

Exclusive: 2015 will be year of streamlined regulations says Dr GN Singh

10 February 2015 | Interviews | By Rahul Koul Koul

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Q: What are your expectations from the meeting with the vaccine industry? How will it help the industry?

The agenda is to take India ahead and make it a global leader in vaccines. We expect a very positive outcome from the interaction and I am confident that the industry will benefit from it. You will be pleased to know that when the National Regulatory Authority (NRA) assessment took place, there in one of the classes, we informed WHO that we have do regular meetings to know the expectations of international agencies. And then pass them on to the manufacturers to help them keep updated on the safety and efficacy guidelines.

Q: In the context of your message on regulatory streamlining, what lies in store for 2015?

The year 2015 is going to be a bright year. The industry is upgrading its capacity and skills. Capacity building is a major thrust of the government of India when we are going to have the regulatory frameworks, tools, setups in place. We intend to graduate to the next level and in 2-3 years, we would be better placed. The industry too is confident after the takeover by the new government. They are keen to invest. So, the indicators are very positive in both medicine and vaccine verticals. A number of units that are not WHO qualified also want to meet the criteria. It is good if we have more functional units meeting the requirements as that would increase the volumes and expand the size of the industry too.

Q: Given the fact that in the past there was a lack of it, has the manpower at CDSCO been upgraded in the last few years?

The government has taken proactive steps. We had the strength of 40 inspectors in 2008 and now it has gone upto 347. There will be the addition of 200 more in next 2 years. The basic issue is to train them as per current national and international expectations. Government is supporting us the regulations stringent yet streamlined.