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(Set up by Ministry of Commerce, Govt. of India)

COPY

Date : 31-05-2010

News / Story reproduced with thanks:- **Pharmabiz**

DBT to frame regulations for the growing biosimilars market in India

Monday, May 31, 2010 08:00 IST

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In order to regulate the growing biosimilars market in the country, the Department of Biotechnology (DBT) is planning to frame some regulations on the lines of the Hatch-Waxman Act of the USA which regulates generic pharma market in the US. At present there is no separate regulation to govern the biosimilars market in India.

In this regard, the DBT will soon hold a high level meeting to discuss the possibility of having India's own regulation for biosimilars. The meeting will focus on the urgent need for written guidelines for biosimilars.

Presently, the biosimilars in India are governed under the Environment Protection Act of 1970, Order 1989 and the Drugs and cosmetic Act. Even though the subject of biosimilars is dealt under these provisions it does not provide much needed regulation with respect to biosimilars. It is to address this seething problem that DBT has initiated steps for having a separate set of regulations for the biosimilars.

Senior officials from the DBT said that the department will soon hold a meeting to discuss and get consensus on the issue. It is expected that if things go as per plan, there will be an independent regulatory body for biosimilars by August this year. A 33-member mega committee was set up for this purpose in 2008 to look over the matter with Dr V P Kamboj acting as the chairperson of the mega committee.

Dr K K Tripathi, Advisor, DBT stressed that once India frames a law for biosimilars it would be called in a different name and not in a name given by foreigners. He said that whenever this law will be enacted he would prefer it to be addressed as 'geneticaceuticals' compared to biogenerics which is a Europeanised name. "The global development of biosimilars is now recognised to be a critical part of the future of biotechnology, thus we need to have our own law so that we are prepared for the challenges thrown at us," Dr Tripathi said.

"We need to have something like the Hatch-Waxman Act in India for geneticaceuticals or biosimilars. Biologics, as a terminology itself does not have a definition. Our regulatory system has been taking the help of the US FDA and EMEA guidelines" Dr Tripathi said. In the case of biosimilars, Europe leads the way in regulating these drugs compared to other regions of the world, he added.

He expressed that it is high time India needs a rapid regulatory development in the biosimilar segment. Currently, DBT has a large committee in the Review Committee on Genetic Manipulation (RCGM) which frequently discusses the current FDA and EMEA guidelines and makes sure that it is updated as per the guidelines in case by case approvals.

Biosimilars appear when a biopharmaceutical patent, which gives the original developer exclusive marketing rights,

expires. Unlike generics, biosimilars are not produced chemically but biologically, taking a biotech drug as a reference.

At present, US is in the process of enacting their legislation, EMEA already has a legislation for which they have five guidelines in place, especially for biosimilars. Even though the regulatory frameworks in Europe and the US are becoming more robust, but still the present guidelines do not allow a standardised approval process but force both agencies to continue with case-to-case decisions.