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ITEM NO.42 COURT NO.2 SECTION PIL

SUPREME COURT OF INDIA

RECORD OF PROCEEDINGS

WRIT PETITION (CIVIL) NO(s). 33 OF 2012

SWASTHYA ADHIKAR MANCH, INDORE & ANR. Petitioner(s)

**VERSUS** 

UNION OF INDIA & ORS.

Respondent(s)

(With appln(s) for directions and intervention and extension of time and impleadment and office report)

WITH

W.P(C) NO. 79 of 2012

(With appln.(s) for directions, permission and impleadment and permission to file additional documents and office report)

W.P(C) NO. 91 of 2004

Date: 21/04/2014 These Petitions were called on for hearing today.

CORAM :

HON'BLE MR. JUSTICE R.M. LODHA HON'BLE MR. JUSTICE KURIAN JOSEPH

For Petitioner(s)

WP 33/2012 Mr. Sanjay Parikh, Adv.

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Mr. Pukhrambam Ramesh Kumar, Adv.

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Ms. Jyoti Mendiratta, Adv.

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Mr. Mahesh Agarwal, Adv.

Mr. Rishi Agrawala, Adv.

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Ms. Manasi Kumar, Adv.

WP(C)NO.33/2012 with connected matters

(21/04/2014)

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For Respondent(s) Mr. Siddharth Luthra, A.S.G.

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(21/04/2014)

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Mr. Rana Mukjerjee, Sr. Adv.

Ms. Kasturika Kaumudi, Adv.

Mr. Shekhar Kumar, Adv.

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## Ms. A. Subhashini, Adv.

UPON hearing counsel the Court made the following ORDER

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 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 17.04.2014) filed by Mr. Lov Verma, Ministry of Health and Family Welfare, Secretary, Government of India, it is not clear whether the Technical Committee and the Apex Technical Committee Global Clinical evaluated Trials (GCTs)/New Clinical Trials (NCEs) having regard three parameters, namely, (i) assessment of risk versus benefit patients, (ii) innovation vis-a-vis to the existing therapeutic option and (iii) unmet medical WP(C)NO.33/2012 with connected matters (21/04/2014)

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 shall above parameters be for Clinical inserted the purpose of New Entities/Global Clinical Trials.

> Ιt is open to the learned counsel for the

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