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Fresh guidelines for biosimilar drug approvals soon

SUSHMI DEY
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Companies such as Biocon, Panacea Biotec and Avesthagen may soon have a separate set of guidelines to manufacture and sell their biotech generic drugs in the country. The Department of Biotechnology, along with the drug regulator, has finalised draft guidelines for biosimilar drugs. The proposed norms outline specific requirements for pre-marketing and post-marketing data apart from guidelines for pre-clinical and clinical trials for biosimilars.

"The draft guidelines have already been prepared and will be placed in public domain for discussion very soon...may be within 15 days," a health ministry official said. The guidelines have been drafted after consultations with industry bodies and other stakeholders.

At present, there is no separate set of guidelines for biosimilars in India and such drugs are approved on the basis of general guidelines. There have also been instances, where biotechnology products were approved without conducting clinical trials on enough number of patients.

"There is need for tailor made guidelines for clinical trials as well as for post-marketing surveillance of biosimilars. We have prepared this draft after considering all the factors so that it helps in creating and maintaining the goodwill of the industry even at the international level," the official said.

The industry is also endorsing the view. According to Panacea Biotec's Joint Managing Director Rajesh Jain, biotechnology products in India have no set parameters and hence, a company may develop a drug and even get it into the market but may later face objections and pull it off.

"In India there are no set standards for biosimilars. One does not know how to make safe and efficacious biotech drugs. There are no parameters for chemical and pharmacological studies or even for conducting clinical trials," Jain said.

The draft guidelines contain introduction, background, objective, and scope of the guidelines along with requirements for pre-marketing and post-marketing data. It also outlines in detail the applicable regulations and norms for developing biosimilars in the country.

The idea is to upgrade and maintain the quality of biosimilar products that are manufactured in India.

The proposed guidelines are also expected to give a boost to the industry in the international space by buying credibility for drugs developed and manufactured in India, Jain said.

While Europe has such guidelines in place for some time, recently the US also introduced norms for biotechnology products.

The official said if the Indian companies are able to successfully adopt the guidelines, the government may also propose to translate it into a law by giving it a shape of an Act.

"The aim is to harmonise the industry and ensure that Indian biotechnology companies and their products are at par with other international drugs. Through these guidelines we want to stress on the need to maintain quality, efficacy and safety of the biosimilar products that are made here," he added.

NEED FOR NORMS TO MAKE & SELL BIOTECH DRUGS

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Regulatory,