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LSW concludes Clinical Research Conference in Mumbai

Provides platform to various industry stakeholders to discuss challenges associated with clinical research

The clinical research industry in India is in the doldrums and both the government as well as industry are trying their best to find common ground early as possible. With an aim to foster better understanding of the issues at stake, **Life Science World (LSW) in association with Association of Clinical Research Organizations (ACRO) and Indian Pharmaceutical Association (IPA**) recently organized a one day conference on 'Clinical research - regulatory norms -current challenges and the future of pharma industry in India' in Mumbai.

The conference witnessed participants from varied disciplines: pharma, law, CROs, insurance and enabled a platform to discuss various issues associated with the industry. The conference registered active participation between the speakers and delegates.

The organisers of the conference invited speakers and panelist to discuss issues and share their knowledge with participants. Dr Surinder Kher, Chief Executive Officer, Ecron Acunova; Dr K Bangarurajan, Deputy Drugs Controller (India), Dr Rao Vadlamudi, President, IPA, Jeroze J Dalal, General Manager, Clinical Research, GlaxoSmithKline; Apurva Shah, Managing Director, Veeda Clinical Research; Dr Kumar Prabhash, Tata Memorial Hospital; Dr Gururaj Rao, Managing Director, International Stem Cell Services;Viveka Roychowdhury, Editor, Express Pharma; Dr YK Gupta, Head, Department of Pharmacology, AIIMS; Dr AK Agarwal, Chairman, Compensation Committee, Government of India; Dr Suganthi Iyer, Assistant Director-Legal and Medical, Hinduja Hospital; Dr Viraj Suvarna, Medical Director, Boehringer Ingelheim India; Dr Milind Antani, Nishith Desai Associates, Legal & Tax Counseling Worldwide and Dr Venu Madhav, COO, Veeda Clinical Research were the speakers of the conference.

The programme began with Dr B M Gandhi, Former Advisor, DBT, Government of India, and currently, CEO, Neo Biomed services sharing an overview of the conference agenda. The day's proceedings were anchored by Dr Surinder Kher, Chief Executive Officer, Ecron Acunova who ably steered each panel discussion as well as summarised the speakers' comments. Dr Rao Vadlamudi, President, IPA delivered the keynote address of the event, who opined that India-specific requirements needed to be kept in kind while creating an ecosystem for clinical research in the country.

The first session of the day featured viewpoints from each stakeholder. While Dr Kumar Prabhash, associate professor and medical oncologist, Tata Memorial Hospital spoke about the his experiences as a principal investigator, Jeroze J Dalal, General Manager, Clinical Research, GlaxoSmithKline gave the sponsor's perspective on the stringent regulations and uncertainty regarding timelines. Apurva Shah, Managing Director, Veeda Clinical Research gave the CRO perspective while Dr SGA Rao, former senior scientist, Cancer Research Institute, Tata Memorial, and managing trustee, Stem Foundation spoke on stem cell trials.

Viveka Roychowdhury, Editor, Express Pharma represented the media while Shraddha Tawade, General Manager – Quality and Training Global Clinical Research, Wockhardt provided the perspective of patients as well as their relatives who wished to join clinical trials. She stressed that it is the patient who needs to really analyse the possible benefits with risks associated with the clinical trial before taking a decision. She also cited several research papers analysing the mindset of clinical trial participants in an effort to gauge why they took part in a trial or not. While summing up her presentation, Tawade emphasised, “The Government can play an vital role in propagating information about clinical trials. I feel they (Government) can put detailed information on their website, and informing people in the society about the importance of the clinical trial in today's world and assuring patients about the safety features.” It seemed that she has high hopes from the new government particularly for the clinical trial sector, as she repeated the now famous election campaign slogan of the BJP: 'Aache Din Aane Wale Hain'!

In the second session dealing with compensation and related issues, Dr YK Gupta, Head, Department of Pharmacology, AIIMS explained details of the compensation formula. He stressed that the regulator was open to consider modifications in the existing formula and is currently evaluating and reviewing issues related to 'failure of investigation product', 'use of placebo' and 'as long as required'. He asked industry representatives to share their inputs on same, ending his speech with the message: “Clarity evolves as we go along.”

Another speaker from the same session, Yasmin Shenoy, Senior Director- Regulatory Affairs mentioned that today compensation is a delicate issue in the industry. “There will be lot of changes in reporting process and time-line required once the current (24 April 2014 draft guideline) becomes a final rule. We have to follow the new formula of reporting process in the clinical trial,” mentioned Shenoy. She further added, “Clinical research is a system for the advancement of science and benefits of mankind. And it must be supported with appropriate regulations and needs to assure that the right checks and balance are in place. We have to start the approval process very fast as we have already missed the bus and need to speed up and bring the drugs to markets which are currently in various stages of the trial process globally.”

It is always better to have regulatory personnel so that the industry understands the if's and but's of a new rule or act. **Dr AK Agarwal, Chairman, Compensation Committee, Government of India revealed the pain and efforts which his committee has taken before presenting the compensation formula to the industry.** He shared, “Framing a formula for compensation was a big challenge for us as there is no formula available today globally. We had started working on this formula in March 2013 and delivered it in September. It took us long time, because we tried to analyse all possibilities before presenting it.

And there are still avenues open for modifications/ changes as the Health Ministry is ready for amendments in the compensation formula.” Agarwal also revealed, “The committee receives nearly 50-60 causality assessment related to deaths cases and each of these are debated internally after a lot of homework. The final outcome is always a combination of clinical sense and pharmacovigilance.”

Agarwal handed over the session to Gupta and the discussion went on to become more interactive as participants, both on and off stage, sought to discuss many ambiguities in the current compensation guidelines.

For instance, Dr Suganthi Iyer, Assistant Director- Legal and Medical, Hinduja Hospital raised many questions on the legalities. What were the consequences if a patient suffers permanent damage during the clinical trial? Is he eligible for compensation and how much? Who should be made a nominee? Can it be anybody or

will it be have to be the immediate dependent from the family or someone outside the family like friends? In reply, Gupta reasoned that this was the decision of the trial participant/patient.

Similarly, regarding permanent damage, Gupta revealed that a lot of work is currently underway to finalise on this issue and he invited her to share her inputs on the April 23 2014 draft as well.

Expressing her views, in her individual capacity Dr Rashmi Hegde, Director-Medical & Regulatory Affairs, Abbott pointed out that the current approval process is delaying the entire process and she opined that the CDSCO office needed to increase manpower strength and invest in upgrading the current infrastructure.

“The approval timeline for new products / clinical trials by DCGI needs to be defined and shortened. I feel there is an urgent need of transparency in the process of entire clinical trial system,” she said,

Insurance providers also play an key role in providing trial insurance and Deepak Gupta, Assistant Vice President – Underwriting, HDFC ERGO General Insurance highlighted the services provided by his company to the clinical trial industry.

Speaking from the legal perspective, Dr Milind Antani, Nishith Desai Associates, Legal & Tax Counseling Worldwide highlighted the importance of appropriate contracts. As an example, he requested all principal investigators to verify their employment contracts to check their liability when it comes to both clinical practice as well as clinical research and trials.

Dr Viraj Suvarna, Medical Director, Boehringer Ingelheim, requested CDSCO for a responsible approach and opines that the recommendations of the Ranjit Roy Chaudhury committee should be acceptable as early as possible.

Throughout the day's programme, Dr K Bangarurajan, Deputy Drugs Controller (India) answered queries and clarified points while updating the industry about ongoing discussions at the central level. He invited industry representatives to share their concerns so that drug controller officers can make joint representations to the Health Ministry. As the new government is now in place, there are long list of the expectations from industry.

Concluding the event, Kher revealed, “We have already proposed a '100 days agenda' with the help of various industry associations. The discussions at this event will be compiled into a report for the government in the hopes that it will help create facilitative rather than regressive regulations. ”

Usha Sharma, **Express Pharma** – ***Mumbai***

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