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## Gutting India's Public Sector Vaccine Makers

By: Sudip Chaudhuri

*India's once-thriving public vaccine manufacturers were absent during the pandemic. This was not due to a lack of capability. The problem has been active neglect by the government .*

During the second wave of the pandemic, with vaccine shortages and desperate attempts to increase production, India strongly felt the absence of state-run vaccine manufacturers. A country with a long tradition of public sector vaccine manufacturing had to rely on two private firms to supply Covid-19 vaccines.

While the private sector stepped up to increase the availability of vaccines, the pandemic has shown the need for a robust public sector to minimise the uncertainty associated with private investments, production, and pricing. Covid-19 may not be the last pandemic. In situations where mass vaccination is required, it is critically important to ensure uninterrupted supplies of vaccines at affordable prices.

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In the mid-1980s, when India had newly launched its Universal Immunisation Programme, the country's public sector units produced enough basic vaccines to make the country self-sufficient (Madhavi 2005; Lahariya 2014). Over the last few decades, though, the public sector has become a marginal player, while private vaccine manufacturers in India have made rapid progress. The installed capacities in the private sector are much more than that in the public sector. Except for anti-rabies vaccines, private firms are sole or dominant suppliers of all vaccines manufactured in India (Central Bureau of Health Intelligence 2020, Table 6.2.12). State-run vaccine manufacturers are either shuttered or in financial trouble, and just one unit, Human Biological Institute, has some presence in the vaccine sector.

The decline of state-run vaccine manufacturers is not due to any inherent deficiencies or lack of capability to deliver, but owes to underinvestment and neglect by the government. The technical knowledge built up over the years in India's state-run vaccine makers and research institutions was unique among developing countries. Had the government built on this base to upgrade technology and diversify into new vaccines, the public sector could have continued to be dominant. But this did not happen.

### Piggybacking on the public sector

India has 21 firms licensed to manufacture human vaccines. Of these, 14 are in the private sector and seven in the public sector. The government units include Haffkine Institute in Mumbai (established in 1899), Central Research Institute (CRI) in Kasauli (1905), Pasteur Institute of India (PII) in Coonoor (1907), and the BCG Vaccine Laboratory (BCGVL) in Chennai (1948).

These units laid the foundations of domestic vaccine manufacturing. CRI started with snakebite and typhoid vaccines and went on to develop vaccines for rabies, Japanese encephalitis, and yellow fever. BCGVL introduced several innovations to the BCG vaccine, including a freeze-dried form and extending its use for cancer therapy. Similarly, PII's work on the anti-rabies vaccine made treatment more affordable and convenient. PII diversified into the DTP group of vaccines and was the first to produce the Trivalent (Sabin) oral polio vaccine (PII 2020, 17).

The public sector units also include Bharat Immunologicals and Biologicals Corporation Limited (BIBCOL), established in 1989, Human Biological Institute (1998) and HLL Biotech Limited (2012). Apart from these vaccine manufacturers, India has 25 research institutes and laboratories involved in vaccine development.

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In the private sector, Biological E was the first to start vaccine manufacturing in India, in 1962. Serum Institute of India (SII) was set up in 1966, Panacea Biotec in 1984, and Bharat Biotech in 1996. Apart from them, local arms of multinational firms GSK and Sanofi import and repackage vaccines for sales (Ghosh 2019, 7-8).

The initial market for the private sector came from government procurement of vaccines for India's immunisation programme. Launched in 1978 with four vaccines — BCG, OPV, DPT, and typhoid-paratyphoid vaccines — the programme expanded in stages. Today it provides free vaccination for 12 diseases. (MoHFW 2021, 60-61).

The private sector also benefited from the expertise of state-run institutions. Technologies for manufacturing several vaccines marketed by private firms were provided or jointly developed by government laboratories. Most recently, Covaxin was developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR) and the National Institute of Virology, Pune (NIV). The country's first r-DNA Hepatitis B vaccine was developed by Shantha Biotechnics in close alliance with the Centre for Cellular and Molecular Biology (CCMB) and other government research institutes.

Other vaccine technologies developed at government laboratories and transferred to private firms include a leprosy vaccine (National Institute of Immunology, New Delhi and Cadila Pharmaceuticals); hepatitis-A candidates (NIV and Bharat Biotech); Rotavirus (ICMR and Bharat Biotech); a cholera vaccine (Institute of Microbial Technology, Chandigarh, National Institute of Cholera and Enteric Diseases, Kolkata, Indian Institute of Chemical Biology, Kolkata, and Shantha Biotechnics (Madhavi 2008, Table 2).

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Technical expertise flowed from state institutions to the private sector in other ways too. As the Javid Chowdhury Committee (2010) observed: “the experience they draw upon is largely through the technical staff of public sector units who are either retirees, or have been poached from public sector units” (p. 23).

For instance, the Poonawallas, the founders of SII, had no prior experience in vaccine manufacturing. They were in the business of racehorse breeding and owned the largest stud farm in the country. They used to donate retired horses to Haffkine Institute, which required the blood of horses to manufacture serum and vaccines. When SII entered the vaccine field, the firm recruited technical staff from Haffkine Institute. (Three of the Haffkine alumni are now [board members](#) at SII.) [GVJA Harshvardhan](#), a key technical functionary at Bharat Biotech, was earlier an employee of Pasteur Institute, where he worked for three decades on the development and production of vaccines.

## Suspending manufacturing

As late as the mid-2000s, public sector units were the predominant sources of vaccine supplies for the immunisation programme. (Javid Chowdhury Committee 2010, Annexure G). Yet, in 2008, the government suspended the licences of CRI, PII, and BCGVL as they were not compliant with Good Manufacturing Practice (GMP) standards, a set of safeguards and procedures to ensure product efficacy and safety.

India had established its GMP standards in 2001, and the vaccine units were supposed to implement them by 2005. The team which inspected the government units for GMP compliance did not recommend suspension of production, only corrective action (Javid Chowdhury Committee 2010). Yet the government promptly suspended the licences and displayed a lack of urgency to make them GMP compliant, suggesting it did not consider the public sector as strategic.

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With the suspension of the licences, production from the public sector ceased. Several states reported vaccine shortages, which had to be met by purchases from the private sector (Javid Chowdhury Committee 2010, para 5.3). Costs went up significantly, as vaccine prices doubled in 2008-09 and 2009-10 (Parliamentary Standing Committee 2009b, pp. 9-10).

Even as it was framing the standards, the government was aware that the public sector units did not conform to GMP. Yet, as two Parliamentary Standing Committees (2009a and 2009b) pointed out, hardly any funds were allocated to the units to upgrade. The three public sector units were under the health ministry and required government approval even for minor matters. Scientists and technical

persons neither had the necessary freedom to make decisions to upgrade technology and ensure compliance nor did they have recourse to funding.

The growth of these units thus depended on what those in the ministry did or did not do. The few initiatives undertaken exhibited a cavalier attitude. At CRI, a private firm was appointed to implement upgrades. Nine years and Rs 11.86 crores later, the firm pulled out, saying it lacked technical competence (Parliamentary Standing Committee 2009a, 3, 9).

When the manufacturing licences were suspended, the government's initial plan was not to revive manufacturing but to convert these units to testing laboratories or training units (Parliamentary Standing Committee 2009a, 11). However, under public pressure and parliamentary censure, the government in 2010 decided to revive the shut units and make them GMP compliant. The progress was extremely slow. It took about a [decade](#) for the units to [restart](#) manufacturing.

To compensate for the loss of production at the shut units, the government in 2008 had announced the setting up of a new integrated vaccine complex at Chengalpattu, Tamil Nadu. Funding for the project, though, was [approved only in 2012](#). Even when construction was completed in 2016, the government did not put in the additional investments needed to operationalise the plant. Instead, in 2017 the government decided to sell all its equity in the project (MoHWF 2021, 313).

The complex remains unused to date. In 2021, the government invited vaccine manufacturers to use the plant but received no responses. The government has also not yet responded to the [proposal](#) of the chief minister of Tamil Nadu to hand over the complex on lease to manufacture vaccines.

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The indifference displayed by the government towards the public sector units leading to their decline coincided with the rise of the private sector. As international organisations like UNICEF and GAVI expanded their efforts to immunise children worldwide, India's private vaccine makers made investments to tap the increased demand for vaccines. They set up plants and established manufacturing processes that complied with WHO standards, in order to prequalify for bids to supply those organisations. Between 1993 and 2021, 111 products — representing different doses of 28 types of vaccines manufactured in India — had been [prequalified](#). All but three products were from the private sector. (Haffkine Institute is the only public sector unit to obtain prequalification, for oral polio vaccines.)

As a result of this new market, India emerged as a leading manufacturer of vaccines, with a one-third [share](#) in the global market. The country exports vaccines to about 170 countries and is the largest supplier to international procurement agencies. Exports now account for more than two-thirds of the total volume of vaccines manufactured in the country. SII has become the world's [largest vaccine manufacturer](#), accounting for 28% of the global volume (the next largest is GSK, with an 11% share) and the fourth largest in value terms, with a 4% share.

## Reorienting policy

The strategic intent to expand and diversify, readily evident in the private sector, has been absent in the public sector. The current government has provided financial aid to private firms like SII and Bharat Biotech (Mani 2021, Annexure 3) but has been unwilling to invest in restarting large-scale public sector manufacturing.

The attitude of the government towards the public sector must change. It is a short-sighted policy to rely solely on the private sector. The growth of the private sector need not be and should not be at the cost of the public sector. A robust public sector is crucial to reducing supply uncertainty and controlling prices. A sizable presence in the vaccine sector will allow the government to directly influence supplies and meet public health needs. The government needs to be actively involved in running the public sector units and facilitating growth. With proper investment and a reorientation of official policies and attitudes, it is possible to revive and make the public sector a significant player.

*(A longer version of this article can be found [here](#) )*

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