SWASTHYA ADHIKAR MANCH

6, Bijasan Road, Opposite Mahavir Bagh, , INDORE, Madhya Pradesh

email-amulyabhai@gmail.com. Ph No.09425311547/ 0993278855

"No Clinical Trials of 157 NCEs till further order & 5 NCEs after proper mechanisms put in place" - Supreme Court

October 21st, New Delhi : 8th hearing of the writ petition filed by Swasthya Adhikar Manch took place today before the bench of the Supreme Court consisting of Justice R.M Lodha and Justice S.K. Singh. The case was filed in February, 2012 and the last hearing was held on 30th September, 2013.

The Hon'ble Supreme Court raised serious concerns over 162 clinical trials of Global Clinical Trial (GCT) including New Chemical Entities (NCEs) / New Molecule Entities (NMEs) out of which 157 were approved before 31st December 2012 and 5 between January to August 2013. In the Court it was admitted by Ministry of Health & Family Welfare (MOHFW) and representative of Drug controller General of India (DCGI) that 157 clinical trials were approved by DCGI on recommendations of New Drug Advisory Committee (NDAC) and without the approval of Apex and Technical Committee formed after order of Court dated 3rd January 2013. The Hon'ble Supreme Court have ordered GoI to reexamine 157 GCT including NCEs by Apex and Technical Committees. Therefore, now Apex and technical committee will have to evaluate these 157 clinical trials particularly in terms of - assessment of risk vs. benefits for patients, innovations to existing therapeutic options and benefits to medical needs of the country. It is only after the assessment of apex and technical committee that the question of commencement of 157 approval will be considered. In case of remaining 5 clinical trials which have been approved in 2013, the Hon'ble Supreme Court ordered MOHFW to conduct it only after ensuring proper mechanism & procedure to ensure safety of the patients along with audio-visual recording of participants maintaining principle of confidentially and preservation of documentation. **The Hon'ble Supreme Court also**

raised its concern that there is no checks and balance in the frame work where investigators are paid by sponsors and ethics committees are part of hospital with absence of proper mechanism to ensure patients safety.

Mr. Sanjay Parikh Senior Counsel for Swasthya Adhikar Manch argued and highlighted the facts in relation to NCEs/NMEs and asked the government to come out with a position paper on how these NCEs/NMEs will be in public and national interest. The Hon'ble Supreme Court also then inquired that out of 162 trials, how many molecules are patented outside country and benefiting MNCs instead of development of new drug for which learned Additional Solicitor General was unable to respond. Mr. Parikh also pointed out contradictions in data given in affidavit filed by MOHFW dated 26th July 2013 wherein it was stated that only 26 GCT were approved while in current affidavit of 18th October 2013, it is stated that only 5 trials are approved after 3rd January 2013 by the apex and the technical committee.

The petitioner asked the MOHFW to provide details of 162 approved clinical trials- Name of molecule, indication, name of sponsor, protocol, sites, number of subjects, name of investigators and minutes of NDAC, apex and technical committee meetings. The petitioner also raised serious concerns about Ranjit Roy Chaudhry Expert Committee report on issues like conflict of interest etc. The Ranjit Roy Committee also was not able to explain benefits to India by allowing NCEs/NMEs testing within the country.

The petitioners have been raising the issue of how NCEs/NMEs are benefiting MNCs at the cost of human life in India. The next hearing is scheduled on 16th December 2013.

Amulya Nidhi (9425311547), Chinmay Mishra (9893278855) - SAM , Dattatraya Taras, Navneet Wadkar

N.D. Jayaprakash (9968014630) (jaypdsf@gmail.com) - BGPSSS, Abdul Jabbar (9406511720) - BGPMUS

for details write to : amulyabhai@gmail.com | Visit - www.unethicalclinicaltrial.org