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CDSCO panel to revise post approval changes of biological drugs

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In order to revise the guidance on post approval changes of biological drugs, the Drugs Controller General of India (DCGI) has constituted a committee of experts which will submit its report to the CDSCO. The committee will have detailed discussions with the stakeholders including the manufacturers and importers of biological drug products. DCGI Dr GN Singh has asked the manufacturers and importers of biological drug products in the country to submit their inputs and suggestions to the committee for the revision of Guidance for industry for post approval changes of biological drug products.

SP Shani, deputy drugs controller (DDI) is the chairman of the five-member committee. Rubina Bose, Swathi Srivastava, IS Hura and Vinod Kumar are the other members of the committee which has invited inputs and suggestions from the manufacturers and importers of biological drug products within one month.

During 2010, the CDSCO had come out with clarification and amendments in guidance for industry with respect to post approval changes in biological products in which it had omitted the provision of automatic approval of post approval change by DCGI, if not opined within the time period of 30 days for Level-I- Supplements (major quality changes) and of 15 days for Level- II- notifiable changes (moderate quality changes), as published earlier by the CDSCO.

If the application for post approval change is for such a change which makes product, a new drug as per definition under rule 122E of Drugs & Cosmetics Rules, in such circumstances, applicants shall apply for new drug permission to DCGI as per requirements of Drug & Cosmetics Act & Rules thereunder with requisite fees as per usual procedures.

As per that amendment, if the application for post approval change is for change in premises of manufacturing, wherein different permission under manufacturing license in form 28-D is required, in such circumstances, applicants shall apply for the said additional product permission to concerned state licensing authorities, zonal offices/ sub-zonal offices & CLAA as per requirements of D&C Act & Rules thereunder with requisite fees as per usual procedures.