

Jananeethi vs Union of Indida

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Court : Kerala

Decided On : Jan-18-2021

Judge : Honourable the Chief Justice Mr.S.Manikumar,Honourable Mr. Justice Shaji P.Chaly

Appeal No. : WP(C)/20140/2012

Appellant : Jananeethi

Respondent : Union of Indida

Judgement :

IN THE HIGH COURT OF KERALA AT ERNAKULAM

PRESENT THE HONOURABLE THE CHIEF JUSTICE MR.S.MANIKUMAR & THE HONOURABLE MR. JUSTICE SHAJI P.CHALY MONDAY, THE 18TH DAY OF JANUARY 2021 / 28TH POUSHA, 1942 WP(C).No.20140 OF 2012(S) PETITIONER: JANANEETHI, P.B.NO.8, MANNUTHY P.O., THRISSUR-680651, RPPRESENTED BY ITS EXECUTIVE DIRECTOR, GEORGE PULIKKUTHIYIL. BY ADVS. SMT.DAISY A.PHILIPOSE SRI.JAI GEORGE RESPONDENTS: 1 UNION OF INDIA REPRESENTED BY THE SECRETARY, MINISTRY OF HEALTH AND FAMILY WELFARE PARAYAVARAN BHAVAN, LODI ESTATE, NEW DELHI-110 007. 2 THE

DRUGS CONTROLLER GENERAL INDIA DIRECTORATE GENERAL OF HEALTH SERVICES, FDA BHAVAN, ITO, KOTLA ROAD, NEW DELHI-110002. 3 CENTRAL DRUGS STANDARD CONTROL ORGANIZATION DIRECTORATE GENERAL OF HEALTH SERVICES, FDA BHAVAN, ITO, KOTLA ROAD, NEW DELHI-110002 REPRESENTED BY THE DRUGS CONTROLLER GENERAL (INDIA). 4 INDIA COUNCIL OF MEDICAL RESEARCH P.O.BOX NO.4911, ANSARI NAGAR, NEW DELHI-110029, REPRESENTED BY THE DIRECTOR-GENERAL. 5 STATE OF KERALA, REPRESENTED BY THE SECRETARY TO GOVERNMENT, DEPARTMENT OF HEALTH AND FAMILY WELFARE, GOVERNMENT SECRETARIAT, THIRUVANANTHAPURAM-695 001. 6 THE DRUG CONTROLLER RED COURSE ROAD, THIRUVANANTHAPURAM-695001. R1 BY SRI.P.PARAMESWARAN NAIR,ASG OF INDIA R1-3 BY ADV. SHRI.P.VIJAYAKUMAR, ASG OF INDIA R4 BY ADV. SHRI.SUNIL JACOB JOSE, CGC R5 BY SR. GOVERNMENT PLEADER SRI.ARAVINDAKUMAR BABU THIS WRIT PETITION (CIVIL) HAVING COME UP FOR ADMISSION ON 18.01.2021, THE COURT ON THE SAME DAY DELIVERED THE FOLLOWING: :: 2 ::

JUDGMENT

Dated this the 18th day of January 2021 Petitioner in this public interest litigation is stated to be a voluntary organization registered under the Travancore-Cochin Scientific, Literary and Charitable Societies Act. Main concern raised in this public interest litigation is regarding the illegal conduct of clinical drug trials in Kerala.

2. Adv.Daisy A.Philipose, learned counsel for the petitioner submitted that

the petitioner had been conducting field studies regarding the clinical drug trials in Kerala, since June 2009. During the study conducted by the petitioner, it is found that there is serious human rights violation and other harms to the participants in the clinical trials, since drug trials are being conducted without the properly constituted Ethics Committees and without the prior informed consent of the trial participants, in violation of the Drugs and Cosmetics Rules.

3. It is contended by learned counsel for the petitioner that physicians

receive incentives to recruit patients into trials, and do this often, without obtaining prior consent. Participants are subjected to unethical practices such as deprivation of effective medicines. Medical treatment and compensation are denied for the growing number of trial-related injuries and deaths. However, it is mandatory that all the proposals on biomedical research involving human participants should be cleared by an appropriately constituted Institutional Ethics Committee (IEC) to safeguard the welfare and the rights of the participants. According to the petitioner that it is unfortunate to note that most of the clinical :: 3 :: drug trials in Kerala is being conducted without a properly constituted Ethics Committee.

4. Another contention raised by learned counsel for the petitioner is that there are serious malpractices in the matter of obtaining the prior informed consent, from the trial participants. As per the Drugs and Cosmetic Rules and the

guidelines on clinical drug trials issued by the 4th respondent/Indian Council of

Medical Research, it is mandatory that participants should be recruited for trials, only after securing their informed consent. Further, the details of drug trials, risks and possible side effects of the trials are not communicated to the participants. The patients are not given the copy of the signed informed consent form, thus depriving them of any documentary evidence to provide their participation in a given trial. According to the petitioner, this is also highly illegal and violates the fundamental right of the citizens not to be deprived of life as provided under Article 21 of the Constitution of India.

5. It is also alleged by learned counsel for the petitioner that there is no

mechanisms for the State Government, for monitoring the clinical drug trials. As a result, the poor and illiterate citizens of the State of Kerala are being used as guinea pigs by the drug manufacturers. Hence this writ petition is filed seeking the following reliefs: i. Issue a writ of mandamus directing the respondent Nos.2 and 3 not to permit any clinical drug trials in the State of Kerala, without the properly

constituted Ethics Committees for each drug trial. ii. issue a writ of mandamus directing the respondents 2 and 3 to :: 4 ::

conduct an enquiry regarding the clinical trials being conducted in the hospitals in Kerala as mentioned in Exhibit-P6 and to stop all the Clinical Drug trials which are being conducted without the properly constituted Ethics Committees and without the prior informed consent of the trial participants, in violation of the Drugs and Cosmetics Rules. iii. issue a writ of mandamus directing the respondent Nos.2 and 3 to publish the details of the Ethics Committees, constituted for each Clinical Drug trial in Kerala.

iv. issue a writ of mandamus directing the 3rd respondent to take strict action to ensure that the investigator of Clinical Drug Trials should send prompt notification of all injuries or deaths, occurring during the trials to respondent No. 2 and 3 and to the Institutional Ethics Committee.

v. issue a writ of mandamus directing the respondent No.2 and 3 to take immediate and effective steps to ensure that the sponsors of clinical Drug trials should provide comprehensive health insurance for all trial participants to take care of all health needs or death and that the trial participants are provided immediate and long-term medical treatment and compensation for any injury or death.

6. A detailed counter affidavit has been filed on behalf of the 4th

respondent/Indian Council of Medical Research wherein, it is stated that the 4th respondent/Indian Council of Medical Research is a body of Scientists, who do not have any regulatory powers conferred on them for the purpose of monitoring the implementation of the contents of the guidelines. It is also submitted that the 4th respondent/Indian Council of Medical Research is only a body with technical know how and is not vested with the power of inspectors nor to monitor the implementation of the Guidelines.

7. A detailed counter affidavit has been filed on behalf of respondents 1 to

3/the Secretary, Union of India; the Drugs Controller General (India), Directorate ::
5 :: General of Health Services, New Delhi and the Central Drugs Standard
Control Organization, Directorate General of Health Services respectively wherein,
it is stated that the Good Clinical Practice guidelines are mandatorily required to
be followed by the Sponsor and Investigator in conduct of clinical trial. The
sponsor is, therefore, required to ensure that the scheme of clinical trials as
provided under Schedule Y also complies with the requirements of Good Clinical
Practice guidelines. It is further submitted that the Schedule Y provides that the
clinical trial on a new drug shall be initiated only after permission has been granted
by the licensing authority under Rule 21(b) and approval obtained from the
respective Ethics Committee(s). Various persons/organization involved in the
conduct of clinical trial and their responsibilities have been specified in the
Schedule Y as well as Good Clinical Practice guidelines. Relevant portion of the
counter affidavit reads as under: 23. It is further submitted that Schedule Y and the
GCP

guidelines provide detailed provisions in respect of enrolment of

clinical trial subjects, responsibilities of the Ethics Committee, sponsor, investigator, medical care of the subject, monitoring and auditing of the records etc. to safeguard the rights, safety and well- being of the subjects participating in the trial. The Good Clinical Practices (GCP) guidelines for clinical trial in India cover the various aspects of clinical trials which include the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects. These ensure that the studies are implemented and reported in such a manner that there is public assurance that the data are credible, accurate and that the rights, integrity and confidentiality of the subjects are protected. GCP aims to ensure that the studies are Scientifically authentic and that the clinical properties of the "Investigational Product are properly documented. These guidelines have been evolved as per the Ethical

Guidelines for Biomedical Research on Human subjects issued by the

:: 6 ::

Indian Council of Medical Research as well as World Health Organisation (WHO), International Conference on Harmonization (ICH), United State Food and Drugs Administration (USFDA) and European Good Clinical Practice Guidelines. These should be followed for carrying out all biomedical research in India at all stages of drug development, whether prior or subsequent to product registration in India. True copy of the Good Clinical Practice Guidelines is produced herewith and marked as Exhibit R1 (d).

24. It is further submitted that the Good Clinical Practice

guidelines are mandatorily required to be followed by the Sponsor

and Investigator in conduct of clinical trial. The sponsor is, therefore, required to ensure that the scheme of the clinical trials as provided under Schedule Y also complies with the requirements of Good Clinical Practice guidelines.

25. The contents of Grounds L and M are wrong and hence

denied. It is denied that there is any violation of fundamental rights under Article 21 of the Constitution of India. It is respectfully submitted that India also has a large disease burden and requires modern medicines for treatment of these diseases. India is considered to be having largest number of diabetes, Cancer and heart patients. Clinical research is the key to the discovery of latest and potent drugs for treatment of such diseases. It is therefore important to generate adequate evidence in the country to establish the safety and efficacy of a new drug for specific indication for which a clinical study under a well-defined and approved

protocol is required to be conducted. It is equally essential that research participants are put to minimum risk and there are adequate provisions to safeguard their rights and well beings.

26. It is further submitted that Schedule Y and the GCP

guidelines provide detailed provisions in respect of enrolment of

clinical trial subjects, responsibilities of the Ethics Committee, sponsor, investigator, medical care of the subject, monitoring and auditing of the records, etc. to safeguard the rights, safety and well being of the subjects participating in the trial. The Good Clinical Practices (GCP) guidelines for clinical trial in India cover the various aspects of clinical trials which include the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects. It ensures that the studies are implemented and reported in such a manner that there is public assurance that the data are credible, accurate and that the rights, integrity and confidentiality of the subjects are protected. Good clinical practice aims to ensure that the studies are scientifically authentic and that the clinical properties of the "Investigational :: 7 ::

Product" are properly documented. These guidelines have been evolved as per the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research as well as World Health Organization (WHO), International Conference on Harmonization (ICH), United State Food and Drugs Administration (USFDA) and European Good Clinical Practice guidelines. These should be followed for carrying out all biomedical research in India at all stages of drug development, whether prior or subsequent to product registration in India.

27. It is submitted that the Good Clinical Practice guidelines

are mandatorily required to be followed by the Sponsor and Investigator in conduct of clinical trial. The sponsor is, therefore required to ensure that the scheme of clinical trials as provided under Schedule Y also complies with the requirements of Good Clinical Practice guidelines. It is further submitted that the Schedule Y provides that the clinical trial on a new drug shall be initiated only after permission has been granted by the licensing authority under Rule 21(b) and approval obtained from the respective Ethics Committee(s). The various persons/organization involved in the conduct of clinical trial and their responsibilities have been specified in the Schedule Y as well as Good Clinical Practice guidelines. These further provide certain provisions for conducting studies in special populations like children, pregnant women, nursing women, elderly patients, patients with renal or other organisc system failure.

8. Adv.Daisy A. Philipose, learned counsel for the petitioner submitted that

after the filing of the writ petition, all other reliefs sought for in the writ petition, except relief No.iii, have been addressed. Relief No.iii is seeking for a direction to respondents 2 and 3 to publish the details of the Ethics Committees, constituted for each clinical drug trial in Kerala.

9. There are sufficient materials to indicate the procedure for clinical trial.

It is evident from the materials available on record that the respondents have amended the Drugs and Cosmetics Rule vide Exhibit R1(a) notification dated 30.1.2013, which is extracted below: :: 8 :: :: 9 :: :: 10 :: :: 11 :: :: 12 :: :: 13 :: :: 14 :: :: 15 :: :: 16 :: :: 17 ::

10. The Ministry of Health and Family Welfare on 1.2.2013 vide G.S.R.63(E)

amended the Drugs and Cosmetics Rule by inserting a new Rule 122 DAC related to clinical trials, which is produced as Exhibit R1(b) and the same reads as under: :: 18 :: :: 19 :: :: 20 ::

11. The Ministry of Health and Family Welfare on 8.2.2013 vide G.S.R.72(E) amended the Drugs and Cosmetics Rule, which reads as under: :: 21 :: :: 22 :: :: 23 :: :: 24 :: :: 25 ::

12. Good Clinical Practice guidelines which are mandatorily required to be followed by the Sponsor and Investigator in conduct of clinical trial is produced as Exhibit R1(d).

13. Placing on record the submission of the learned counsel for the

petitioner, we are of the view that no further directions are required in this writ petition. As regards publication, it is for the petitioner to obtain the details and to workout the remedies under the provisions of the Right to Information Act, 2005. Accordingly, writ petition is disposed of. sd/- S.MANIKUMAR CHIEF JUSTICE sd/- SHAJI P. CHALY JUDGE jes

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