether a specific electronic item poses a security risk. For instance, "electronics that can be connected to the internet, can be controlled remotely or which radiate energy (excluding cell phones), will be classified as sensitive", says a home ministry note, a copy of which was reviewed by ET. Though there is no specific reference to imported tablets or smartphones, "electronic equipment capable of receiving or transmitting images, voice and data" will also be tagged security sensitive. Justifying its stance, the home ministry has cited the examples of the US and China, claiming that both the countries rely "entirely on indigenous capacity to meet their requirement of sensitive gear and embedded systems". It further said that the UK does import electronic items and added that the British international procurement policies involve risk profiling and management of sensitivity considerations through a mix of "testing, inspection and securitisation". The latest developments come at a stage when the government is about to notify the final preferential market access norms (PMA) that will mandate a minimum 30% domestic sourcing of security-sensitive electronic products by all central ministries, excepting defence. The home ministry's plans could stir a hornet's nest in international business circles, especially at a time when leading global lobbies, including the US India Business Council, Information Technology Industry

Council, Digital Europe and the Telecommunications Industry Association of the US, among several others, have decried India's plans of extending the PMA provisions to private mobile phone companies, claiming that the proposed norms "represent an unprecedented interference in the procurement of commercial entities and would also run afoul of India obligations to the World Trade Organisation (WTO). The home ministry note, however, asserts that India's security-related concerns are in sync with the WTO agreements, "which are based on the premise that it is the legitimate role of the member states and governments to take action that the member country alone in its sole discretion considers necessary for protection of its essential security interests". It further claims that "it is legitimate to include security-related conditions in tender specifications". "Provisions may be invoked on grounds of national security to place embargo on products originating from certain countries and the manner of placing such embargo may be determined in consultation with the commerce ministry," the interior ministry note said. The home ministry's concerns also come in the wake of the National Security Council's recent warning that Chinese gear makers pose a security risk to Indian telecom networks, and that India must expedite steps to overhaul its domestic manufacturing capabilities to "check, investigate and ultimately replace risks that come with foreign electronics equipment".

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