Exclusive: Apex committee on clinical trials takes steps to streamline regulations

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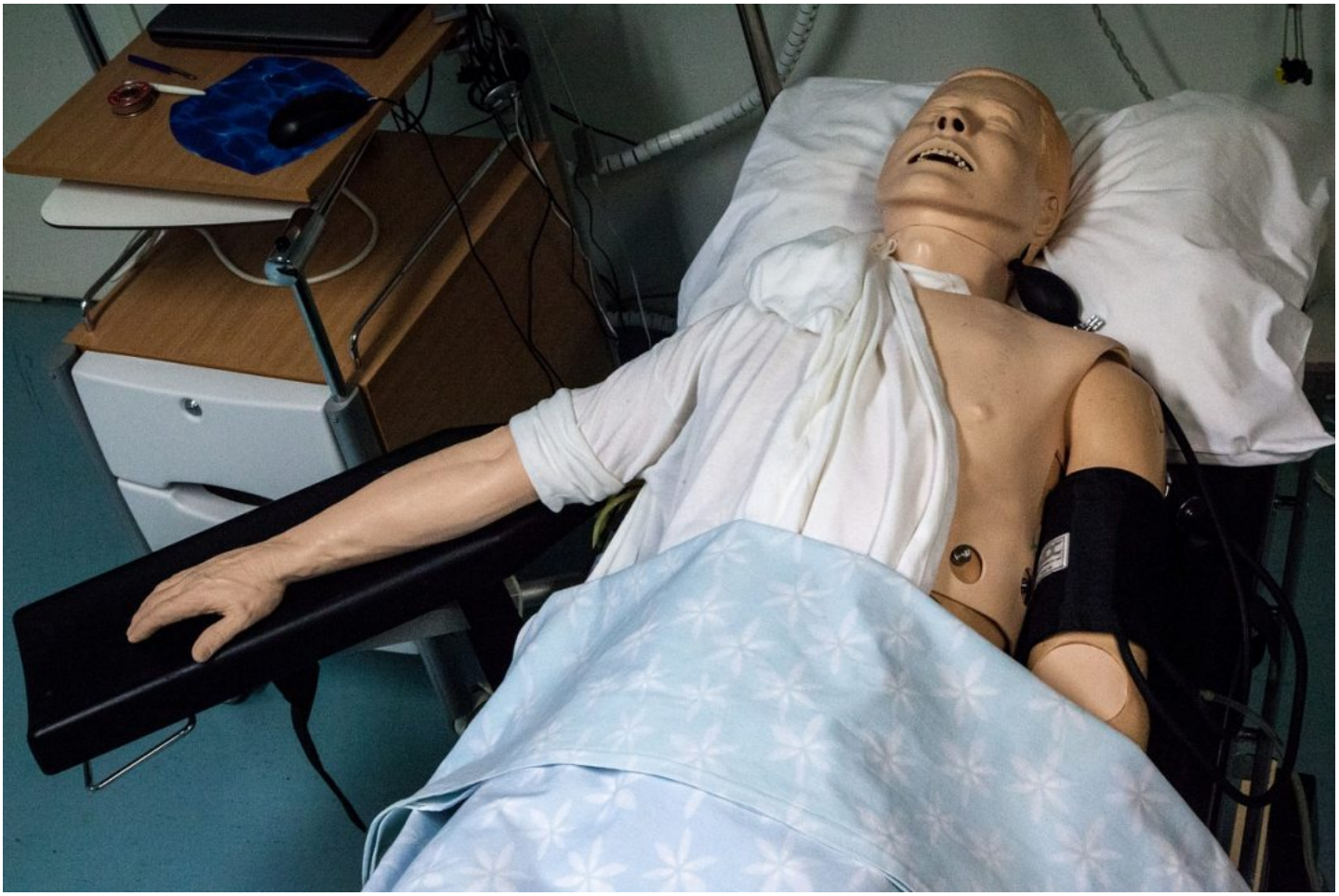
By : Rahul Koul - June 9, 2017



New Delhi: The long waiting period in the clinical trial approval timelines is a subject that has been consistently raised in the past by the concerned stakeholders. Moreover, the delays that happen even after Subject Expert Committee's (SEC) review, has been an issue raised recently by the many bodies of clinical research organization (CROs) including the Indian Society for Clinical Research (ISCR) besides top voices within pharma industry.

In this context, the 34th meeting of the Apex Committee was held on May 02, 2017 under the chairmanship of Mr C K Mishra, Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare for supervising clinical trials on new chemical entities.

As per the minutes of the meeting in possession of the *BioVoice News*, the Committee was apprised that the system of examination of proposals in Central Drug Standards Organization (CDSCO) has since reached a maturity and, therefore, it will be appropriate that the approval processes should be streamlined.

Apart from Mr C K Mishra who is the Chairman of the Apex Committee, Dr Soumya Swaminathan, Secretary, Directorate of Health Research and Director General (DHR), Indian Council for Medical Research (ICMR), Dr Jagdish Prasad, Director General-Health Services and Mr K L Sharma, Joint Secretary Department of Health and

Family Welfare attended the meet. Also present were the Special Invitees, Mr R K Vats, Additional Secretary and Director General (CGHS) Ministry of Health and Family Welfare and Dr G N Singh, Drug Controller General of India (DCGI).

After discussion, it was decided that the proposals relating to GCT should be placed before the SEC and where these are accepted or rejected by the SEC, no further approval of the Technical Committee or Apex Committee will be required.

In cases, where DCGI is not in agreement with the recommendations of SECs in case of clinical trial application, the matter may be placed before the Technical Committee for a final decision within a month of the recommendations of the SEC.

Now on the cases rejected by the SEC shall, in case the applicant feels aggrieved, be placed before the Technical Committee for its consideration. Where the Technical Committee decides, for reasons to be recoded in writing, to overrule the SEC, the decision of the Technical Committee shall be final.

It was also decided that the IND Clinical trial applications shall be placed before the IND Committee and the decision taken by the IND Committee shall be final. DGHS or Spl DGHS may be invited to the meetings of IND Committee. In rare cases, where the IND Committee, considers it necessary to keep the Apex Committee informed, the matter may be placed before the Apex Committee for guidance.

A brief summary of the applications received, proposals pending, proposals rejected, clarifications sought, and approved at different levels shall be submitted for the perusal of the Apex Committee every month. CDSCO will, in consultation with C-DAC, examine whether the report can be generated through SUGAM.

Meanwhile, the proposals of the clinical trial of 11 new chemical entities (NCEs) came up before the Technical Committee in its 40th meeting held on May 03, 2017. After detailed discussion and analyzing the proposals, the committee gave the go-ahead to the new clinical trials subject to conditions in few cases.