



Research Article

www.ijrap.net



RECENT CHANGES IN THE CLINICAL TRIALS REGULATORY FRAMEWORK IN INDIA; THE ROAD AHEAD FOR AYUSH SECTOR

Pradeep Dua^{1*}, Pamila Dua²

¹Research Officer, CCRAS, Department of AYUSH, Janakpuri, New Delhi, India

²Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), Ansari Nagar, New Delhi, India

Received on: 05/10/13 Revised on: 30/10/13 Accepted on: 27/11/13

*Corresponding author

E-mail: duadradeep@gmail.com

DOI: 10.7897/2277-4343.04612

Published by Moksha Publishing House. Website www.mokshaph.com

All rights reserved.

ABSTRACT

The clinical trials in India are regulated by Schedule 'Y' of the Drug and Cosmetics Rules, 1945 which defines the requirements and guidelines for import and/or manufacture of new drugs for sale or for clinical trials. However, owing to the changing International regulatory scenario, increased awareness about the rights/welfare of the trial participants and recent exposure of certain unethical practices being adopted in the conduct of clinical trials in the country, an overhaul of the clinical research related regulatory framework was long overdue. It has also been reported that due to lack of appropriate regulation in clinical trials, India is losing out to Malaysia, China and Singapore. The health ministry's proposal for a biomedical and health research bill is, therefore, a welcome step. The proposed law intends to ensure compliance with the regulatory provisions and ethical guidelines to ensure well-being of the clinical trial participants.

Keywords: Clinical Research, Drugs and Cosmetics Rules, Informed Consent, Ethics Committee, CDSCO, PATH, CTRI, AYUSH

INTRODUCTION

The Indian clinical trials regulatory scenario has witnessed a sudden onslaught of several amendments in the Drugs and Cosmetics Rules, 1945 during the recent past, the probable reasons being active involvement of the print media in highlighting the alleged irregularities in the conduct of clinical trials as well as approval of new drugs and increased awareness among the masses who wish to be treated in a more humane and ethical manner than being mere guinea pigs. As reported in the Times of India dated 25th August, 2012, "drugs continue to be approved in India without having undergone proper clinical trials on the local population. The Parliamentary Standing Committee on health has exposed how the Central Drugs Standards Control Organization (CDSCO), the country's highest office on drugs, approved 33 new drugs between January 2008 and October 2010 without testing them on Indian patients. Between January and July 2012, the CDSCO has approved 14 new drug molecules of which only nine have undergone clinical trials. In 2011, 41 new drugs were approved by the CDSCO out of which only 38 had undergone clinical trials. In 2010, 65 such molecules were approved of which 52 had undergone trials. In 2009, 72 new molecules were approved of which as many as 12 had not undergone clinical trials. The number of clinical trials taking place in India has increased substantially since 2005. As many as 2282 trials have been approved by the DCGI between 2005 and 2010. As per the Union Health Ministry's status note, a total of 1514 subjects have died during 2008 to August 2010, during the clinical trials". The Times of India dated 23rd February, 2013 reported, "Permission for 529 trials were given in 2010, 283 trials in 2011 and only 253 trials in 2012. Also, 668 people died in 2010, 438 in 2011 and 436 in 2012 during clinical trials in India". The recent reporting of controversial drug trials being conducted in Indore by

private practitioners and doctors of the government medical college involving 'mentally challenged' patients served as a stimulus to have a relook into the need to overhaul the existing clinical trials regulatory scenario in the country. In the said case it was alleged that for more than two years i.e. from 2008 to 2010, the trials were conducted ignoring the existing ICMR ethical guidelines. The Madhya Pradesh Government levied a fine of Rs. 5000 each on the doctors involved, and this was seen widely as being paltry and insufficient punishment. The 72nd report of the Parliamentary Standing Committee on alleged irregularities in the conduct of the studies using Human Papilloma Virus (HPV) vaccine¹ by a foreign NGO named Programme for Appropriate Technology in Health (PATH) in India was presented to the Rajya Sabha on 30th August, 2013 and laid on the table of the Lok Sabha on 30th August, 2013. The report stated that the multi-country clinical trial was conducted in Peru, Vietnam, Uganda and India. In India, the tribal girls were included in Phase IV trial of Human Papilloma Virus (HPV) vaccine. PATH was granted the permission to conduct trials in Khammam district, Andhra Pradesh, India and Vadodra district, Gujarat, India. There were reports of deaths of 7 girls in the same trial which led to suspension of the whole process a year later on April 7, 2010 and a committee was constituted to enquire into the alleged irregularities. The committee indicted the NGO on several grounds including irregularities in the methods of monitoring the Serious Adverse Events and remedial measures for the same and indirect coercion through the statements in the consent forms stating "you will not be charged for your daughter to receive the vaccine". The report also mentions that in Andhra Pradesh out of the 9543 forms, 1948 forms have thumb impressions while hostel wardens have signed 2763 forms. In Gujarat, out of the 6217 forms 3944 have thumb impressions and 5454

either signed or carried thumb impressions of the guardians. The report also mentions that out of 100 consent forms from Andhra Pradesh, India project, 69 forms have not been signed by any witness. On many forms there were no dates. Also, one particular person had signed seven forms. It was also observed that in many cases, the date of vaccination was much earlier to the date of signature by the parents / guardians on the consent form.

New Regulations

With a view to ensure the safety of the clinical trial participants and regulate the conduct of clinical trials in the country, the Government of India has come out with several provisions / amendments in the Drugs and Cosmetics Rules, 1945 namely:

- Registration of the clinical trial with the Clinical Trials Registry, India
- Compensation in case of injury or death during clinical trial
- Permission to conduct a clinical trial
- Registration of Ethics committee
- Audio-visual recording of the Informed Consent process
- The Drugs and Cosmetics (Amendment) Bill, 2013 (Bill No. LVIII of 2013)
- Proposed Comprehensive Law for Regulating Clinical Research

Registration of the clinical trial with the Clinical Trials Registry, India

Several National as well as International guidelines have now made it mandatory to register the clinical trials with a central registry. The International Committee for Medical Journals Editors (ICMJE) released an editorial statement on compulsory registration of clinical trials in 2004. According to this statement, the ICJME proposed comprehensive trial registration as a solution to the problem of selective awareness and announced that all eleven ICJME member journals would adopt a trials-registration policy to promote this goal. These days ICMJE member journals require submission of the trial registration number prior to consideration of clinical trial data for publication. The same was published in the prestigious New England Journal of Medicine². In addition, Editors of Biomedical Journals of 11 major journals of India, in February 2008, also called for trial registration in a publicly accessible database. This was also published in the Indian Journal of Medical Research³. Importantly, the Drugs Controller General (India) has made trial registration in the CTRI mandatory with effect from 15th June 2009. The information to this effect was also notified by the World Health Organization⁴.

Compensation in case of injury or death during clinical trial

The Drugs and Cosmetics Rules have been amended vide GSR 53(E) dated 30th January, 2013 wherein Rule 122DAB and a new Appendix-XII in Schedule ‘Y’ has been inserted in the Act. The amendment specifies the procedure for processing of reports of Serious Adverse Events (SAEs) including deaths occurring during clinical trial to arrive at the cause of death/injury to the subject, and to determine the quantum of compensation, if any, to be paid by the Sponsor in a time bound manner. As per the provisions of the said amendment, an Independent Expert Committee shall examine the report of serious adverse event of death and give its recommendation to the DCGI within thirty days of receiving the report from the concerned Ethics Committee. The DCGI shall, then decide the Quantum of Compensation to be paid by the Sponsor or his representative and shall pass order as deemed necessary within three months of receiving the report on the Serious Adverse Event of death. The DCGI constituted an Expert Committee on 14th March, 2013 to examine the Serious Adverse Events of deaths occurring during clinical trials, and to determine the quantum of compensation, if any, to be paid by the Sponsor or his representative. The Committee after detailed deliberations prepared a formula taking into consideration the major factors like age, risk involved and a base amount to be followed for the determination of Quantum of Compensation in case of Clinical Trial related death. As per this formula

$$\text{‘Compensation} = \text{BX F x R} / 99.37\text{’}$$

Where, B = Base amount (i.e. 8 lakhs);

F = Factor depending on the age of the subject; and

R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:

1. 0.50 terminally ill patient (expected survival not more than (NMT) 6 months)
2. 1.0 Patient with high risk (expected survival between 6 to 24 months)
3. 2.0 Patient with moderate risk
4. 3.0 Patient with mild risk
5. 4.0 Healthy Volunteers or subject of no risk

Thus, it will be seen that the compensation amount will vary from a minimum of Rs. 4 lakhs to a maximum of Rs.73.60 lakhs depending on the age of the deceased and the risk factor. However, in case of patients whose expected mortality is 90 % or more within 30 days, a fixed amount of Rs. 2 lac should be given⁵.

Table 1: Calculation of Compensation for death during clinical trials

S. No.	Age	F (factor)	Compensation amount (in Rupees lakhs)				
			R = 4	R = 3	R = 2	R = 1	R = 0.5
			Healthy volunteers	Pt with mild risk	Pt with moderate risk	Pt with high risk (survival 6-24 months)	Terminally ill pt (survival NMT 6 months)
1	20	224.00	72.13	54.10	36.06	18.03	9.01
2	25	216.91	69.85	52.38	34.92	17.46	8.73
3	30	207.98	66.97	50.23	33.48	16.74	8.37
4	35	197.06	63.45	47.59	31.72	15.85	7.93
5	40	184.17	59.30	44.48	29.65	14.82	7.41
6	45	169.44	54.55	40.92	27.28	13.64	6.82
7	50	153.09	49.29	36.97	24.64	12.32	6.16
8	55	135.56	43.65	32.74	21.82	10.91	5.45
9	60	117.41	37.80	28.35	18.90	9.45	4.72
10	65	99.37	32.00	24.00	18.00	8.00	4.00

Ever since this development has been made public, the stakeholders have been expressing their doubts and apprehensions regarding the provisions for compensation to the trial participants. The provisions like compensation to be provided in case of failure of an investigational product to provide intended therapeutic effect (lack of efficacy); administration of placebo providing no therapeutic benefits or adverse effects due to concomitant medications; the clause which states that free medical treatment is to be provided in case of “any injury occurring to the clinical trial subject” and financial compensation over and above any expenses incurred on medical management of the subject for “injury that is related to the clinical trial” need a relook into as such provisions on one hand may lead to an inducement for participation in the trial and on the other hand may serve as a deterrent to academia as well as investigator initiated trials thereby making the job of conducting the clinical trials a privilege of the multinational companies only.

Permission to conduct a clinical trial

The Gazette Notification GSR 63(E) dated 1st February, 2013 inserts Rule 122 DAC in part X-A of the Drugs and Cosmetics Rules, 1945 which makes it mandatory to take prior permission from the licensing authority to start a clinical trial and states that a clinical trial shall be conducted in compliance with the approved protocol, requirements of the Schedule ‘Y’, Indian GCP and other applicable regulations. Also, approval of the Ethics Committee shall be obtained before the initiation of the study and the clinical trial shall be registered with the CTRI, annual status of the trial will be submitted to the DCGI, and any report of SAE shall be forwarded within 10 days in prescribed format of Appendix-XI to the DCGI office. Although, there is no denying the fact that the said provisions are aimed at ensuring the compliance of the clinical trials with the existing regulations yet strict adherence to the timelines warrants for a provision of exclusively dedicated permanent staff at the trial site as well as in the Ethics Committees. Flexibility in registering the trial with CTRI ‘retrospectively’ may also be allowed to continue⁶.

Registration of Ethics Committee

The Gazette Notification GSR 72(E) dated 8th February, 2013 inserts Rule 122 DD in the Drugs and Cosmetics Rules, 1945 which makes the Registration of an Ethics

Committee mandatory. Once accorded, such registration shall be valid for three years unless it is suspended or cancelled. The said provision states that no Ethics Committee shall review and accord its approval to a clinical trial protocol without prior registration with the Licensing Authority as defined in clause (b) of rule 21. The notification defines an Ethics Committee as a committee comprising of medical, non-medical, scientific and non-scientific members whose responsibility is to ensure the protection of the rights, safety and well being of the human subjects involved in a clinical trial and it shall be responsible for reviewing and approving the protocol, the suitability of the investigators, facilities, methods and adequacy of information to be used for obtaining and documenting informed consent of the study subjects and adequacy of the confidentiality safeguards. This is indeed a welcome move as it will make the Ethics Committees who are responsible for the safety as well as well being of the trial participants and custodians of all confidentiality pertaining to a clinical trial more organized, responsible, transparent and accountable⁷.

Audio-visual recording of the Informed Consent process

The Draft Gazette Notification GSR 364(E) dated 7th June, 2013 proposed in the Drugs and Cosmetics Rules, 1945 relates to the process of ‘Informed Consent’ and makes mandatory an audio-video recording of the informed consent process of the individual subjects. It also states that the investigator shall maintain a record of the procedure of providing information to the trial subjects and their understanding on such consent. The notification also proposes to include in the Appendix-V under heading 1-subheading 1.1 relating to ‘Essential Elements’ two additional points viz: (14) Statement that there is possibility of failure of investigational product to provide intended therapeutic effect and (15) Statement that in case of placebo controlled trial, the placebo administered to the subjects shall not have therapeutic effect. This notification is indeed an attempt in ensuring the inherent sanctity of the phrase ‘informed’ in the Prior Informed Consent. However, this needs to be clarified that how the investigator is supposed to ensure that the prospective trial participant (who is most of the times an ill and depressed soul) has understood the pros and cons of participating in the trial. Such an arrangement would require additional paraphernalia at the trial site and there

would always be a consternation regarding usage of such videos to reveal the identity of the participants. Moreover, going by the Indian scenario, video recording may not be acceptable to some participants owing to their disease like HIV / AIDS, etc., religious beliefs and societal constraints. We ponder if we are heading to a scenario where consent from the prospective participant would be required to video graph the consent process?⁸

The Drugs and Cosmetics (Amendment) Bill, 2013 (Bill No. LVIII of 2013)

The Drugs and Cosmetics (Amendment) Bill, 2013 introduced by the government in the Rajya Sabha on August 29, 2013, is a comprehensive legislation to cover various aspects of drugs and cosmetics including regulation of clinical trials and medical equipment sector, having separate chapters on clinical trials and medical devices. The bill, which seeks to replace the Drugs and Cosmetics Act, 1940, was introduced in the Rajya Sabha by the honourable Union Health Minister Sh. Ghulam Nabi Azad. The new bill seeks to establish the Central Drugs Authority (CDA), a 19-member overarching body to regulate the drugs and cosmetics sector, which will be headed by the secretary, health and family welfare. The new bill, excludes all provisions relating to AYUSH drugs for which a separate bill will be brought in Parliament.⁹

Proposed Comprehensive Law for Regulating Clinical Research

'The Hindu', September 19, 2013 reported that the government proposes to regulate all biomedical and health research activities by bringing them under a law to ensure ethical research in all institutions with proper care, and a compensation policy for human participants. It is estimated that more than 1500 research institutions are engaged in biomedical and health research in India and more than 1000 ethics committees are reviewing research protocols involving human participants. Seeking to set up a Biomedical Research Authority, the proposed law will ensure compulsory registration and evaluation of ethics committees set up in all kinds of research institutions and will have penal provisions for unauthorized research and unethical practices. It will also cover institutions and sponsors undertaking unethical biomedical research at places with inadequate facilities. There is also a provision for establishing a 'Research Related Injury Relief Fund' from which compensation will be paid. The Bill will confer statutory powers on the ICMR Ethical Guidelines for Biomedical Research involving Human Participants, 2006. The Health Ministry has drafted a Cabinet Note and circulated it to various ministries for their views on the Bill. Once vetted by the Law Ministry, it is likely to be introduced in the winter session of the Parliament. Recently, it was in the news that probably as a consequence of the amendments in the Drugs and Cosmetics Rules as enumerated above especially the one that ensures that all the persons who are harmed by participation in the clinical trials shall have to be compensated, some American and Canadian research institutes have stopped their trials in several centers across India. The US National Institutes of Health reportedly suspended 40 uncompleted clinical trials in India in July,

2013. According to a report published by the Central Drugs Standard Control Organization, 262 clinical trials were approved by the Drug Controller General of India and registered in the Clinical Trials Registry of India in 2012. India has 16 % of the world's population and 20 % of the global disease burden but less than 2 % of the global trials take place in the country¹⁰. With a view to Formulate Policy and Guidelines for Approval of New Drugs, Clinical Trials and Banning of Drugs, the Government of India constituted a committee under the Chairmanship of Professor Ranjit Roy Chaudhury (National Professor of Pharmacology; Adviser - Department of Health and Family Welfare Govt. of NCT of Delhi, India and Former Member, Board of Governors Medical Council of India) in July 2013. The committee has made some thought provoking, bold and visionary recommendations which if implemented in letter and spirit may help in augmenting the credibility of the clinical research in addition to ensuring the welfare of the trial participants. Some of the Salient recommendations¹¹ are:

1. Clinical trials can only be carried out at centers which have been accredited for such purpose. The principal investigator of the trial should be an accredited clinical investigator. The ethics committee of the institute must also have been accredited. Only those trials conducted at centers meeting these stipulations will be accepted by the Drugs Controller General of India (DCGI).
2. A Central Accreditation Council should be set up to oversee the accreditation of institutes, clinical investigators and institute ethics committees.
3. Selection of assessors for accreditation and of experts to review new drug applications and other purposes will be made by a blind randomized procedure from a Roster of Experts. This Roster will be prepared after a nationwide search of appropriate experts and approval by the Technical Review Committee. The selection will have built-in safeguards for gender sensitivity and geographical representation.
4. A roster will be maintained of accredited institutes and medical centers approved for carrying out clinical trials. Pharmaceutical houses will be permitted to identify centers from this roster where they wish a particular clinical trial to be carried out.
5. The 12 drug advisory committees which are functioning at present will be replaced by one broad expertise-based Technical Review Committee to ensure speedy clearance of applications without compromising on quality of data and rules and regulations. The Committee would be assisted as required by appropriate subject experts selected from the Roster of Experts.
6. An informed consent from each participant is a mandatory prerequisite for a clinical trial. In circumstances where informed consent has to be obtained from special groups of people who have diminished capacity to protect their interests or give consent for them, the consent given by the guardian should be witnessed by an independent person who also has to sign the informed consent document. Audiovisual recording of the informed consent

- process should be undertaken and the documentation preserved, adhering to the principles of confidentiality.
7. If any adverse effect (AE) or serious adverse effect (SAE) occurs during a clinical trial, the sponsor / investigator will be responsible for providing medical treatment and care to the patient at his/their cost till the resolution of the AE/SAE. This is to be given irrespective of whether the patient is in the control group, placebo group, standard drug treatment group or the test drug administered group.
 8. Compensation need not be paid for injury or death due to totally proven unrelated causes. In all other cases of death or injury/disability, compensation should be paid to the participant or his legal heirs.
 9. Compensation will be paid to the trial participant if any drug-related anomaly is discerned at a later stage and accepted to be drug related by a competent authority whether in India or abroad.
 10. Any SAE arising in the group receiving the placebo in place of the standard treatment should also be compensable if the SAE is related to the use of placebo.
 11. There must be strong provision for ancillary care to cater for patients suffering from any other illness during the trial.
 12. No compensation needs to be paid for therapeutic inefficiency, since the very purpose of a clinical trial is to determine the efficacy and safety of a given drug/vaccine/device.
 13. Academic research may be approved by the institute ethics committee (IEC). However, if a new drug is being evaluated or a new use for an existing drug is being evaluated, then approval of the DCGI is needed.
 14. The Government of India, state governments and institutions should create a fund in order to encourage academic and clinical research (non-pharmaceutical company related) in institutions. The fund may be raised by imposing a cess if needed. This fund will be available to the institution for paying compensation.
 15. In cases of clinical trials being carried out on patients suffering from terminal illnesses such as cancer, compensation may be payable if the IEC, after deliberation, is of the considered opinion that:
 - there is an increase in the number of SAEs occurring in such a patient as compared to a standard treatment, and which may be irreversible; or
 - Life expectancy has been severely curtailed.For such patients, compensation may not be given if the primary end-point is death, as per the clinical trial protocol.
 16. The IEC, assisted if necessary by experts, will determine if the drug under trial is the cause of injury or death. The opinion of the investigator and the sponsor will be reviewed by the IEC. The IEC will forward its recommendation to the DCGI, who will ordinarily accept the recommendations of the IEC on the causality.
 17. Phases I to IV clinical trials of all new entities developed in India to be marketed in India will need to be carried out in India.
 18. All NCEs/NMEs undergoing clinical trials anywhere can also undergo parallel Phase II and Phase III trials in India after carrying out a safety assessment through Phase I trials.
 19. Drugs which have already been on the market in well-regulated countries with good post-marketing surveillance (PMS) for more than four years and which have a satisfactory report may be granted marketing license, subject to strict PMS for four to six years. The period of four years may be reduced or waived off in cases where no therapy or only palliative therapy is available, or in national healthcare emergencies.
 - First-time generics manufactured in India will undergo bridging Phase III trials and bioequivalence (BE) studies in humans.
 - BE studies in humans should be undertaken in subsequent generics along with strict PMS.
 - Similar biologics (bio-similars) will undergo both pre-clinical development and bridging Phase III clinical trials as per Department of Biotechnology (DBT) - Central Drugs Standard Control Organization (CDS CO) guidelines.
 20. In cases where new chemical entities (NCEs)/ new biological entities (NBEs) or new drug substances or their generic drugs or similar biologics are to be introduced in India, bioavailability / bioequivalence (BA/BE) studies in patients should be done preferably as a part of the clinical trial.
 - BA and BE studies of new drug substances discovered abroad and not marketed in India should not be approved to be conducted in India.
 - BA and BE studies once conducted with a generic should not be repeated for export purposes only.
 21. The CDSCO will provide a written assurance to the pharmaceutical house or investigator seeking approval for a clinical trial that if all the papers needed for the review are complete, then a decision, either interim or full, will be given within three months.
 22. At any point of time, the representative of the pharmaceutical house or investigator shall have the right of dialogue with an officer of the CDSCO regarding the application on payment of a fee for such consideration.
 23. Information technology will be used at all steps of a clinical trial to ensure total transparency in the system. From the first step when the application is placed at the single window, till the final approval is received, every step will be recorded and made available in the public domain.
 24. Three types of activities should be initiated at the state level to help in monitoring clinical trials carried out in state institutions. These are:
 - Joint monitoring of clinical trials with personnel from CDSCO
 - Coordination and information sharing
 - Training of state drug regulatory personnel.
 25. A Special Expert Committee should be set up independent of the Drug Technical Advisory Board to review all drug formulations in the market and identify drugs which are potentially hazardous and/or of doubtful therapeutic efficacy.
 - A mechanism should be put in place to remove these drugs from the market by the CDSCO at the earliest.

26. The CDSCO needs to be reorganized, upgraded and strengthened if it is to perform the various functions envisaged above.

Vide a recent direction by the honorable Supreme Court of India on 30th September, 2013, the clinical trials should not be allowed for new drugs till a mechanism is put in place to monitor them and to protect the lives of the people on which the drugs are tested. The apex court has ordered for a review of one hundred and fifty seven clinical trials by the Technical committee and the Apex committees before these are resumed. This verdict is a strong message for all the stake holders in the clinical trials industry and a wakeup call for the regulatory authorities to devise more robust and patient friendly transparent mechanisms and provisions in the regulations so that the safety of the trial participants is ensured to the maximum possible extent.

Proposed Road Map for AYUSH

In view of rapidly transforming regulatory scenario of clinical research in the country, it is a need of the hour to consider the implementation of the following measures by the Department of AYUSH at the earliest:

- Setting up of an AYUSH Clinical Trials Accreditation Council (ACTAC) comprising of suitable experts that will look into the:-
 - accreditation of the clinical trials investigators
 - accreditation of the clinical trials sites
 - accreditation of the Institutional Ethics Committees
 - accreditation of the Contract Research Organizations
- Inclusion of a new schedule on the lines of Schedule 'Y' in the existing Drugs and Cosmetics Act to regulate the clinical trials in the AYUSH sector till the time an entirely separate AYUSH Drugs and Cosmetics Act is not made available.
- Creation of an entirely new AYUSH Drugs and Cosmetics Act in consultation with the Researchers, Clinicians, Academia, Ethicists, Regulators as well as Industry representatives and other stake holders wherein, the AYUSH specific regulatory provisions are drafted keeping in view the history of safe use of Ayurvedic and other traditional drugs of hundreds of years.
- Provision for considering the grant of regulatory approval to the clinical trials based on the 'Reverse Pharmacology' approach.
- Provision for a Regulator in the CDSCO who is exclusively responsible for the matters related to the clinical trials in the AYUSH systems.

- Provision for a separate registry 'AYUSH Trials Registry, India' (AYUSHTRI) for the registration of all the pre-clinical as well as clinical trials related to the AYUSH systems.
- A separate team of experts to scrutinize the clinical trial protocols of the proposed clinical trials in the AYUSH systems. All Academic research with classical AYUSH drugs / interventions may be approved by the IECs but all other non-classical trial interventions need to be approved / prior permission taken from this team of experts.

CONCLUSION

In the light of the recommendations proposed vide The Drugs and Cosmetics (Amendment) Bill, 2013 (Bill No. LVIII of 2013) tabled in the Rajya Sabha on August 29, 2013 wherein it is stated that none of the provisions mentioned in the Chapter 1 B (Clinical trials) of the Drugs and Cosmetics Act pertain to the Ayurvedic, Homeopathic, Siddha or Unani systems of medicine, it is an ardent need of the hour to formulate an AYUSH specific Drugs and Cosmetics Act to regulate and facilitate the research in a more organized manner in the AYUSH systems of medicine.

REFERENCES

1. Parliament of India, Rajya Sabha, Department-Related Parliamentary Standing Committee, 72nd report on alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) Vaccine by PATH in India (Department of Health Research, Ministry of Health and Family Welfare) presented to the Rajya Sabha on 30th August, 2013 and Laid on the Table of the Lok Sabha on 30th August, 2013.
2. Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors' N Engl J Med 2004; 351: 12 www.nejm.org september16.
3. Statement on Publishing Clinical Trials in Indian Biomedical Journals Indian J Med Res 2008; 127: 104-105.
4. WHO Registry Platform e-Note Issue 3; 2009.
5. Gazette Notification GSR 53(E) dated 30th January; 2013.
6. Gazette Notification GSR 63(E) dated 1st February; 2013.
7. Gazette Notification GSR 72(E) dated 8th February; 2013.
8. Gazette Notification GSR 364(E) dated 7th June; 2013.
9. The Drugs and Cosmetics (Amendment) Bill; 2013 (Bill No. LVIII of 2013).
10. India's amended trials regulations spark research exodus" Shubhalakshmi shukla Lancet 2013; 382.
11. Report of the Professor Ranjit Roy Chaudhury Expert Committee to Formulate Policy and Guidelines for Approval of New Drugs, Clinical Trials and Banning of Drugs; 2013.

Cite this article as:

Pradeep Dua, Pamila Dua. Recent changes in the clinical trials regulatory framework in India; The road ahead for AYUSH sector.. Int. J. Res. Ayurveda Pharm. 2013;4(6):841-846 <http://dx.doi.org/10.7897/2277-4343.04612>

Source of support: Nil, Conflict of interest: None Declared

Disclaimer: The views expressed in the document are purely independent views of the authors and need not be considered as views of the organizations to which the authors are affiliated.

No responsibility is assumed by IJRAP, its staff or members of the editorial board for any injury and/or damage to persons or property as a matter of products liability, negligence or otherwise, or from any use or operation of any methods, products instruction, advertisements or ideas contained in a publication by IJRAP.