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PARTNERS IN GLOBAL HEALTHCARE

11th July 2013

Dr. Arun K Panda
Jt Secretary
MINISTRY OF HEALTH & FAMILY WELFARE
(Department of Health)
New Delhi

Subject:- Drug and Cosmetics (Second Amendment) Rules, 2013 - Notification dated 7th June 2013

Dear Sir,

We have read and scrutinized the notice dated 7th June 2013 with regards to insertion in para 2 on "CLINICAL TRIAL", in sub-paragraph (4) relating to 'Informed Consent', after the clause (iii), the following -

"(iv) An audio - video recording of the informed consent process of individual subject, including the procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record.";

In this context we are objecting to the same since:

- ❑ This will result in the issue of confidentiality.
- ❑ Such practices are not followed anywhere in the world.
- ❑ Record maintenance / Storage / cost will increase the expenses for the study and result in making the product more costly.

Hence, it is but logical that such a procedure must not be imposed compulsorily especially since even other countries have no such provision. However, if this is to be insisted upon, in view of the issue of patient privacy, there should be a provision for patients having a right of refusal to be video / digitally recorded.

As far as the other two points* are concerned, we are in agreement with the same.

(ii) in APPENDIX V, under heading 1, in sub heading 1.1 relating to 'Essential Elements', the existing entry 14 shall be re-numbered as entry 16 and before entry 14 as so re-numbered, the following entries shall respectively be inserted, namely:-

"14. Statement that there is possibility of failure of investigational product to provide intended therapeutic effect.

15. Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have therapeutic effect."

We would thus look forward to your concurring with our views and refrain from inserting the clause regarding video recording of the informed consent.

Thanking you

DR R K SANGHAVI
Chairman, Medical Subcommittee

MR MANISH DOSHI
President

Cc to

Dr G N Singh
Drugs Controller General (India)
Directorate General of Health Services
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