Government of India introduces Guidelines to meet the new EU [bulk] drug import rules

The Indian Government last week announced a set of guidelines for Indian exporters of pharmaceutical products to the European Union to help the sector meet new standards for import of bulk drugs into the 27-nation economic block.

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, 2013, 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 EU Directive:

The EU "directive" is a legislative act that sets out a goal that all EU countries must achieve. European Union issued a new directive, **Directive/2011/62/EC** on June 8th 2011 amending earlier directive Directive 2001/83/EC 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. It controls manufacture and import to marketing, wholesale and retail distribution.

Need for the New 'Directive':

The directive was brought in the wake of growing concerns over 'falsified medicinal products':
*"… **alarming increase of falsified medicinal products detected in the Union** in relation to their identity, history or source. Those products usually contain sub-standard or falsified ingredients, or no ingredients or ingredients, including active substances, in the wrong dosage thus posing an important threat to public health."* The directive notes, *"…Past experience shows that **such falsified medicinal products do not reach patients only through illegal means, but via the legal***

***supply chain as well**. This poses a particular threat to human health and may lead to a lack of trust of the patient also in the legal supply chain. Directive 2001/83/EC should be amended in order to respond to this increasing threat."*

New Definition of Falsified Product:

Any medicinal product with a false representation of:

a) *Its identity, including its packaging and labeling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;*
b) *Its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorization holder; or*
c) *Its history, including the records and documents relating to the distribution channels used.*

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.

The directive quotes the, 'Principles and Elements for National Legislation against Counterfeit Medical Products' endorsed by International Medical Products Anti-Counterfeiting Taskforce ('IMPACT') set up by World Health Organization (WHO).

Changes in the new Directive:

The changes from the earlier directive include:

'Article 46b

… Active substances shall only be imported if the following conditions are fulfilled:

a) *the active substances have been manufactured in accordance with standards of good manufacturing practice at least equivalent to those laid down by the Union pursuant to the third paragraph of Article 47; and*
b) *the active substances are accompanied by a written confirmation from the competent authority of the **exporting third country** of the following:*

(i) the standards of good manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to those laid down by the Union pursuant to the third paragraph of Article 47;

(ii) the manufacturing plant concerned is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the Union; and

(iii) in the event of findings relating to non- compliance, information on such findings is supplied by the exporting third country to the Union without any delay.

In light of these amendments, an **Indian company** looking to import its bulk drugs in Europe will *now* be required to produce a 'written confirmation' by a competent authority nominated by the Government of India:

1. *that the API has been manufactured in accordance with EU-GMP standards, and;*
2. *that the Manufacturing Facility where the API was manufactured is subject to control and enforcement of GMP standards and is equivalent to those in the EU countries.*

The 'Indian' Guidelines:

The Commerce and Industry Ministry, Government of India, issued the new guidelines on May 23, 2013 for pharmaceutical manufacturer exporting to EU, to comply with the European Union (EU) Good Manufacturing Practice (GMP) standards. The announcement notes:

1. Central Drugs Standard Control Organization (CDSCO) to be the 'competent authority' for the purposes of EU directive and issuing of 'Written Confirmation' Certificate, declared by the Department of Health & Family Welfare.
2. Introduction of a new protocol for the procedure to be complied by the India API Exporters laid down by the CDSCO which includes:
   a) *Application for issue of "written confirmation" for APIs for medicinal products for human use is to be made by the exporter in the prescribed format.*

b) *After satisfying the completeness of documents submitted, inspection to be conducted and after satisfactory outcome thereof, formal written confirmation to be issued.*
c) *Non-compliances noticed after inspection shall be communicated to the EU as per their requirement.*
d) *A time frame of 45 days has been prescribed for disposal of satisfactory applications and the written confirmation shall be valid for the three years.*
e) *Online application filing and tracking system to be evolved later to bring in sufficient expediency and transparency in the system.*

Our Views: These guidelines are a welcome step by the Indian authorities in ensuring that the Indian drug exporters are able to meet the requirements of and are able to comply with the new EU directive which will become operational from July 2, 2013. Though, there have been certain concerns reported on the compliance of Indian exporters with the directive within the time frame, we believe that the strict timelines and support for online filings proposed in the announcement will help the Indian companies meet the requirements in time and will also promote speedy decisions and will bring transparency in the functioning of the office.

About RNA: RNA is a full service Intellectual Property Law Firm with offices in Gurgaon and Chennai in India. If you require more information or need assistance in getting the 'Written Confirmation' certificate from the CDSCO, please contact: info@indiaiprights.com

Vatika Towers
10th Floor Block-B
Sector-54
Gurgaon-122002
National Capital Region (Haryana)
India

Tel. +91 124 4655999
Fax. +91 124 4045047
Email info@indiaiprights.com