ACRO BULLETIN

New Government should get its regulatory role restored

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Over the last three years medical research in India has been brought to standstill. Clinical trials are essential for affordable and accessible healthcare. In 2013, India approved 80 per cent less clinical trials than in 2010. Major problems to be resolved by the Health Minister and PMO are:

Supreme Court formulating clinical research regulation

A PIL in the Supreme Court by an NGO has alleged that patient safety is not adequately protected by DCGI. Ineffective response in the last two years by Ministry of Health (MOH) and its lawyer, led to the Supreme Court losing confidence in DCGI as a regulator. It directed MOH, to modify the regulation to protect the interests of just one stakeholder - the patient, whereas responsible medical research requires several stakeholders' interest to be balanced.

Not balancing the interests of other stakeholders like medical researchers, pharma companies and the Government (which wants to bring affordable vaccines, medicines to citizens), has made conduct of medical research very onerous, risky, leading to the research grinding to a halt.

SC, having lost confidence in DCGI, suggested that instead of DCGI, Health Secretary (HS) should be personally accountable for research. To honour SC, the previous government created committees like NDAC, Technical Committee, Apex Committee between DCGI and Health Secretary.

Committees have slowed down scientific/ medical decisions in new drug development, without adding value. This has resulted in very few inordinately delayed decisions, which has further devalued DCGI.

The new government should get its regulatory role restored. **Ministry of Health has to win back SC's lost trust in DCGI.** A competent government lawyer should argue the importance of restoration of the regulatory role to the Government and the necessity of balancing the interest of patients, doctors, government, pharma companies etc while laying down regulations. It can propose to the court that:

- Instead of HS becoming accountable for responsible clinical research, DCGI's position should be upgraded to the level of HS and DCGI will be made an independent regulator. This has been recommended by the past Parliamentary committees and is the norm in advanced countries.
- One sided regulatory changes implemented in last two years, which has made other stakeholders shy to take up medical research should be modified as per 'Stakeholder Recommendation Jan 2014'.

  This involved a two-day review of regulations by stakeholders which included medical researchers (AIIMS), global practitioners (Multi-Regional Clinical Trial Center of Harvard Medical School), MOH (Health Secretary, Dr Desiraju and team), pharma companies and patient advocacy group. Recommendations of this group will be adopted to make the modified regulation take care of multi stakeholders' interest.

- If argued forcefully and if a time-bound implementation of three months is offered, the SC is likely to restore the regulatory role back to MOH.

Approval process and timelines

The approval for clinical trial of new drugs takes six to nine months and approvals go through three committees. The recommendation is to decrease the decision cycle to six months including clearance from all the committees. Once DCGI's position is elevated to the HS's level, it will no longer be necessary to pass application through Technical and Apex Committees. For BA/BE studies this approval process should be decreased from 45 days to 30 days.

At DCGI there should be a one-window consultancy opportunity in line with Scientific Advise in EU and Pre IND meeting with US FDA. Pharma companies and CROs should have an opportunity to discuss the drug development strategy with competent authorities and make an application addressing the discussion points.

Compensation guidelines

For the compensation guidelines related to injuries in case of deaths and serious adverse events, the opinion of all the stakeholders needs to be looked into. A lot of ambiguity in compensation needs to be removed through guidelines based on clear rational thought.

Medical management

Currently there is lack of clarity on situations where medical management needs to be paid and sponsors are asked to pay for related or non-related serious adverse events. Additionally, too much liability is being put on sponsors. This practice is against the standard practice followed all over the world.

Limit on number of trials per investigator

The cap on maximum number of studies that an investigator can do should be removed. As per current regulations the number of trials an investigator can do is three.

This number should be decided by institutional Ethics Committees who are better aware of investigators' capability, site infrastructure and investigators' experience to support higher number of trials.

With a result-oriented PM, physician Health Minister and physician Minister of Science, we have confidence that the above changes will be brought about. This will stimulate medical research in the country and bring new drugs to the market faster!

- DA Prasanna, Chairman, ACRO India

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