UNION HEALTH MINISTRY MAKES IT MANDATORY FOR PHARMA UNITS TO COMPLY WITH THE GOOD LABORATORY PRACTICES

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Union Health Ministry makes it mandatory for pharma units to comply with the Good Laboratory Practices

The Ministryhas made it mandatory for pharmaceutical units to comply with the GLP. The state drug controllers have been asked by the DCGI to begin implementation of the GLP from November 1, 2010. The decision to implement GLP was taken by the government in 2008 and the pharmaceutical industries were given a time period of two years to comply with GLP. Globally, countries require manufacturers of industrial chemicals, pharmaceuticals etc., to ascertain that the products being manufactured by them are safe for humans and the environment. The enforcement of GLP shall ensure that the products being manufactured are of non-hazardous nature and safe for humans and the environment.

PSA view – Indeed the pharmaceutical companies were given adequate time to take steps and to comply with the GLP. However, the cost involved in complying with the GLP norms is exorbitant. As per the GLP, industries are required to have costly machines like Fourier Transform Infrared Spectroscopy, IR machines etc in every unit, thus adherence to these norms would require considerable investment from small scale units, consequently making survival difficult for these units. The Ministry, to insure a level playing field, must first impose these norms on the pharmaceutical giants and slowly enforce the GLP upon the smaller players.

DCGI forms sub-committee to review guidelines on Spurious Drugs Act

The Actalso known as the Drugs and Cosmetics (Amendment) Billwas passed by the parliament in October, 2009 and the bill was notified on August 10, 2010 by the Ministry. Ever since, there has been strong opposition against the Act as the industry fears that the several provisions of the Act can be misinterpreted and misused by the drug authorities which would lead to harassment of genuine manufacturers. In September 2010, the Ministry did promise to release a set of guidelines that would assure that the genuine manufacturers are not harassed. In October 2010, the Ministry issued a statement that general directives would be issued to the state drug authorities whereby the need to consult the guidelines attached to the Act before initiating any prosecution against the manufacturers for manufacturing and marketing spurious drugs would only be stressed. Now, the Ministry is further delaying the matter by setting up a sub-committee under the Drugs Consultative Committee (“DCC”) to review this issue as the DCGIfeels that the guidelines cannot be brought under section 33P of the Drugs and Cosmetics Act, 1940. The DCC has been asked look into the

matter and submit a report before the next DCC meeting which is scheduled for February, 2011.

PSA view –To insure that the genuine manufactures are not harassed the Ministry must issue these guidelines. These guidelines must be made mandatory and the Ministry must not release a general directive whereby the need to consult the guidelines would only be stressed. The government must act fast and release the guidelines.

New rules under the FSSA likely to be notified by December 2010

The Minister has promised that the new rules under the FSSA would be notified for public consultation by the government by December this year. The new rules shall govern the manufacturing, sale and import of food items. The Minister further state that a unified food law for the country is the need of the hour and the implementation of the FSSA would be a step in this direction.

PSA view –TheFSSA aims to set a standard for articles of food and to regulate the manufacture, storage, distribution, sale and import of such articles and ensure food safety. Furthermore, all food business operators ("FBO") in the country are required to be registered under the FSSA, thus making it easier to monitor the FBO's. A step in this direction will surely improve the standards of food safety in India.

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