



“VACCINE INDUSTRY HAS EARNED INDIA A SPECIAL PLACE IN THE GLOBAL ARENA”

Hyderabad based Sathguru Management Consultants in association with Confederation of Indian Industry recently released a white paper on vaccine market scenario in India. In the same context, Ms Pushpa Vijayraghavan, Director, Sathguru shared her views on the critical aspects of Indian vaccine market in an exclusive chat with the BioVoice News. Pushpa believes that the Indian vaccine industry broke the existing affordability barriers, making India a bright spot of the global vaccine map. Read the detailed interview below:

BY RAHUL KOUL



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What are the key ingredients for success of the vaccine industry in India? Please list out the top five milestones of the Indian vaccine industry so far?

The vaccine industry is driven by its capability to supply high volume yet high quality vaccines for addressing global public health needs. The industry has established a high reputation for doing so by repeatedly accomplishing this for several established and emerging vaccines. Indian vaccine companies have excelled at successfully collaborating with global academic and corporate partners for technology access and product development, been adept at adopting new technologies and working with global public health authorities to proactively address immunization priorities. Lastly, an active and critical role has been played by the Indian Government and regulator. Having a National Regulatory Authority recognized by WHO has enabled

several Indian companies to wade through WHO prequalification process efficiently and participate in global procurement processes.

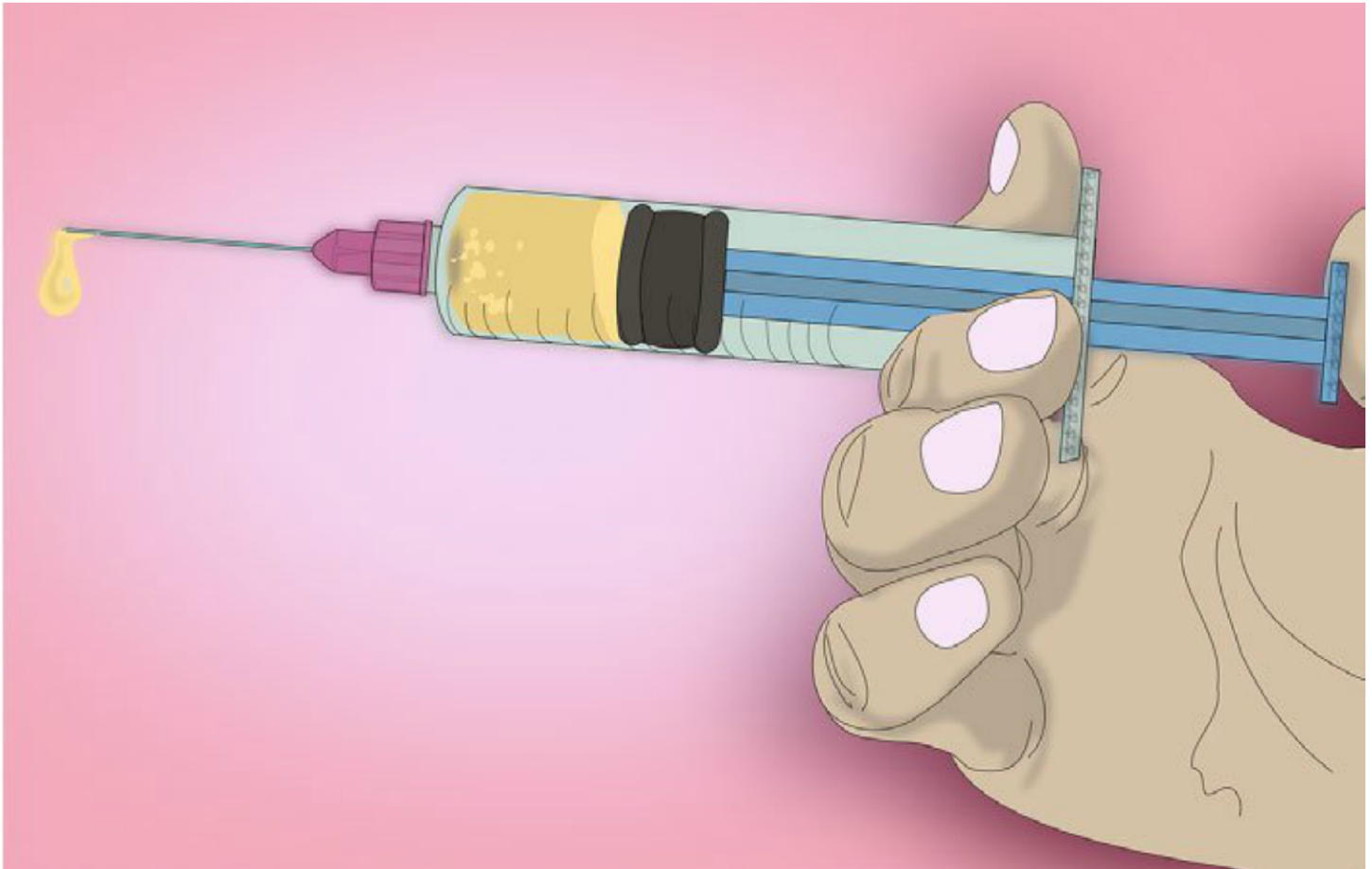
The Indian vaccine industry has time and again, broken affordability barriers, addressed technology challenges and has earned India a special place in the global arena. Noteworthy achievements of the industry include:

- Addressing close to 100 percent of Indian immunization needs with affordable yet technically advanced vaccines produced domestically. There is minimal import dependency and India is largely self-sufficient for vaccines for the national immunization program, a stellar Make-in-India success story chartered over the last two decades.
- Proactive technology adoption and ensuring Indians have access to vaccines that are not affordable but are also contemporary - Shantha Biotech and Bharat Biotech's indigenous Hepatitis B vaccine

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(the first recombinant vaccines to be produced in India) which brought down the vaccine cost from \$ 23 a dose to \$1 a dose. Similarly, the industry has repeated this success for pentavalent vaccines, more recently the rotavirus vaccine and is currently in the process of doing so for the PCV vaccine.

- Extending the breakthrough cost and affordability advantage



to the poorest countries in the world – A great illustration is Serum Institute’s Meningococcal A vaccine which now covers 100 percent of GAVI supply of 70 million doses for 15 countries. Prior to Serum the vaccine was supplied only by multinationals producing in high cost countries and was not affordable to majority of the underdeveloped and developing world where it was needed most. India accounted for more

than 60 percent of the vaccines supplied to GAVI in 2014 and supplies more than 80 percent of GAVI procurement for 4 vaccines.

How has been the growth of the sector so far and the prediction for next few years?

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We expect this robust growth to be sustained with support from increasing public awareness and high government focus on enhancing vaccination coverage. Private market for discretionary vaccines has also been rapidly growing and we expect the trend to continue

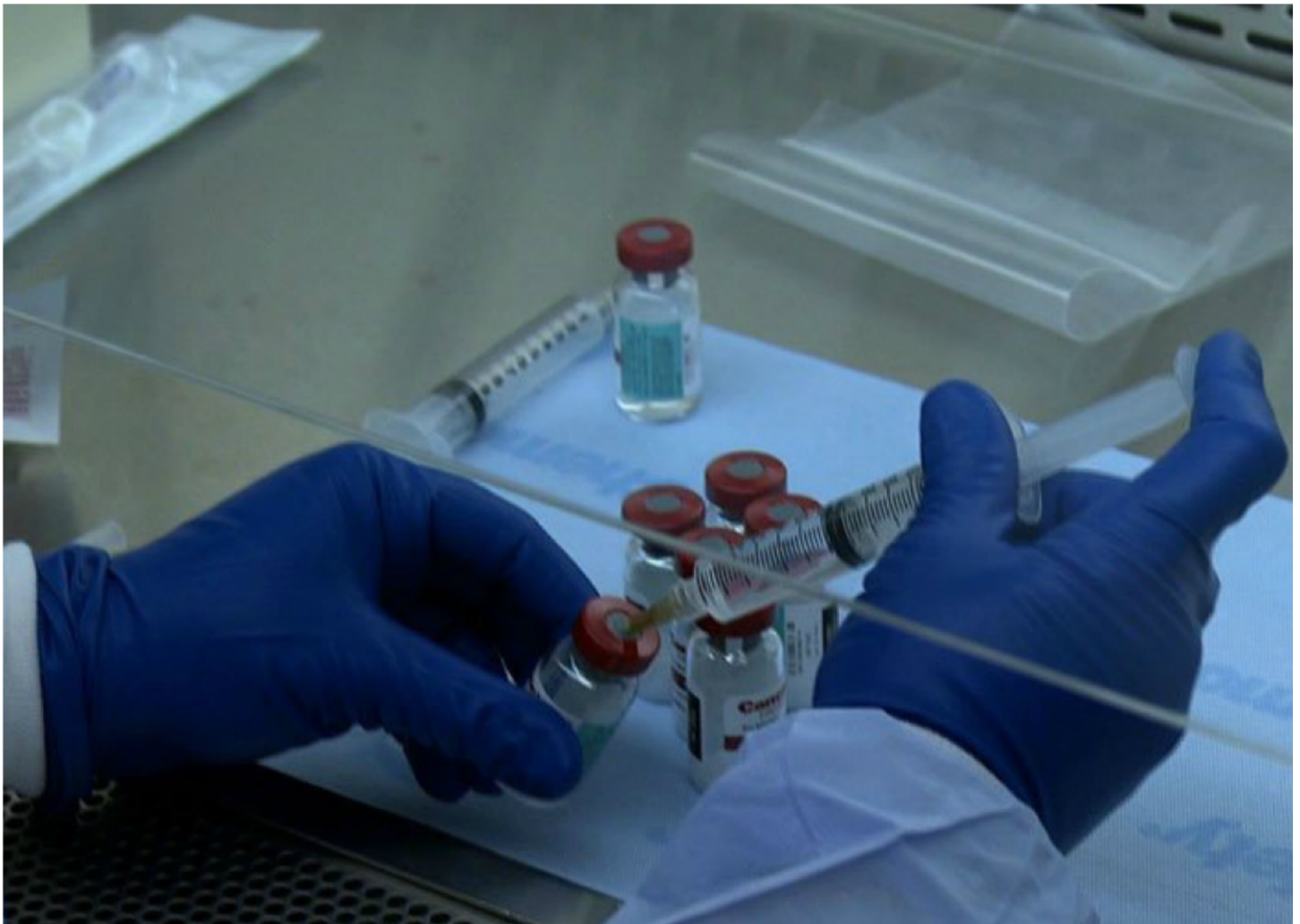
for select vaccines where high perception of clinical benefit will drive increased market penetration.

Why don't we find many more vaccine startups coming up while the market share is mostly held by few players?

Both technology and capital requirements

are significant barriers to entry for startups in the segment. Most of the current vaccines are technologically very complex and even leading Indian companies with in-house research capacity are leaning on partnerships to gain technology access. Even where a startup has a technology advantage, the capital requirements are hard to surmount

and serve as a significant deterrent. While initial proof of concept funding in the form of non-dilutive grants is now available to innovators, subsequent rounds of funding for clinical validation are hard to access given the continuing paucity of risk capital for biotech product development and the co-funding requirements of grants.



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How do you react to the statements that vaccine industry is a bubble created by lobbyists to earn bucks? There are also few who say that immunization campaigns is marketing for MNCs?

There is global evidence on impact of vaccines in

reducing disease burden and the health economics are well established. In a high transmissibility environment such as India, vaccines are an import part of the Government’s arsenal to address the looming problem of communicable diseases. The polio vaccine success in India is globally recognized

as a landmark effort that has successfully eradicated a once dreaded disease. While I strongly believe that public health stakeholders should not be deterred by such comments, I would also recommend that we adopt a data driven approach to putting any such concerns to rest. As a country, we

need to improve our focus on health economics and impact measurement. Such a data driven approach will put any concerns to rest on criticality of immunization programs for public health concerns where it is an appropriate measure.

We should also assess if the specific products we are using in the immunization programs are economically effective in addressing our goals and means to do so more effectively. A great example could be the BCG vaccine that has been used for prevention of TB. It will be a worthwhile for us to assess economic merit of a more effective TB vaccine and this would justify renewed and significantly higher investments in a critical research area.

Lastly, on private vaccines that are now driven more by a pharma styled sales approach, the clinical utility could be debated in several cases. However, as these are out of net of public expenditure in a largely out of pocket market, these are less

likely to be part of this debate.

What are the major policy related challenges that are acting as bottlenecks for further growth?

From our interactions with the industry for the regulatory round table, the main challenges we note are misconstrued inclusion of vaccines in National List of Essential Medicines (NLEM), dearth of funding mechanisms for scale-up and technology access, several redundancies in current regulatory pathways and lack of defined timelines causing undue delays in new product launches. Eliminating redundancies in the regulatory process and creating efficiency in the approval pathway is critical to ensure that the country realizes benefits of the current pipeline of high value vaccines such as PCV. These are high public health priorities and delay in approval of Indian vaccines only extends the period of dependency on couple of multinationals whose

vaccines are currently priced at more than Rs 3000 per dose for a 3 dose schedule.

How do you look at the future trends that would shape up Indian vaccine industry?

We expect India vaccine industry to continue on the current accelerated growth path for the next decade as well. It is critical that the current strength to proactively embrace innovation and build pipeline of complex products is channelized and intensified in an appropriately rewarding ecosystem. On the commercial front, we anticipate two key developments - greater participation in private market and the holy grail in value realization, entering regulated markets. While we currently dominate low and middle income vaccine supply, in the next decade Indian vaccine industry is poised competitively to make its mark in regulated markets. ■