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Tighter clinical trial regulation is need of the hour

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Recently, the Supreme Court managed to stir the $600 million (Rs 3,246 crore) Indian bioservices industry, when it asked for greater accountability from the Drug Controller General of India (DCGI) for the conduct of clinical trials. The general perception was that, this would serve as a blow to the the sector, which witnessed a growth of over 15 percent in 2011-12 as against the previous year's growth of 23 percent.

However, at a recent annual conference on clinical research organized by Indian Society for Clinical Research (ISCR), industry experts opined that the court order should not be taken as a setback, but rather as a measure to keep spurious practices at bay. Ms Suneela Thatte, executive director, Customer Operations, Quintiles says, "The court order does not disempower clinical research organizations (CROs) in India and should not make a major difference. It only asks for the previous directives to be followed. This includes furnishing details in different cases such as the one where the relevant states are being asked to submit all the data surrounding the clinical trials for the Supreme Court to study."

A copy of the Supreme Court order, in possession of BioSpectrum, explicitly asks the Central Drugs Standard Control Organization (CDSCO), India's main regulatory body for pharmaceuticals and medical devices or the Ministry of Health and Family Welfare (MoHFW) to submit the affidavit as requested earlier within four weeks. It has also directed the chief secretaries of all states other than Madhya Pradesh, Manipur, Dadra Nagar Haveli, Daman and Diu to file written responses on an affidavit. Finally the Supreme Court reiterated by saying that, clinical trials regarding any new drug should be carried out under the direct supervision of the secretary, MoHFW until further notice. Besides, referring to the 59th Parliamentary Committee Report, which had indicated a collusion between pharma companies and regulatory authorities, the apex court further pointed out that the government needed to wake up and address the situation.

Last year, several media reports surfaced claiming that clinical trials were being conducted without the patient's consent, resulting in deaths of the patients in states such as Madhya Pradesh, Andhra Pradesh, and other North East states of the country. Considering the severity of cases, Swasthya Adhikar Manch, a Madhya Pradesh-based NGO, filed a Public Interest

Litigation (PIL) with the Supreme Court. In response, the apex court asked the Madhya Pradesh government to constitute a committee to oversee the conduct of any clinical trials in the state and formulate guidelines to regulate the trials.

The Supreme Court then, on October 8, 2012, asked the Ministry of Health and Family Welfare to submit an affidavit with the details of clinical trials conducted along with the deaths and compensation associated with them. Due to the noncompliance of this specific order, the Supreme Court reprimanded the representative of the ministry for "slipping into a deep slumber" and not submitting the information.

However, the data regarding clinical trial sites, number of deaths associated, and compensation paid, traditionally lies with the central approving authority, the DCGI. Industry sources say that, asking the state governments to furnish these details, without outlining the procedure will only result in more delays, since many would be ill-equipped to handle such requests.

Sharing his views on the developments, Mr Ranjit Sahani, vice chairman and MD, Novartis India said, "There is no need for us to make a knee jerk reaction to the apex court order. It is time for us to take a step back and analyze the situation and assess what all the stakeholders in the clinical trials industry need to do in this situation. There is a need for clear communication about issues such as compensation to be discussed by the government."

Dr Krathish Bopanna, CEO, Semler Research Centre and also president ISCR seconds Ms Thatte by saying, "The order should not affect any legitimate CRO in India, as it only asks for the reinforcement of existing rules. It is directed towards outfits which are fly-by-night operators, who have been indulging in malpractices that are in the news."

In a similar instance, on January 8, 2013, the Supreme Court responded to a PIL filed against vaccine majors, Sanofi Pasteur MSD and GSK (GlaxoSmithKline) for allegedly conducting clinical trials on nearly 24,000 tribal girls in Andhra Pradesh and Gujarat, even before the vaccine was licensed by the DCGI. The Supreme Court has not only directed the Union Government to respond to the allegation, but also asked Christian Medical College, Vellore to analyze the medical reports of the girls who allegedly succumbed during the trials.

Delays abound

The Supreme Court orders and the subsequent debate over clinical trials in India have only dampened the operations in the CRO space in India through indirect repercussions felt by the industry in the form of delays. Since 2011, the 12 new drug advisory committees (NDAC) that were set up to review new drug applications in different areas of specialization such as neurology and cardiology, were supposed to respond with their comments within six weeks of receiving the applications. These comments were to have been discussed at joint meetings and approvals be granted subject to their responses. In reality, however, industry sources note that no NDAC meeting has been held in the last three months. Some are slated to start this month. However, the inordinate and more so indefinite delays will only make it difficult for small and mid-sized CROs to survive and operate in the coming years.

The bioservices sector has been on the decline since 2005-06, the year when the sector witnessed a growth of 69 percent. Of the current scenario, Dr Arun Bhatt, an industry veteran and president, ClinInvent Research said, "It has become difficult to get clarity on clinical trial approvals for not just drug companies but also academic and research institutes. Delays have become commonplace. What the industry needs now is a change in the mindset, when it comes to approving sites or specific studies."

However, no one can deny the existing lacunae in the structure that allow for malpractices in clinical trials to occur. Several measures are being suggested to curb incidences such as those reported in Madhya Pradesh a year back. Ms Thatte suggests a national list for noncompliant sites can be formulated and made public. Other initiatives like publicly blacklisting errant organizations could go a long way in restoring public faith, which of late has taken a severe beating.

For now, Dr Bopanna states that they will wait and watch."Since the court order is only asking for CROs to abide by the given guidelines, ISCR will not be initiating any response".

Experts from the industry cite that, the need for a strong and robust industry will be felt even more urgently, once, more domestic pharma companies mature and develop drugs in this decade. For this, the organized clinical trials industry needs to take a more active initiative to differentiate itself from the unauthorized entities and co-operate with the country's drug regulator to adhere to the judiciary's requirements. Greater dialogue with more accountability is therefore the need of the hour.