

## Minutes of the meeting of MLSI dated 22 August 2023

Online meeting of MLSI was organised on Tuesday 22 August 2023 at 8.50 pm It was attended by more than 75 participants from all over India representing various organisations including :

Dr. Sanjay gupte	Dr. Devraj Raichur
Dr. N J Karne	Dr. Suyash Kulkarni
Dr. Shubhangi Mundhada	Dr. Rahul agarwal
Dr. Mahesh Sinha	Dr. Asha Agarwal
Dr. Murugesan V	Dr. Nirmala Gulati
Dr. C.P. Tiwari	Dr. Srikanth K N
Dr. Muneesh Kapoor	Dr. Vikas nagargoje
Dr. Kandada	Dr Vaishali Chavan
Dr. Ratan lal parakh\	Dr Roshni
Dr. Hafiz	Dr. Kundan Khamkar
Dr. Kunal Sethi	Dr. Rajesh S
Dr. R. Ravikumar	Dr. Dhwani Mehta
Dr. Ramesh Kumar Saharia	Dr. Uma Shetty
Dr. Shrikant Pensalwar	Dr. Nilakshi
Dr. Gazella Bruce	Dr. Vani R
Dr. Ratan lal parakh	Dr. Rajasekaran A
Dr. Akila Ravikumar	Dr. Aditya Jain
Dr. Aarathi S \	Dr. Asha Jain
Dr. Raj Kumar\	Dr. S Sundarakumar
Dr. Santhakumar Subramanian	Dr. Chandra Chauhan
Dr. Murugesan V	Dr. Hemanga Baishya
Dr. Nivedita Rathod	Dr. K N Rao
Dr. Roshni	Dr. Deepak Sharma
Dr. Kailash Singh	Dr. Mandar Paranjape
Dr. Pushkar Khair	Dr. Akola Ravikumar
Dr. Rajeev Joshi	Dr. Ashish Khatod

Apologies for missing the names of few attendees who joined late, attended for a while and left in between.

Following points were discussed during meeting

Dr. Rajeev Joshi introduced and informed in brief about MLSI and work done till date by MLSI i. e. PIL & IA before Bombay HC regarding violence against medical professionals, IA before Kerala HC in Kerala Private Hospital Owners Association ( KPHA) versus State of Kerala case regarding violence against medical professionals and suggestions of providing paid security through SISF was given by MLSI which was accepted by HC, IA in writ petition filed by Sunit Upadhyay ( husband of late Dr. Archana Sharma) and requested to prescribe guidelines regarding the process to be followed in case of medical negligence. After this he informed about action taken by MLSI in NMC's regulation matter and requested attendees to suggest and discuss their opinion on this subject.

Dr. Kundan Khamkar informed that according to discussion held with pharma fraternity there is clear definition of generic drugs. He has experience that Jan Aushadhi stores find it difficult to match generic to brand names. He suggested that writing both generic and brand name on prescription is a better and practical solution to this problem.

Dr. Suyash Kulkarni questioned the efficacy of generic medicines and raised a concern that medical practitioners will be held responsible for not getting expected results or relief from medicine. For example if generic paracetamol does not work, pharmacy stores will not be responsible.

Dr. Srikanth asked whether writing generic names is mandatory or optional as the words used are shall, should and not must? and raised a concern that the number of PM JAN AUSHADHI KENDRA is not enough, so how can it provide medicine to the huge population of our country?

Dr. Ravikumar asked, whether it is possible to organise CME with sponsorship of pharma companies without displaying the name of that company or any brand of medicine?

Dr. Kankada said whether there is any way in which we can collect data to indicate that drug A is working and drug B is not working so that there can be a database of generic medicines which are not working.

Dr. Sheela Matrya who is working as intensivist also raised similar concerns about the quality of medicine. She said there should be clear definition of generic medicines and whether use of generic drugs is

mandatory is not clear. She said that meropenem is available from Rs 100 to 2000 and who will take responsibility if quality is not satisfactory. Does government give assurance that it has ensured the quality of generic medicines, as we can not afford to use drugs with substandard quality.

Dr. Bhumish Kumar from IADV L said that for skin diseases there are no generic medicines available. What should dermatologists do?

Dr. Rishbh Rana asked whether the government has structure to find whether the generic medicines have quality. He said that there is no doubt that patients will get low cost drugs but whether they will get quality? He gave an example of Demonetization in which the idea was good but there was poor implementation. It was supposed to help people and the nation, but in fact people got harassed, and benefits to the nation could not be achieved. Dr. Rana added that until and unless the government develops enough mechanisms for testing the quality of drugs, this compulsion of writing prescriptions by only generic names of medicine should be abandoned.

Dr. Joshi informed about contents and issues raised in a letter sent to PMO in detail and various discussions done by MLSI.

Dr. Raichur shared his opinion about the meaning of words regulation, guidelines, shall, must, may which are written in NMC's EMRB's regulations. He further raised his objection over the sentence "generic drugs are as effective as branded drugs" as there is no proof. He said that if the government is promoting generic drugs, there should be evidence that it will be effective. The value of the prescription of generic medicines and the problems associated with them must be weighed by the government. He also said that prohibition of CME Sponsorship is against one of the fundamental duties of citizens prescribed under Article 51A (h) of constitution as "to develop the scientific temper, humanism and the spirit of inquiry and reform".

Dr. Rao said that he talked with a lawyer who was one of the members of the committee who drafted these regulations. As per his opinion all these regulations and guidelines are mandatory unless and until expressly relieved by NMC. He further suggested that as a short term solution of this problem we come to a common consensus of adopting the practice of writing both generic and brand name of

medicine along with disclaimer as " not supplying prescribed brand of medicine to a patient who is willing to buy branded medicine is violation of patient's right and doctor shall not be responsible for medicine." He further added that uniformity among all medical practitioners will ipso facto create authenticity and importance of such practice. He shared his experience with the practice of consent which all practitioners are following in his city. He said that the mandator is NMC and mandated is the RMP. Mandatees must use generic though words used are shall or should indicating that it is not mandatory. Mandator may be flexible in some cases as it has discretionary powers. We all feel that supplanting patients' right to health, medico legal rights of the doctors should also be protected. He said that there should be uniformity in the disclaimer written by all doctors after brainstorming. If action is taken against any doctor, the association should get impleaded to protect his interest.

Dr. Ravishankar said that there is provision of punishment in these regulations due to which panic is created among medical practitioners. Dr. Gupte suggested to discuss on action plan as members of various associations are present in the meeting.

Dr. Rao requested attendees to become members of MLSI so that we can associate together on this Dr. Joshi advised interested attendees to share their contact details with him through WhatsApp.

Dr. Ravikumar said that there is no platform for reporting on the effectiveness of generic medicines. Dr. Joshi suggested that this can be done through google form, whereas Dr. Rao suggested creating such a platform in the form of a webpage. Dr Karne said that doctors will be afraid to give inputs because they will be afraid whether the pharmaceutical companies will file a case against them for submitting such reports, and raised concern about the issue of confidentiality. Dr. Joshi assured that confidentiality can be maintained for which a web based mechanism can be created in about a week's time. MLSI will submit reports to the government from time to time and if any pharmaceutical company wants to take action, let it file a case against MLSI. MLSI will collect name email mobile nos of doctors who will file complaints, but will never disclose them to government or pharma. Dr Rao said that pharmacovigilance cell collects such data and acts on it. Dr Joshi said that in that case MLSI will collect data and send to

pharmacovigilance without disclosing names of doctors, and then follow up about action taken etc.

Dr. Suyash Kulkarni said that there are generic drugs which are sold at higher prices than branded drugs also and gave a few examples.

Dr. Raichur brought attention towards section 12 B in which it is prescribed that "Drugs prescribed by RMP or bought from the pharmacy for a patient should explicitly state the generic name of the drug" means RMP will be held liable if the generic name is not written on Medicine which is neither prepared nor sold by him. He added that Issue of making informed consent mandatory is a violation of guidelines prescribed by the Supreme Court in Sameera Kohali case in which real and valid consent is considered as sufficient.

Dr. Karne said that there are different definitions of generic drug. He read out a few slides which he has been presenting to various fora from 2017 in which these definitions are seen to be contradicting with each other.

Dr. Gupte pointed out that we can not insist on getting sponsorship for conferences from pharmaceuticals as it will show doctors trying to protect their own interest rather than the interest of patients. He also thanked all attendees for coming together to fight. He said that we have to discuss this with all stakeholders and come out with an action plan for next step/s to be taken.

Dr. Joshi informed that technically we will have to file IA in the PIL filed by an advocate for directing the government to take action against doctors who are not prescribing medicine in generic name. While we will not oppose regulation of the pharmaceutical industry, doctors should not be punished as there is no mechanism to assure quality of medicines. Any untoward effect of medicines will be detrimental to patients and finally doctors will be exposed to unnecessary litigation, which should be prevented. If there is no response / action from the government, we will have to file a PIL either in Delhi HC or SC.

Dr Joshi requested all participants of today's meeting to send him details of points discussed by them by email so that it will be easy to include the suggestions in further communication with the government. Meeting ended at 10.45 pm.

Dr. Ashish Khatod

Dr. Rajeev Joshi