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New guideline compounds complexity to clinical trials

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According to the new order, organizations wanting to carry out clinical trials in India need to justify how the country would benefit from the trial.

The companies are expected to provide details on the following three parameters:

- Risks vs Benefits to the patients
- Innovation vis-Ã -vis existing therapeutic options
- Unmet medical needs in the country

"Obviously drug innovation is about addressing unmet medical needs and improving medical outcomes. However, it is not possible to guarantee or predict therapeutic benefits of a molecule before the clinical development process is completed. For example, we got a 'placebo effect' when we conducted trials on our oral insulin molecule IN105, but the therapeutic intent was powerful," expressed Dr Kiran Mazumdar-Shaw, CMD, Biocon.

Clinical trials are an indispensable part of drug discovery and development research, and it is at the heart of all medical advances, offering hope for millions of patients, and an opportunity to help researchers find better treatments for future generations.

Moreover, companies can also learn a great deal from the trial data, instilling confidence to pursue a particular molecule.

"No company will try and develop a new drug if it does not bring benefit. Thus, this mandate is both unnecessary and completely redundant. It sounds like a meaningless bureaucratic barrier created to deter clinical trials and scripted by a 'babu' who does not understand drug innovation! Such mandates will stall and delay approvals and only encourage pharma companies to conduct clinical trials in other parts of the world. This will be a huge setback not just for Indian innovators but

more importantly for Indian patients," explained Dr Kiran.

However, on the other hand, Dr Suresh Menon, executive committee member, Indian Society for Clinical Research (ISCR) does not see any impact by the new order.

"This has been in practice for around a year now and so this is not something new. What the recent order has done is to pass that responsibility onto the sponsors of clinical research. While the assessment of risks vs benefits to patients and details on innovation vis-Ã -vis existing therapeutic options are factors that every trial must take into consideration whether a legal requirement or not. The details of whether the investigational product meets an unmet medical need in the country is open to interpretation. Ideally it should be the regulators who should evaluate these parameters based on clearly defined guiding principles," Dr Menon added.

Commenting on the parameters, Dr Kiran asks, isn't it common sense that drug innovation considers most of these criteria? "I'm concerned about how the term 'unmet medical needs' is being defined. Unmet needs, for example, can range from affordability to new therapies. Unless defined clearly, such a parameter can end up creating confusion and disincentivize pharma companies from conducting trials in India," she warned.

She also pointed out another serious concern on the stipulation of restricting clinical trials to 3 per investigator.

"This is absurd given that we have a shortage of clinical investigators in India. In fact, most investigators in the US or Europe are engaged in a far larger number of clinical trials at any given time. This mandate will only serve to restrict drug innovation," opined Dr Kiran.

Dr Menon believes, "As long as there is clarity and guidance provided ensuring decisions are objective, having patients interest and safety and the larger healthcare requirements of our country in mind, we do not believe these orders will affect clinical research in India. There are some biopharma companies who believe it could act as a disincentive, but it is too early to comment specifically," he voiced.

Conversely, Dr Kiran feels that the new guidelines will only add to the complexity of the trial process, proving to be counter-productive.

She opined, "The ongoing clinical trials controversy has already severely hampered drug development in India. The concerns around ethics and safety pertained only to a few trials, but the entire sector has had to pay the price."

Parallelly, for the online filing of returns for the monitoring or revising of drug prices, the National Pharmaceutical Pricing Authority (NPPA) has asked pharmaceutical companies to register under Integrated Pharmaceutical Database Management System (IPDMS).

The use of IPDMS is seen as a favorable move by NPPA thereby increasing transparency. "However, the NPPA can improve the drug pricing exercise by consulting stakeholders before issuing new price orders. Moreover, it is unfair to compare prices of drugs manufactured by large, reputed manufacturers with those made by SMEs. Investments made by large players in ensuring high quality standards need to be considered when calculating price ceilings,"

In May this year, the NPPA also came up with a new guideline allowing it to have the power and control over drug prices. However, now the Authority has withdrawn this guideline brining back cheers to the pharma world.

"Very few of our products fall into the new list of products put under price control, hence there will be a very marginal impact. Having said that, it is heartening to see that the NPPA has withdrawn the controversial guideline that gave it sweeping powers to set the price of even those drugs that are outside the National List of Essential Medicines (NLEM). It will be in the interests of all concerned, if NPPA stops acting unilaterally and consults all stakeholders before taking a decision," said Dr Kiran Mazumdar.