Review Article

Ravindra B. Ghooi

Scientia Clinical Services, Pune, Maharashtra, India

Address for correspondence:
Dr. Ravindra B. Ghooi,
G 801, RohanNilay (I), Aundh,
Pune - 411 007,
Maharashtra, India.
E-mail: ravindra.ghooi@gmail.com

Expert committee to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs-comments

Abstract

All is not well with the clinical research industry. Instances of scientific misconduct by investigators, cutting corners by sponsors, irregularities by regulators, have brought a bad name to the industry. These however form a small part of the clinical research done in this country. The US FDA has conducted over 40 audits, and not made any major observations, suggesting that the clinical research in India is by and large above board. Regulators have amended trial rules recently which have cost the industry dear. A committee appointed to formulate the policy and guidelines for approval of new drugs, clinical trials and banning of the drugs has made 25 recommendations of which most are either superfluous or not likely produce the desired effect. Clubbing banning of the drugs with approval of new drugs and clinical trials also does not make sense, since the mechanisms involved are totally different. Barring a few, most recommendations are counterproductive and should be rejected outright. It is time we learnt that appointment of a committee is not the best way to solve a problem.

Key words: Clinical research, drug development, guidelines, policies, regulations

INTRODUCTION

The three amendments of 2013 to the drugs and cosmetics rules[1-3] and the draft rule on videography,[4] have delivered a body blow to the clinical research (CR) industry. It was felt that with these behind us, the industry would grow and regain its growth rate of yesteryears. However, any sigh of relief proved to be premature. The industry now has to contend with the recommendations of the Prof. Ranjit Roy Chaudhury committee to formulate policy and guidelines for the approval of new drugs, clinical trials and banning of the drugs.[5]

A few unprincipled investigators and sponsors have conducted unethical trials in gross violation of all guidelines and rules.[6] These however represent a minority, in an industry, that has been responsible for improving the quality and quantity of human life. The print and television media focussing on the unethical few, has painted the entire industry with the same brush. Peoples' representatives and the courts were quick to brand clinical research as a rogue industry, and are bringing new drug trials to a screeching halt.

To a large extent stake holders in CR are also to blame for this state of affairs. When the media accused the industry of using people as 'guinea pigs', there was no rebuttal from the industry. Numerous allegations made against the investigators, sponsors and EC members went unanswered, which emboldened the media to sharpen their attack. Allegations of unethical research, repeated and unchallenged, were believed by the people at large. By then the reputation of the industry has reached such a low, that people would believe any allegation against it.

Stake holders in CR have been reticent, and avoided the spot light. Over years they have failed to project their work and even to defend themselves against the false allegations.

Access this article online

Quick Response Code:

Website: www.picronline.org

DOI: 10.4103/2229-3485.134304

The corporate world, otherwise a publicity seeking entity, avoided any discussion with the media on this issue. They were probably not convinced of the good that CR was achieving.

Clinical research was pilloried on the TV, in the parliament and in the courts. The defence of the CR industry put up by the regulators was inadequate. Unlike the US, where the regulators and pharmaceutical industry are partners in the drug development, the regulators in India never considered themselves as partners of the industry. This alienation came out strongly when both the industry and the regulators were put in the line of fire.

The neglect of CR is not a new phenomenon. After an early impressive growth, the slump began and since the last two years it has shown negative growth.[7] India's record in the new drug development has been very poor, the little contribution the country made, was in CR. With the strengthening of the anti CR sentiment, even this contribution dwindled. The policy makers fail to realize that under the TRIPS our scientists will not be able to resort to reverse engineering, and our people will become dependent on developing countries for new drugs, at prices that they dictate. In fact the country failed to realize the importance of CR.

With the statistics as shown below [Table 1], it is strange that allegations are made that developed countries are dumping trials on India. What is further strange is that this is widely believed too. In clinical research the subject's interest is above all, but the lay press labels clinical trial participants as guinea pigs, and all readers accept without question.[10,11]

To advice the government a committee was appointed under the chairmanship of Dr. Ranjit Roy Chaudhury, an eminent medical scientist. The mandate of this committee was to develop the policy and guidelines for approval of new drugs, clinical trials and banning of drugs. The recommendations of the committee are now available and are under consideration by the central drugs standards and control organization (CDSCO). These have not yet been accepted by the government and the regulators, it is necessary that the industry voices its opinions on these. The industry must stand united to oppose those recommendations that are harmful and support those which are in favor of the industry. We have examined these recommendations and place our views about them.

Table 1: Contribution of different regions to the new drug development (Clinical trials)

Country/ Region	Population (million)[8]	Clinical trials[9]	Trials per million
Canada	34.56	11,441	331.04
United States	316.6	71,785	226.73
Europe	509.4	41,732	81.92
Mid East	394.3	6,345	16.1
South America	387.2	5,218	13.47
China	1,349	13,779	10.21
India	1,220	2,689	2.20

The committee met large number of people, representing the civil society, clinical research industry, investigators and pharmaceutical manufacturers. Thus, consultations were held with people who had expertise in the clinical research, though the expertise of the committee in this field is doubtful. The committee members are all respected and acknowledged experts in their own fields, but have little expertise in new drug development or clinical research as it is done today. Ironically the expert committee had no real expert with hands on experience in any of of the three areas they studied.

One experiences a sense of déjà vu on seeing familiar names on government committees. We see a single person as a chairperson or member of numerous committees, probing or advising on a variety of issues, outside his/her core competence. There need to be some guidelines about the expertise qualifying a person for committee membership. There also needs to be limit to the number of committees a person can serve as a chairperson or member. Membership to committees is not manna to be distributed to friends and colleagues! Like gift authorship, a new system of gift membership is operating at the center.

One would have ignored the recommendations of this expert committee, but the risk is that the government may accept the recommendations. All those concerned with CR should voice their opinion, and not allow such recommendations to be incorporated in the rules by default.

Individual recommendations and comments

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).
   The first question that comes to the mind is why investigators and sites should be registered? As it is, a sponsor cannot choose any investigator or site. The power to allow a particular investigator and site to conduct the study rests with the regulator. If the regulator is not satisfied with the credentials of an investigator, approval for the trial can be refused, then how does the need to register the investigator or site arise?
   Rule 122 DD made registration of ethics committees essential before they could approve any new proposal.

About six months were lost as registration papers were examined and registration letters issued; yet it must be acknowledged that this work was done at an unbelievable speed. Anyone who has the experience of interacting with the regulators would agree that the alacrity demonstrated by CDSCO was unprecedented. Registration of sites and investigators will take an equal if not more time; this means that around 12 months are going to be lost as they are registered. During registration of ethics committees, India is reported to have lost 40 trials from NIH alone.[12] One wonders how many trials we will lose while the registration of investigators and sites is in progress.

2. A central accreditation council should be set up to oversee the accreditation of institutes, clinical investigators and institute ethics committees.

   Establishing a new committee (by any name) is not likely to solve the existing problems. The central council will be established no doubt with a preponderance of former ICMR and DCGI employees. The names that appear on many committees of the central government will reappear on this committee. There will again be very few members who have any hands-on experience in the drug development or ethics committees. Past experience suggests that such accreditation will not be merit based and hence it would not serve the intended purpose.

   Srinivasan and Jessani commenting on the 59th report of the Standing Committee of Health and Family Welfare wrote,

   "Second, many experts appointed on the CDSCO's advisory committees are from Delhi and surrounding areas, so much so that one expert from Delhi sat on 5 of the 6 committees".[13]

   Anyone familiar with the working of CDSCO would whole heartedly agree with this, yet few have the courage to say it aloud.

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.

   The country has a large amount of expertise lying unutilized because it is among the retired people.[14] A number of retired professors and scientists could be usefully employed in advisory activity, but one finds that very few among them are so employed. The very parameters for selection become grounds for defending the appointment of the privileged few. Serving and former employees of central institutes and influential organizations tend to dominate these committees. Sometimes they have the expertise, but they have little time to devote to this, and hence there are more delays. The snail paced regulatory process will suffer as more and more committees are involved in the process.

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.

   This restricts the freedom of sponsors to identify the talent in institutes not registered. Also, will the roster be really exhaustive and will the institutes on the roster have all possible expertise? If a new therapy is developed for an orphan disease, what will be done if none of the institutes on the roster have the required expertise? There is also a possibility of lobbying by institutes to be rostered, the most influential ones would benefit, while those who fall out of favor of the technical review committee could be de-rostered. It is common knowledge that a bunch of institutes and scientists corner a lion's share of research funds, while others starve for grants. This recommendation is an extension to the first recommendation and could prove to be the nemesis of CR in India.

5. The 12 drug advisory committees which are functioning at present will be replaced by one broad expertise-based technical review committee to ensure the speedy clearance of applications without compromising on quality of the data and rules and regulations. The committee would be assisted as required by appropriate subject experts selected from the roster of experts.

   This recommendation will not change the situation dramatically, as the technical review committee must have the expertise of the 12 disbanded committees. What is likely to happen is that an influential scientist will head the technical review committee, constituted by the members of the defunct committees. This recommendation will merely reorganize the committees and will not really speed up the review process.

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 themselves, 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.

   Anyone familiar with CR would recognize that this procedure is already in use. An independent

witness has been added when a legally authorized representative (LAR) is used. There is a distinct difference between an LAR and witness. An LAR, on one hand, is an individual who takes a decision to participate on behalf of the incompetent subject; on the other hand the witness merely affirms that the consent process was carried out in his/her presence. There seems little advantage in having another person witness an LAR's decision. In any case, it will not improve the situation, since witnesses can be easily manipulated. Audiovisual recording (as recommended here) has already been mooted by the regulators in a draft rule.[4] The author's view on the audio video recording has appeared elsewhere in this journal.[15]

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.
   In view of rule 122 DAB (5), this recommendation is superfluous. Many clinical research sites used to pay compensation even before the rule came into force, now compensation is paid all over. There still are issues with it, since the rule does not distinguish between SAE due to participant's carelessness and an SAE related to the trial. The committee should have addressed these issues rather than stating what is already the law.
8. (a) Compensation need not be paid for the 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.
   (b) 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.
   Recommendation 8a is covered under the rule 122 DAB. In fact section 5 of the rule clarified what a trial related injury is. The recommendation 8b is a logical sequel to the rule 122 DAB, but has been voiced now.
9. 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.
   This point has been covered in the rule 122 DAB (5) d, and in the knowledge of the author this is already being done. However as previously noted, placebo controlled trials, in which standard therapy is denied are not encouraged and hence such situations are few and far between. What should have been elaborated is, should compensation be paid when the injury or death is due to the failure of the standard drug to produce its intended effect, or adverse reactions of the standard?
10. There must be strong provision for ancillary care to cater for patients suffering from any other illness during the trial.
    This recommendation is superfluous since almost every guideline, from the Nuremberg code to the ICMR guidelines speaks of this in different words. The ICH GCP guidelines specifically states that the principal investigator is responsible for all medical decisions regarding the subject and elaborates that,
    During and following a subject's participation in a trial, the investigator/institution should ensure that adequate medical care is provided to a subject for any adverse events, including the clinically significant laboratory values, related to the trial. The investigator/institution should inform a subject when medical care is needed for intercurrentillness(es) of which the investigator becomes aware.
    (ICH E6 4.3.2)
11. 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.
    This recommendation is in line with the demand from the CR industry for over nine months now. However, it should be noted that the DTAB has made this recommendation in its meeting on 16th May 2013.[16] Thus this recommendation is but a reiteration of the industry's demand and DTAB recommendation, yet it is a welcome one.
12. Academic research may be approved by the institute ethics committee (lEC). 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.
    This recommendation reiterates the existing rules and procedures.
13. 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.
    The author may be pardoned for believing that this was the purpose of setting up the ICMR, DST, CSIR and DBT at the center and similar organizations in the state. The recommendation states the obvious.
14. In cases of clinical trials being carried out on patients suffering from terminal illnesses such as cancer, compensation may be payable if the lEC, 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.

This recommendation sounds good, but is going to be difficult to implement. Incidence of SAEs differs from individual to individual, and it will be very difficult to opine whether incidence of SAEs is higher in the test drug or the standard drug group. More so when a large number of trials conducted today are double blinded. Double blinding is the gold standard for clinical trials of drugs; hence it is going to be very difficult to judge which patients are receiving the investigational product and which are receiving the standard product.

The author had raised the issue of SAEs and deaths in trials of palliative drugs.[17] That issue has not been clarified. While the committee considered the peculiarities of cancer trials, it has failed to examine all relevant aspects. In all honesty, it must be accepted that at times the death of a cancer patient, is a financial and mental relief to the family, compensating for such cases does not appear logical.

15. 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 lEC. The IEC will forward its recommendation to the DCGI, who will ordinarily accept the recommendations of the IEC on the causality.

    This recommendation is in line with the rule 122 DAB and current practice, but seems to ignore the existence of the expert committee. Presently the EC has the authority to recommend compensation and the amount, which is considered by the expert committee, who shall advise the regulator. The present recommendation seems to do away with the expert committee. This demonstrates a disconnect between the thinking of the regulator and that of the committee members. It is also an accepted fact that assigning the injury or death to a particular cause is not easy. Different organizations have different parameters for gauging the relatedness of an AE to the trial drug.[18]
16. 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.
17. 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.

    These recommendations could be clubbed into a single one. Whether developed in India or otherwise, all trials need to be done in India if the drug is to be launched in the Indian market.
18. (a) 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 licence, 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.

    This recommendation pushes the Indian new drug scene back to the 1990s, where a molecule marketed abroad and found safe would be allowed in the country without any clinical trials. It negates the second amendment (2005) to the drugs and cosmetics rules, which required collection of Indian data before a drug can be marketed in India.

    (b) First-time generics manufactured in India will undergo bridging Phase III trials and bioequivalence (BE) studies in humans.

    (c) BE studies in humans should be undertaken in subsequent generics along with strict PMS.

    (d) Similar biologics (biosimilars) will undergo both pre-clinical development and bridging Phase III clinical trials as per department of biotechnology (DBT)- central drugs standard control organization (CDSCO) guidelines.
19. (a) 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 (BA)/BE studies in patients should be done preferably as a part of the clinical trial.

    (b) BA and BE studies of new drug substances discovered abroad and not marketed in India should not be approved to be conducted in India.

    (c) BA and BE studies once conducted with a generic should not be repeated for export purposes only.

    To be fair to the committee these are among the few recommendations that make sense. These may not have been mentioned in the rules, but this was the practice followed. Recommendation 19 (b) will hamper the export of formulations, that are not approved in the country. Recommendation 19 (c) calls for a comment; the industry does not perform expensive BA/BE studies out of their own interest, but usually because the studies are required by the overseas clients.
20. 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.

    Among the many factors identified for success in the clinical research, time bound regulatory clearance is an important one.[19] Time bound clearances have been the demand of the industry for at least the last eight years, so far the regulators have not accepted it. The industry will support this recommendation whole heartedly, but

will regulators accept it, or selectively reject it, is the question. Many countries have such a mechanism in place, and if this is accepted, it will do much to hasten the drug development process.

21. 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.
22. Information technology will be used at all steps of a clinical trial to ensure the 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.

    These are welcome recommendations, such dialogue and transparency marks the drug regulatory process in many countries and it is hoped that this will bring the regulator and the industry closer. Consultations are common in the US, at these meetings the sponsor may discuss the requirements of the FDA and often obtain an opinion on the drug development plans.[20] This mechanism was long needed in India. It is difficult to understand why the pharmaceutical house needs to pay a fee for this. Every application to the CDSCO is already accompanied by a hefty fee.
23. 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.

    The Drugs and Cosmetics Act of 1940, has clearly demarcated the powers and responsibilities of the center and the state, since public health is on the concurrent list. However, public health is not synonymous with the drug development or even control of drugs. Inconsistencies do exist in the government, thus drugs control is under the ministry of health and family welfare, while Narcotic control is under the Finance Ministry and Drug Pricing under the Ministry of Chemicals and Fertilizers. There is no real need to involve the state drug control in clinical trials. The relation between the states and the center is a tenuous one in India. State governments often do what they please without regards to the wishes of the central government (more so in states where the opposition is in power). Center state conflicts are common in every area, but the new drug activity has so far been spared. Involving the state drug authorities in this activity, long the center's preserve, will bring about a clash in the already chaotic field.

    There was a move to withdraw the powers of the state drug authorities, due to their over-stepping the powers. This move was successfully scuttled by the states, now to hand them power to monitor trials would be disastrous. The lack of expertise at the CDSCO office has been commented upon often, though the situation in the states has not been adequately studied, but it could hardly be better than at the center. Involving the state authorities in the new drug development will also be counter-productive, unless training of the state drug regulatory personnel has been satisfactorily conducted. Incidentally the committee also recommends training of state regulatory personnel.
24. (a) 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.

    (b) A mechanism should be put in place to remove these drugs from the market by the CDSCO at the earliest.

    The mandate of this committee was to formulate policy and guidelines for approval of new drugs and banning of drugs. Of the 25 recommendations made only this one refers to banning of drugs, and it suggests that the job of be delegated to a new committee. Without going into the demerits of the DTAB, a new committee is recommended, giving yet one more opportunity for influential serving and former employees to draw an honorarium.

    The role of the DTAB is to "advise the central government and the state governments on technical matters arising out of the administration of this (Drugs and Cosmetics) act and to carry out the other functions assigned to it by this act." It is the role of DTAB to advice the government on issues such as rationality of drugs in the market. By appointing another committee, there will be a duplication of efforts and possibly a clash between the two committees.

    Presently the DTAB consists of the following:

    - The Director General of Health Services, (DGHS) *ex officio*, Chairman
    - The Drugs Controller, India, (DCGI) *ex officio*
    - The Director of the Central Drugs Laboratory, Calcutta, (CDL) *ex officio*
    - The Director of the Central Research Institute, Kasauli, (CRI) *ex officio*
    - The Director of Indian Veterinary Research Institute, Izatnagar, (IVRI) *ex officio*
    - The President of Medical Council of India (MCI), *ex officio*
    - The President of the Pharmacy Council of India (PCI), *ex officio*
    - The Director of Central Drug Research Institute, Lucknow (CDRI) *ex officio*

- Two persons from state drug control
- A pharmacy teacher recommended by PCI
- One person recommended by MCI
- One person from the pharmaceutical industry recommended by central government.
- One pharmacologist recommended by ICMR
- One person recommended by Indian Medical Association
- One person recommended by the Indian Pharmaceutical Association
- Two government analysts.

The top rung members of DTAB are concerned with formulating rules and guidelines, expecting them to advice about the validity of those very rules and guidelines is strange. Ethically this would amount to a conflict of interest. Another issue is the expertise, the above officials are experienced administrators, but do these officials have the expertise in identifying the harmful drug formulations or formulating policies concerning CR?

At the 61st meeting of DTAB held on 24th July 2012 twelve of the 18 members were present. At the 62nd meeting held on 30th January 2013 ten members were present, at the 63rd meeting on 16th May 2013 seven members were present. At the 64th meeting on 19th July 2013, nine members were present. It does appear that the members do not take DTAB meetings very seriously. Decisions taken at meeting where there is no representative from affected parties is bound to be resented by them.

It is necessary to reconstitute the DTAB by including the experts in drug development and clinical research from the pharmaceutical and CR industries. Members on this board should possess appropriate qualifications, training and experience in the field that is under discussion. In fact there should be no permanent members, depending on the subject to be discussed, experts should be invited by the board chairman.

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

The industry will stand and applaud this recommendation as one man. The pharmaceutical industry, investigators, sponsors, ethics committee members in fact all stake holders agree that the CDSCO needs a total over haul.[5] But then reorganization, upgradation and strengthening are required not only for the CDSCO, but for state drug control departments, and a host of other government organizations. The report of the Roy Chaudhury committee in its preface states.

"What was remarkable was that even though there were markedly different perceptions about specific issues, there was total unanimity that a robust regulatory system was the need of the hour and that this would be welcomed by all."

The committee has expressed the satisfaction that the CDSCO has changed its mission statement from 'to meet the aspiration. demands and requirements of the pharmaceutical industry' to

'To protect and promote public health in India'. Changes in mission or vision statement without implementation are futile. The mission of the pharmaceutical and CR industry is to provide better drugs to the people, if CDSCO's mission is in line with that of the industry, indirectly it supports the health of the people.

One of the first things that needs to be changed at the CDSCO is the method of appointment of the DCGI. It has been seen that at least in the last 30 years a senior government employee is appointed as the DCGI, without any consideration of his suitability. There are more efficient people with adequate expertise outside the government, who should be considered. The drugs controller does not manage government employees, but a large and complex pharmaceutical industry; hence experience of the industry would be more desirable than government experience. Also the DCGI works with the DGHS and the health secretary, both of whom are senior government officials, thus the government remains in the loop.

In terms of turnover, the Indian pharmaceutical industry is not very large, but it is highly fragmented. India has the largest number of formulations of any drug in the market. To control this effectively CDSCO requires a large staff, but it is understaffed. By trying to save on employee salary, the government is losing millions through inefficiency. One wonders how the government can allow posts to lie vacant in important departments like health, defence and finance, while wasting funds elsewhere.

Though much smaller than the US industry, the Indian drug industry is highly fragmented. The current staffing of CDSCO includes of 6 deputy drugs controllers (DCs) and 18 assistant drugs controllers (ADCs), assisted by 75 drug inspectors and 55 technical data associates on contractual basis. The US FDA has a total technical staff of 13,496,[21] and the MHRA has a staff of 900.[22] It is doubtful whether the regulatory office will ever achieve the efficiency of its western counterparts, given its low strength and budget.

CONCLUSION

As has been pointed out, the woes of the industry are due to failures at many levels. They begin with poor regulatory

control, and are aided by misconduct on the part of investigators and sponsors. Irrational regulations made by the authorities contribute significantly towards damage to the drug development industry. Rejecting clinical research because of a few lapses on the part of some individuals is literally throwing the baby out with the bath water.

India's only contribution to the world's struggle against the disease was in the area of clinical trials, curbing this activity will hurt the future of medicine in this country. A sentence from the ISCR media statement is worth repeating.

India has 16% of the world's population and 20% of the global disease burden and yet, less than 2% of global trials take place in India. If we have to find better and more cost effective cures for these diseases in a population that is multi-racial and heterogeneous, it is necessary to conduct clinical research in India.[23]

Appointing new committees does not solve problems; rather it creates more of them. Whenever a committee is set up to solve some problem, it recommends the setting up of more committees. The situation on the ground does not change. Then a new committee is set up to find out what went wrong with the last committee and the game goes on. Let us put an end to it.

REFERENCES

1. CDSCO GSR (53E) Available from: http://www.cdsco.nic.in/GSR%2053(E)%20dated%2030.01.2013.pdf[Last accessed on 2013 Oct 08].
2. CDSCO GSR (63E) Available from: http://www.cdsco.nic.in/GSR%2063(E)%20dated01%20.02.2013.pdf[Last accessed on 2013 Oct 08].
3. CDSCO GSR (72E) Available from: http://www.cdsco.nic.in/html/G.S.R%2072(E)%20dated%2008.02.2013.pdf [Last accessed on 2013 Oct 08].
4. CDSCO GSR 364 (E). Available from: http://www.cdsco.nic.in/GSR%20364Ejune13.pdf [Last accessed on 2013 Oct 08]. Available from: http://www.cdsco.nic.in/Report_of_Dr_Ranjit_Roy.pdf [Last accessed on 2013 Oct 10].
5. Report of the Prof. Ranjit Roy Chaudhury Expert Committee to Formulate Policy and Guidelines for Approval of New Drugs, Clinical Trials and Banning of Drugs.
6. Gupta A. Fraud and misconduct in clinical research: A concern. Perspect Clin Res 2013;4:144-7.
7. Shah A. Clinical research in India comes of age. Future Medicine 2013; Available from: http://www.futuremedicineonline.com/detail_news.php?id=76 [Last accessed on 2013 Oct 08].
8. The World Factbook. Available from: https://www.cia.gov/library/publications/the-world-factbook/rankorder/2119rank.html. [Last accessed on 2013 Oct 08].
9. Studies on map. Available from: http://clinicaltrials.gov/ct2/search/map [Last accessed on 2013 Oct 08].
10. SC wants check on clinical trials; PIL claims 'Indians used as guinea pigs'. Available from: http://www.hindustantimes.com/India-news/NewDelhi/SC-wants-check-on-clinical-trials-PIL-claims-Indians-used-as-guinea-pigs/Article1-1099154.aspx [Last accessed on 2013 Oct 08].
11. Human guinea pigs of India. Available from: http://www.thedailystar.net/beta2/news/human-guinea-pigs-of-india/[Last accessed on 2013 Oct 08].
12. US FDA NIH Halts Clinical Trials in India, Cites Uncertainty Over Compensation Rules. FDAnews Drug Daily Bulletin 2013; 10. Available from: http://fdanews.com/newsletter/article?articleId=157847andissueId=17061 [Last accessed on 2013 Oct 08].
13. Srinivasan S, Jesani A. Standing committee report on CDSCO: Hard facts confirm an open secret. Indian J Med Ethics 2012;9:148-50.
14. Raikwar M, Khan AM. A comparative study of engagement of retired men and women. HelpAge India Res Development J 2012;18: 19-31.
15. Ghooi RB. Ensuring that informed consent is really an informed consent: Role of videography. Perspect Clin Res [In Press].
16. Minutes of the 63rd DTAB Meeting held on 16.5.2013. Available from: http://www.cdsco.nic.in/Minutes_63rd_dtab%20.pdf [Last accessed on 2013 May 16].
17. Ghooi RB. Injury and death in clinical trials and compensation: Rule 122 DAB. Perspect Clin Res 2013;4:199-203.
18. Goldfarb NM. Adverse event terminology. J Clin Res Best Pract 2012;8:1-17.
19. Joseph J. Entering the contract research industry in India. Contemp Clin Trials 2008;29:311-3.
20. Black LE, Bendele AM, Bendele RA, Zack PM, Hamilton M. Regulatory decision strategy for entry of a novel biologic therapeutic with a clinically unmonitorable toxicity into clinical trials: Pre-IND meetings and a case example. Toxicol Pathol 1999;27:22-6.
21. Food and Drug Administration Distribution of Full-Time Equivalent (FTE) Employment Program Level Available from: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM301553.pdf [Last accessed on 2013 Oct 07].
22. MHRA Available from: http://www.mhra.gov.uk/Aboutus/Workingforus/index.htm [Last accessed on 2013 Oct 07].
23. ISCR Press statement 4.10.2013(personal communication).

How to cite this article: Ghooi RB. Expert committee to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs-comments. Perspect Clin Res 2014;5:100-7.

Source of Support: Nil. **Conflict of Interest:** None declared.