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# Indian apex court raps govt over clinical trial data

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Giving a clear call for accountability, the Supreme Court of India, on January 3, 2013, sternly reprimanded the Ministry of Health and Family Welfare and Central Drugs Standard Control Organization (CDSCO), India's main regulatory body for pharmaceuticals and medical devices, for not filing data regarding diverse aspects surrounding clinical trials, as per its an earlier order. Referring to the 59th parliamentary committee report that had indicated a collusion between pharma companies and regulatory authorities, the apex court pointed out that the government needs to wake up and address the situation.

The Supreme Court rap came following a public interest litigation (PIL) filed by the Swasthya Adhikar Manch, an NGO based out of Madhya Pradesh, a state in central India. Last year, several media reports surfaced claiming that clinical trials were being conducted in Indore, Madhya Pradesh, without patient consent. In response, the 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.

On October 8, 2012, the Supreme Court then 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 non-compliance of this order, the Supreme Court on January 3, 2013, pulled up the representative of the ministry for "slipping into a deep slumber" and not submitting the information.

The Supreme Court order of January 3, a copy of which is with BioSpectrum, asks that the CDSCO or the ministry submit an affidavit as requested earlier within four weeks. It also directs the chief secretaries of all states other than Madhya Pradesh, Manipur, Dadra Nagar Haveli, Daman and Diu to file written responses within four weeks. The Supreme Court has also reiterated that clinical trials regarding any new drug should be carried out under the direct supervision of the secretary of the Ministry of Health and Family Welfare until further notice.

However, data regarding clinical trial sites, deaths associated, compensation etc., traditionally lies with Drug Controller General of India (DCGI), which is the central approving authority of clinical trials. Industry sources say 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.

**Order not a setback**

"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," says Mr Ranjit Shahani, vice chairman and MD, Novartis India. "There is a need for clear communication about issues, such as compensation, to be discussed by the government."

Many in the industry are of the opinion that this is a blow to the $600 million (Rs 3,246 crore) bioservices industry in India, since it will only add to delays in other projects as well. However, at a recent annual conference on clinical research organized by the 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.

"The court order does not dis-empower 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 one where the relevant states are being asked to submit all the data surrounding the clinical trials, for the Supreme Court to study," says Ms Suneela Thatte, executive director, customer operations, Quintiles.

Dr Krathish Bopanna, chief executive officer, Semler Research Centre and president, ISCR, agrees. "The order should not affect any legitimate CROs in India, as it only asks for the reinforcement of existing rules. It is directed towards outfits that are like fly by night operators who have been indulging in malpractices that are in the news," says Dr Bopanna.

In another instance, on January 8, 2013, the Supreme Court responded to a PIL filed against vaccine majors Merck and GlaxoSmithKline (GSK) 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 likely**

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. In 2011, 12 drug advisory committees were set up to review new drug applications in different areas of specialization such as neurology and cardiology, that were supposed to respond with their comments within six weeks of receiving the applications. It was decided that their comments would be discussed at joint meetings and approvals will be granted subject to their responses. Industry sources say no such committee meetings have been held in the last three months. Some are slated to start this month. Such delays will only make it difficult for small and mid-sized CROs to survive and operate in the coming years.

"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," says Dr Arun Bhatt, an industry veteran and president, ClinInvent Research.

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 ago. Ms Suneela Thatte suggests a national list of non-compliant sites can be made public. Other initiatives for publicly blacklisting errant organizations could go a long way in restoring public faith, which has of late taken a severe beating.

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

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