

## A killer shot to vaccine makers

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Human health has improved tremendously in the last seven to eight decades due to the widespread use of vaccines to prevent the occurrence of some of the diseases which were the cause of millions of death around the world till the 20th century. In fact, some of the killer diseases of 19th century such as small pox were successfully eliminated from the Earth in the 20th century.

Independent India too has been a major beneficiary of the use of the world's most advanced vaccines and both government-funded and private vaccine manufacturers have played a major role in boosting India's health indicators. One of the most visible sign of this is the doubling of the life expectancy of an Indian citizen from mid-30s to the current average of over 70 years of age.

However, some of the gains of these hard fought campaigns by the nation are now sought to be derailed by the current regulatory regime in the country due to its cussed approach to regulation. India is one of the founding members of the World Health Organization (WHO), the United Nations agency tasked with providing health inputs to the whole world. WHO has been ensuring that essential vaccines and drugs produced around the world are of the highest standards and they promote, and not endanger public health.

Experts from WHO found three government-run vaccine manufacturing facilities in India to be of poor quality and these have since been shut down. India's private vaccine manufacturers such as Serum Institute of India in Pune and Shantha Biotech,

Hyderabad and another half a dozen companies supply world class quality vaccines to most countries in the world, on the basis of WHO certification.

This dominance of Indian vaccine companies is under threat because one of the government agencies, the Central Research Institute (CRI), in Kasauli, Himachal Pradesh was also the accredited testing agency for India's drug regulator, DCGI. Since CRI's vaccine production has been stopped, WHO and other global buyers of vaccine from India, have started to doubt the quality of the products made here. The credibility of the country's drug regulatory system has been questioned.

This is leading to a dangerous situation. Approvals to a dozen new vaccines made by India companies in the last 12-18 months have been put on hold. The country and world needs these vaccines even as more infectious diseases threaten people's health in many regions. The government has to invest a few hundred crore Rupees to modernize the testing laboratories and certification agencies, set up a modern regulatory agency equipped with experts and equipment to handle advanced vaccines and other drugs.

Such a task is certainly not beyond the nation which is preparing to send an exploratory space mission to the moon and build some of the world's advance nuclear power reactors.

What is lacking is the political will. That too from a government, which has put a lot of emphasis on socio-economic transformation of the nation and wants to ensure equity to all the citizens.

The country's biotech industry leaders have provided the provided the prescription for saving the nation's vaccine industry at a special meeting organized by BioSpectrum in Mumbai on August 28, with the support of Bio-Rad and UK Trade & Investment. Even though this issue is dedicated to contributions from the readers, BioSpectrum team made an exception to highlight the problems faced by the vaccine industry. A small report on the August 28 discussions has been included in this issue. Otherwise, this issue is almost fully written by the readers. We were flooded with contributions and only a selection of them has been used in the September issue. The remaining articles will be used in the subsequent issues.

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