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Ms. A. Subhashini, Adv.

UPON hearing counsel the Court made the following
O R D E R

Having regard to the objections raised by Mr. Sanjay Parikh, learned counsel for the petitioners in Writ Petition (Civil) No. 33 of 2012, with regard to non-compliance of our previous orders dated 21.10.2013 and 10.03.2014, Mr. Siddharth Luthra, learned Additional Solicitor General, prays for time to seeks instructions and file comprehensive affidavit on behalf of the Union of India through competent authority.

Comprehensive affidavit shall be filed by the Union of India within eight weeks.

From the additional affidavit dated 10.03.2014 (filed on 17.04.2014) filed by Mr. Lov Verma, Secretary, Ministry of Health and Family Welfare, Government of India, it is not clear whether the Technical Committee and the Apex Technical Committee have evaluated Global Clinical Trials (GCTs)/New Clinical Trials (NCEs) having regard to three parameters, namely, (i) assessment of risk versus benefit to the patients, (ii) innovation vis-a-vis existing therapeutic option and (iii) unmet medical need in the country as indicated in the order dated 21.10.2013. To obviate any controversy in future in this regard, we direct that henceforth in the Format seeking information from the applicants, three specific columns regarding the above parameters shall be inserted for the purpose of New Clinical Entities/Global Clinical Trials.

It is open to the learned counsel for the

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petitioners and intervenors to supply within ten days from today notes of comments to Mr. Siddharth Luthra, learned Additional Solicitor General, to enable him to seek instructions in that regard and also incorporate response to those notes of comments in the comprehensive affidavit.

List the matters on August 25, 2014.

(Rajesh Dham)
Court Master

(Renu Diwan)
Court Master