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Too Much Of A Good Thing- COVID-19 Vaccines?

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Thinking long term to ensure that huge amounts of vaccines are not wasted, manufacturers need to have a far-sightedness and not just go on a production spree

During the first half of 2021 vaccine manufacturers were on a spree to launch their products anticipating that public apprehension will remain the same in 2022 as it was there in 2019 when COVID-19 struck. Three years down the line it is a different story altogether. Indian manufacturers Serum Institute of India (SII) and Bharat Biotech have now decided to stop manufacturing COVID-19 vaccines altogether due to hesitancy among the general public.

During the recently held annual general meeting of the Developing Countries Vaccine Manufacturers Network (DCVMN) in Pune, Adar Poonawala, CEO, SII, was quoted saying “To be honest, I am fed up with COVID vaccines.”

The COVID-19 vaccination drive began on January 16, 2020, with much fanfare and in 2022 it all fizzled out. The Government of India announced a free booster campaign from July 15 to September 30, 2022. More than 150 million adults received booster doses. More than 95 million people between 18 and 45 years received precautionary doses till September 29, according to the Health Ministry. The count of people between 45 and 60 years who have taken their boosters has increased 12-fold — from 3.7 million up to July 15 to 48 million on September 29.

Despite all the moves, it was found that large proportions of eligible adults shied away from booster doses where only 95 million opted for booster doses out of the 515 million that went in for the second dose.

Way back in 2020

It was in the year 2020 when 30 vaccine projects were initiated in India. India adopted a cross-functional collaborative approach, globally and locally, wherein currently 30 vaccine projects are afoot against COVID-19.

Apart from SII, Bharat Biotech, companies like Biological E., Panacea Biotech, Premas Biotech etc. took part in vaccine development activities. Vaccine manufacturers also teamed up with the academia and government to accelerate indigenous development of the COVID-19 vaccine. Indian Council of Medical Research (ICMR) and Hyderabad-based Bharat Biotech

have partnered to develop a fully indigenous vaccine for COVID-19 using the virus strain isolated at ICMR's National Institute of Virology (NIV) in Pune. In the form of another industry-academic tie-up, the Indian Institute of Technology Guwahati (IIT-G) collaborated with Ahmedabad- based pharmaceutical company Hester Biosciences for vaccine development against COVID-19. Researchers from the Hyderabad-based Centre for Cellular and Molecular Biology (CCMB) embarked upon developing an inactivated virus vaccine for the dreaded novel coronavirus.

Besides IIT Kanpur; Gennova Pharmaceuticals, Pune; Auro Vaccines, Hyderabad; Christian Medical College, Vellore; IIT Delhi; IIT Kharagpur; Central Drug Research Institute, Lucknow; National Institute of Immunology, New Delhi; International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi; Seagull Biosolutions, Pune; Mynvax, Bengaluru etc. all took part in the vaccine development activities. And the list goes on.

Despite all the initiatives and a lot of money being invested, two years down the line, all the enthusiasm has been lost. Researchers burned the midnight oil, and overcame regulatory hurdles, to launch life saving vaccines. Whether the vaccines were launched or did they see the day of light remains a mystery. And with no taker, it dealt a final blow to the initiatives.

A worrying trend

A lot of money was invested to manufacture the vaccines besides building capacity. Anticipating a huge demand then, the two major vaccine manufacturers are now on a move to eradicate the vaccines.

Bharat Biotech's Covaxin was sold for Rs 400 per dose to the government and Rs 1200 for private hospitals whereas AstraZeneca's Covishield was sold at Rs 300 per dose to government hospitals and Rs 600 per dose to private hospitals.

A whopping amount of 50 million doses of Covaxin produced by Bharat Biotech is set to expire in 2023 due to poor demand. The production has already stopped.

SII has already stopped the production of Covishield in December 2021. Poonawala also mentioned that the company will dump at least 100 million doses after the products expire.

The Government of India has decided against procuring more COVID vaccines as of now. The health ministry is surrendering Rs 4,237 crore of the 2022-23 budget allocation for inoculation purposes, to the finance ministry.

It may be noted that the same companies were also moving ahead to launch vaccines for children. There was a general perception of fear among the public with health experts mentioning that COVID may turn fatal for children. Here also, the vaccine manufacturers failed to make their mark. The entire concept of children getting vaccinated against COVID has lost somewhere with the government not commenting either on what is the future of the vaccines that were to be administered.

According to the COWIN website, Covovax, Corbevax and Covaxin are available for children.

Recently, there was news about Bharat Biotech producing Covaxin in a hurry due to political pressure. The allegations were, however, refuted both by the Government of India and also by the company.

And no one is talking about ZyCov-D, the world's first DNA –based vaccine that was developed by Cadila Healthcare in partnership with the Department of Biotechnology. Russia's Sputnik vaccine is priced at around Rs 1145 per dose.

The mRNA vaccine for COVID-19 was touted as a game changer. Pune-based Genova Biopharmaceuticals, a subsidiary of Emcure Pharmaceuticals, has announced that its mRNA vaccine – GEMCOVAC-19 - has received the Emergency Use Authorization (EUA) from the office of the Drugs Controller General of India (DCGI). Nothing much has happened on this front.

According to **Dr (Prof) Ajay Gambhir, Chairperson, Vaccine India and Ex National Technical Advisory Group on Immunisation (NTAGI) member**, "The industry got full support of the international agencies, governments, Drug Controller General of India (DCGI), NTAGI, World Bank, Bill & Melinda Gates Foundation (BMGF) and other agencies. However, their over-dependence on government for technical, financial, administrative and distribution (without scientific and serological follow up) led to inconsistency in the vaccine dosage (varying from one to three in short period of time) which further led to confusion and low confidence in public on the vaccine; over-dependence on the vaccine to curb and control the pandemic, in which we failed to earn confidence of public and academia. This may be due to lack of data, follow-up services and to produce omni-potent vaccines .Also led to the failure to address the serious adverse events, both in youth and elderly and win public confidence."

He went on to add, "As pandemic weaned off, the role and scope of the vaccine also weaned off by the government due to less availability in poor countries and ineffectiveness in the rich countries also due to vaccine hesitancy in most of the

countries. Few countries were producing and storing most of the vaccines, while the other countries did not even get the single dose for their healthcare workers and essential workers first vaccine. This led to global and regional disparity, questions of equity, equality along with availability and affordability came at the international level. So, the role of vaccines after the pandemic was over, became questionable as the industry was unsuccessful in delivering cheap vaccines to masses and poor countries."

Echoing similar views, **Ashok Bhattacharya, Global Health Care Consultant & Growth Enabler and Former Executive Director / Country Manager of Takeda Pharmaceuticals India** mentions, "We have witnessed that Serum Institute was under tremendous pressure to make Covishield available not only across the country but also in many other countries across the globe. Bharat Biotech had to respond to higher demands. High investments were made to increase the manufacturing capacity. The demand was significantly high and considering the magnitude of high infection rates coupled with government pressures for higher stock, the demand projections were more leading to higher production and inventory levels. With reduction in infection levels, there has been less interventions by the government.This has also led to idle capacity. It's time for the organisations not to dismantle the production facility but to look forward to R&D in the area of preventive medicine, develop newer vaccines and try maximum usage of the production capacities."

What next?

Vaccine manufacturers need to go back to the drawing board to take stock of what went wrong. Manufacturing millions of doses without anticipating what is in store for the future was a wrong decision by the manufacturers not only in India but also abroad.

The government also started the 'Har Ghar Dastak' campaign to propel the vaccination drive in November 2021. In May 2022, the second part of the campaign was launched to propel the vaccination drive in school, however, the public response was less.

We may come across many more diseases, more serious than COVID-19. Before launching any new vaccines, companies need to understand the future sentiments and anticipate the future outlook before joining the fray to launch a large number of vaccines.

The lesson learnt is that vaccine manufacturing plants should be decentralised and each country/continent should have its own vaccine manufacturing process, depending upon the local needs. There must be sharing of data and technology amongst all countries- poor or rich during the pandemic. Adverse Event Following Immunization (AEFI) should be monitored, informed, counselled to win public confidence. Latest data must be shared with the public and made available to academia to contest any false claim or mis-information. Free vaccination drives by the government for a longer period may have made the matter less serious.

Sanjiv Das

sanjiv.das@mmactiv.com