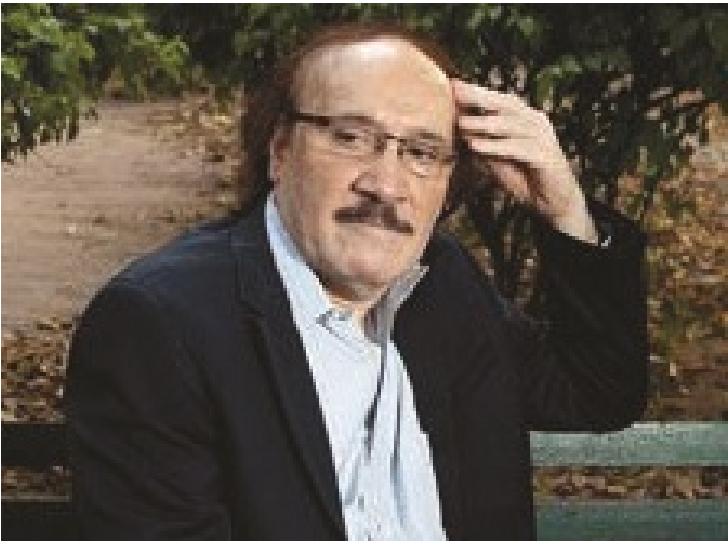


## “Things have started moving for good”?

25 April 2015 | Interviews | By Rahul Koul Koul

### “Things have started moving for good”?



**Q: Congrats to you as the rotavirus vaccine development has finally reached its culmination. Could you share some experiences that would benefit others?**

**Dr MK Bhan:** There are two, three issues here. One is professional capabilities in academia and industry comes by from experience. You collaborate globally and slowly build the capacity. Suppose there was no Gates Foundation, who would have done these trials? Nobody I guess. Would they have given the money? Not in case of absence of a smart team. Capabilities and trust building issues therefore too play a role here.

Now people are saying give us data on rare side effects and it costs another Rs 40 crores to give that. The doctors on committees don't have expertise on clinical trials. There are money issues. In a country like India, when the system is not ready, we can't expect a cakewalk. What is called hurdles in a general way is to work hard and build capabilities. Nothing is easy as it takes hard work and you have to work well. But let us see and not ignore the overwhelming positive side of picture too.

**Q: Critics from the industry feel that the regulatory regime is a big dampener. Do you see any change in the scenario over time?**

Many people are hiding behind incompetency and to blame DCGI for our innovation problem is not really realistic. There were issues at DCGI at some point but to say that things haven't improved, would be to turn a blind eye. They deserve credit for that and people should appreciate the change.

I agree because the international companies were not applying to the same degree. There was lack of clarity on certain

issues and lack of communication. But have seen it change now. They are applying and they see improvements. I oversee at least ten clinical trials on complex subjects as a chair of a steering committee.

I for one, have noticed improvements though nobody can deny that it has become expensive yet tougher too. Media persons like you must therefore do some investigation to find out the comparative analysis of situation now and then. However, I believe things have started moving for good.

**Q: On GM crops issue, the things are stuck due to regulation. Coordination between center and states is lacking too?**

We have to remember that on GM crops, it not just India but the whole world has divided opinions. But we have to move forward. There is no problem with agriculture regulations but the overall policy.

Maharashtra has moved forward on allowing trials. Can we push others to follow is the real question? Conversation has to begin so that there are creative solutions. Centre has not started it yet. They must open a dialogue with states on the subject.