Swasthya Adhikar Manch and Ors

v.

Union of India (UOI) and Ors

(Supreme Court Of India)

HON'BLE JUSTICE R. M. LODHA HON'BLE JUSTICE SHIVA KIRTI SINGH

Writ Petition (Civil) No. 33 And 79 Of 2012 | 21-10-2013

1. This order is in respect of 162 cases for which approval has been granted by DCG(I). The matter was kept today as on the last date, i.e., 30.09.2013, Mr. Siddharth Luthra, learned Additional Solicitor General, prayed for time to place on record the report of Prof. Ranjit Roy Chaudhury and also the details of the existing regime which ensures the safety of the subjects of clinical trials and avoid any serious adverse event by such clinical trials. In pursuance of the order dated 30.09.2013, an additional affidavit has been tendered by Mr. Siddharth Luthra, learned Additional Solicitor General. The same is taken on record.

2. In the additional affidavit filed by Mr. Keshav Desiraju, working as Secretary, Ministry of Health & Family Welfare, Government of India, it is, inter alia, stated that since 2011 when the New Drug Advisory Committees (NDACs) were constituted, 78 meetings of these committees have taken place. During these 78 meetings held by NDACs so far, 1122 applications came to be evaluated by these committees. of 1122 applications, 331 applications were related to approval of Global Clinical Trials (GCT), including clinical trials of New Chemical Entities (NCEs). of these 331 GCT applications, NDACs have recommended approval of 285 applications and have not recommended approval for the remaining 46 applications. These 285 applications which have been recommended for approval by NDACs include clinical trials for investigational products relating to Anti-AIDS, Oncology, Cardiology, Neurology, Psychiatry, Metabolism, Endocrinology, etc. NDACs have evaluated carefully pharmacological, toxicological data, clinical data and protocol for the clinical trials including the objective of the study, eligibility criteria of the subjects, treatment, safety and efficacy assessments, etc. of these 285 applications, DCG(I) has given approval to conduct clinical trials in 162 cases till 31.08.2013. Out of 162 approvals, 157 approvals were given by the DCG(I) before 31.12.2012 which were prior to directions of this Court on 03.01.2013. The DCG(I) has given the approval to conduct clinical trials in the remaining 5 cases from 01.01.2013 till 31.08.2013 after the approval of the Apex Committee assisted by the Technical Committee.

3. The above facts show that insofar as 5 cases out of 162 cases which were given approval by DCG(I) are concerned, these 5 cases had undergone the three-tier screening. First by NDACs, then by the Technical Committee and the Apex Committee and thereafter the approval has been given by the DCG(I).

4. However, as regards 157 approvals which were given by the DCG(I) before 03.01.2013, learned Additional Solicitor General fairly submits that these cases have not been evaluated by the Technical Committee and the Apex Committee. He submits that the Central Government is agreeable that these 157 cases may be evaluated by the Technical Committee and the Apex committee as well, as has been done for the 5 cases for which approval was given after 03.01.2013.

5. We accept the statement of the learned Additional Solicitor General. We, however, observe that the Technical committee and the Apex Committee while evaluating the above 157 cases shall keep in view all relevant aspects of safety and efficacy particularly in terms of assessment of risk versus benefit to the patients, innovation vis-a-vis existing therapeutic option and unmet medical need in the country.

6. In the light of the above, it is not possible to pass any order today with regard to 157 cases and the same will be considered after the reports of the Technical Committee and the Apex Committee in respect of 157 cases are submitted before this Court.

7. As regards 5 cases for which approval has been given by the DCG(I) after 03.01.2013, we record and accept the statement of Mr. Siddharth Luthra, learned Additional Solicitor General that before the clinical trials are conducted, appropriate provision shall be made or administrative direction shall be issued which ensures that audio-visual recording of the informed concerned process of the participants is done and the documentation preserved, adhering to the principals of confidentiality, In other words, the clinical trials in respect of five cases shall commence after proper framework is in place concerning audiovisual recording of the informed concerned process and the preservation of documents while adhering to the principals of confidentiality.

8. List these matters on the date already fixed, i.e., December 16, 2013.

Interlocutory Application No. 8 of 2013 in Writ Petition (Civil) No(s). 33 of 2012

Interlocutory Application No. 8 of 2013 is allowed. Indian Pharmaceutical Alliance is permitted to intervene in the present case. They will be shown as intervenor in the cause title. Amended cause titled shall be filed within two weeks.