LSW's Interactive Conference May 27, 2014 – A Report

Highlights

LSW LifeScienceWorld Online magazine on Pharma & Biotech industry

LSW Conference: "Clinical Research – Regulatory Norms-Current Challenges and the Future of Pharma industry in India", May 27, 2014, The Orchid Hotel, Mumbai.

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The objective of this conference was to bring together the regulator and the clinical trial industry to focus on issues related to clinical research/trials area, identify the gap areas, if any in view of the new guidelines released by DCGI office, CDSCO and the Health Ministry and highlight the suggestions / recommendations / solutions consideration of regulatory agencies and wider circulation amongst the clinical trial industry.

Inaugural Session – (From Left to Right: Dr. Surinder Kher, Dr. B M Gandhi, Dr. K Bangarurajan, Dr. Rao Vadlamudi, Dr. Milind Antani)

The Conference provided an opportunity to clinical trial industry to interact directly with the regulator, policy makers, legal experts, experts in the field associated with the health ministry and the experts from the industry to discuss recent amendments in Schedule Y; challenges to bring new drugs to global market; perspectives on clinical trial sector in India; compensation and related issues; liabilities of stakeholders and mitigation; other related issues.

There was a good response to the conference and representatives from more than fifteen industries directly involved with clinical trials and more than 30 potential beneficiaries participated in the meeting.

Proceedings:

Dr. Surinder Kher, CEO, Ecron Acunova- Conference Chairperson

The conference was chaired by Dr. Surinder Kher, CEO, Ecron Acunova, who conducted the day long proceedings so beautifully, that despite long sessions and short lunch break and almost without tea break, the audience stayed put on their seats and interacted with the speakers, panelist and the regulator.

Dr. B M Gandhi, Former Advisor, DBT, Govt. of India addressing the Conference
Overview

Dr. B M Gandhi, Former Adviser, Government of India, Department of Biotechnology introduced the conference to the delegates in light of recent amendments to the schedule y of the Drugs and Cosmetics Act, report of the Ranjit Rai Chaudhry, mandatory audio-visual

recording of the consent, serious adverse reactions and compensation and registration of ethics committees linked to the topics of the agenda.

Dr. K Bangarurajan, Deputy Drug Controller of India, West Zone rendering the Inaugural Address

Dr. K. Bangarurajan, Deputy Drug Controller (India) gave the inaugural address highlighting the "Regulations-Past, Present & future Scenario" highlighting the implications of the recent amendments in schedule Y, monitoring the clinical trials, NDACs, Ethics Committee registration and related issues.

Dr. Rao Vadlamudi, President, Indian Pharmaceutical Association rendering the Keynote Address

Dr. Rao Vadlamudi , President, Indian Pharmaceuticals Association in his keynote address highlighted the challenges to bring new drugs to global market in present scenario of clinical research in India and advocated for GCPs in clinical research, enough number of sites, adequate regulatory support, sufficient resources and timely clearances by the regulatory bodies, responsive media for educating public and politicians and political will.

This was followed by "View Point" a session titled **"My Perspective on Clinical Trials sector in India-Where are we? Where are we going? Where we should be going?"** Significant contributions were made by

Jeroze Dalal (Glaxo SmithKline), Apurva Shah (Veeda Clinical Research, CRO),
Dr. Kumar Prabhash, Head of Oncology, Tata Memorial Hospital, . representing Investigators,
Dr. Gururaj Rao, Managing Director, International Stem Cell Services Ltd on stem cells trials,
Viveka Roy Choudhury, Editor, Express Pharma from the media's perspective and
Shradha Tawade, GM, Wockhardt (wife of patient who underwent clinical trial).


Jeroze. J Dalal


Apurva Shah


Dr. Kumar Prabhash


Dr. Gururaj Rao


Viveka Roy Choudhury


Shradha Tawade

Elaborated session on “Compensation and Related Issues, Liabilities of Stakeholders and Mitigation” generated good interest and attraction.

Panelists of Session titled “Compensation and Related Issues, Liabilities of Stakeholders and Mitigation”.From L-R: Dr. Y K Gupta, Dr. suganthi Iyer, jeroze Dalal, Dr. A K Agarwal, Yasmin Shenoy and Dr. Venu Madhav

Dr. Y K GuptaDr. Y. K. Gupta, Professor and Head, Department of Pharmacology, AIIMS discussed detailed information on recent amendments and post-scenario implications on compensation and related issues like basis of calculation of compensation and factors which entitles quantum of compensation. He informed that a Committee is already compiling the suggestions and recommendations in this regard and further suggestions, if any received, would also be considered.

Dr. A K AgarwalDr.

A. K. Agarwal, Chairman, Compensation Committee, Government of India also informed that suggestions are open for debate and change. He further observed that about 50-60 cases of death are being reported in clinical trials besides subjects reporting permanent or partial damage/disability.

Dr. Milind Antani

Dr. Milind Antani highlighted the importance of contract with the Project Investigator, Institute and Sponsors; role of CROs and Insurance Package for trial related injuries. Mitigation strategy should deal with liability and project Investigators should also get indemnified under the Professional Negligence Policy.

Other speakers included Dr. Suganthi Iyer of Hinduja Hospital, Jeroze Dalal from GSK, Dr. Venu Madhav, COO, Veeda Clinical Research and Dr. Prabhash Kumar as Panelists.

Presentations were made by industry professionals comprising Yasmin Shenoy, Sr. Director, Regulatory, Sanofi India on “Beneficiary of Clinical Trial”; Dr. Rashmi Hegde, Director-Medical, Abbott India on “Liabilities of Stakeholders”; Deepak Gupta, Asst. Vice President, HDFC ERGO “on New areas of Clinical Trials That Can Be Covered by Insurance “Dr Viraj Suvarna, Medical Director, Boehringer Ingelheim India” Impact on Sponsor Company”; Milind Antani “Contracts” and Prabhash Kumar “Practical Issues and Concerns” These presentations were followed by in-depth discussions.


Yasmin Shenoy


Dr. Rashmi Hegde


Deepak Gupta


Dr. Viraj Suvarna


Dr. Milind Antani

(Some of the other panelists: L- R: Dr. Viraj Suvarna, Dr. Rashmi Hegde, Dr. Kumar Prabhash, Deepak Gupta, Dr. Venu Madhav and Dr. Milind Antani)

The highlight of the conference was the presence of Dr. K Bangarurajan, Deputy Drug Controller of India, West Zone representing DCGI during the entire course of discussions at the conference and actively interacting with the participants. He addressed to all their queries on implications of the new guidance media perceptions. In his closing remarks, he assured the participants that he would carry forward all the discussion points and the suggestions made at the conference to the notice of CDSCO, DCGI and the Health Ministry.

Closing Remarks by Dr. K Bangarurajan, Deputy Drug Controller (3rd from left). Others in the pic. (From L-R) Dr. Milind Antani, Dr. Surinder Kher and Dr. B M Gandhi
The details of the discussions and the recommendations made at the conferences and comments would be available on this site soon.