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MINUTES OF THE FIRST MEETING OF THE APEX COMMITTEE HELD ON 27-02-2013 UNDER THE CHAIRMANSHIP OF SECRETARY, HEALTH AND FAMILY WELFARE FOR SUPERVISING CLINICAL TRIALS ON NEW CHEMICAL ENTITIES IN THE LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME COURT OF INDIA DATED 03.01.2013

Present :

1. Shri Keshav Desiraju, Chairman
Secretary, Department of Health and Family Welfare.
2. Dr. V M. Katoch, Member
Secretary, Department of Health Research, and Director General, ICMR.
3. Dr. Jagdish Prasad, Member
Director General of Health Services,
4. Dr. Arun. K. Panda, Member-Secretary
Joint Secretary,
Ministry of Health and Family Welfare.

The Committee was apprised of the background in which the Apex Committee for supervising clinical trials on new chemical entities had been constituted. The Hon'ble Supreme Court of India, in its order dated 03.01.2013 in the matter of W.P. (C) No. 33/2012 of Swasthya Adhikar Manch, Indore Vs. Ministry of Health and Family Welfare & Ors. along with WP(C) No. 779/2012 on clinical trials, had directed that until further orders by this Court, clinical trials of new chemical entities shall be conducted strictly in accordance with the procedures prescribed in Schedule Y of the Drugs and Cosmetics Act, 1940 under the direct supervision of the Secretary, Ministry of Health and Family Welfare, Government of India.

In compliance to the said order of the Hon'ble Court, Ministry of Health & Family Welfare has put in place a system of supervision of clinical trials of new chemical entities conducted in the country by constituting the Apex Committee under the Chairmanship of Secretary, HFW and a Technical Committee under the Chairmanship of Director General of Health Services.

The Technical Committee will meet every month to review the approvals of clinical trials granted by DCG(I) and forward its recommendations to the Apex

Committee for its consideration and giving appropriate directions. The Apex Committee under the Chairmanship of Secretary, Health and Family Welfare will also meet every month to consider the recommendations of the Technical Committee on the approvals of clinical trials and other related issues for appropriate direction in the matter.

The first meeting of the Technical Committee was held on 27-02-2013 to review the approvals of clinical trials, granted by DCG(I) including recommendations of the New Drug Advisory Committees (NDACs) for taking decision in respect of such approvals and other related issues. The minutes of the meeting of the Technical Committee was circulated to the members of the Apex Committee for their perusal.

The Apex Committee noted that the Technical Committee after reviewing the status of approvals of clinical trials including the functioning of the NDACs and the Investigational New Drugs (IND) Committee, has made certain recommendations as under:

- Approval details along with the recommendations of NDACs and IND committee should be forwarded by the Office of DCG(I) to the members of the Technical Committee through e-mail for their detailed review.
- Clinical trials should only be conducted in government medical college / institutions and institutes of repute including reputed corporate hospitals under the supervision of Investigators who have experience, knowledge and are known for their integrity.
- The Committee also desired that IT-enabled database of clinical trials giving information about all elements of clinical trials need to be created.

The Apex Committee considered the issues relating to approval, monitoring and supervision of clinical trials in the country. In regard to approval of clinical trials, the Committee noted that the NDACs and IND committee consisting of medical experts from various Medical Colleges/ institutions across the country are in place to evaluate the applications of clinical trials of new drugs of various categories including clinical trials of New Chemical Entities.

As regards to the monitoring / supervision of the conduct of clinical trials, the Committee was apprised that CDSCO through its zonal and sub-zonal offices carry out clinical trial inspections as and when required. The recent amendment in the Drugs & Cosmetics Rules, dated 1st February 2013 in this regard has provisions authorizing CDSCO to conduct inspections of sites of Investigators and Sponsors to verify the regulatory compliance in conduct of clinical trials. The amendments also provide authority to DCG(I) to take action like debarment of the Investigator, the Sponsor including his representatives in case of non-compliance to the provisions of Drugs and Cosmetics Rules. The Chairman also directed the DCG(I) to ensure the conduct of

regular inspections of the clinical trial sites through the Zonal and Sub-zonal offices of CDSCO, and submit the reports to the Technical Committee.

The Committee noted that most of the clinical trials are multi-centric trials conducted simultaneously in more than one hospital/institution at various locations in the country. The respective Ethics Committees that review and accord approval to a clinical trial protocol for conduct of the clinical trial in a particular center, play major roles in safeguarding the rights, safety and well-being of trial subjects. However, earlier there was no regulatory provision for monitoring the functioning of such Ethics Committees. The recent amendments made under the Drugs and Cosmetics Rules, 1945, dated 8th February 2013, making it mandatory for registration of Ethics Committees by the CDSCO and providing authority to CDSCO for inspection of the working of such committees would go a long way in safeguarding the rights, safety and well-being of trial subjects. The Committee further desired that the details like name, address, contact details of Chairman etc. of each Ethics Committee functioning in the country for reviewing and according approval to clinical trial protocols, should be put on the website of CDSCO.

The Committee also desired that details of clinical trials approved including number of subjects, names, qualifications of Investigators, address of the clinical trial sites etc. and the amount paid by the Sponsor or his representative to the Investigators for conducting the clinical trial should be made available on CDSCO website.

The Chairman while taking note of the functioning of NDACs desired to know the status of applications received, deliberated by NDACs for approval of various categories of new drugs and clinical trials including clinical trials of new chemical entities before and after 03.01.2013. He also desired that timelines should be fixed by CDSCO for processing of such applications.

While taking note of the three recent amendments in Drugs and Cosmetics Rules related to clinical trials, the Chairman mentioned that some concerns have been raised by various stakeholders on certain clauses of the amendments. The Committee also noted that the Technical Committee in its meeting held on 27.2.13 has also taken note of these concerns and has recommended for further consideration. The Apex Committee after deliberation decided that the representations received on certain clauses of the amendments as mentioned above along with the recommendations of the Technical Committee should be placed before the DTAB for its consideration and recommendation.

The meeting ended with a vote of thanks to and from the chair.
