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Reviving Public Vaccine Manufacturing in the BioE3 Era

By: Soumya Kanti Ghosh

India's BioE3 policy envisions nationwide biomanufacturing hubs to drive bio-innovation. However, a key unresolved issue is whether the hitherto ignored public sector vaccine manufacturers will secure a meaningful role within India's emerging sovereign vaccine value chain.

As India sets its sights on achieving a \$300-billion domestic bioeconomy by 2030, the government has [launched advanced biomanufacturing hubs](#) under the Biotechnology for Environment, Economy and Employment (BioE3) policy. These hubs are to be built across the country to turn India into a powerhouse of bio-innovation and to provide a shared platform for academic researchers, small and medium enterprises (SMEs), start-ups and industry. Amid these ambitious national goals, a pressing question remains-will India's public sector units (PSUs) manufacturing vaccine have a meaningful role in the evolving story of the country's sovereign vaccine value chain?

Rise and Downfall

Once the backbone of the country's immunisation efforts, PSUs making vaccines today stand at the margins of a market dominated by private giants. Before their downturn, the public sector supplied the bulk of essential immunisation doses, manufacturing 100% of BCG (Bacillus Calmette-Guérin), 78% of DT (Diphtheria-Tetanus), 64.3% of tetanus toxoid, and 59.1% of DPT (Diphtheria-Pertussis-Tetanus) between 2004 and 2008 (Choudhuri 2022). Currently, they cover only two diseases-anti-rabies vaccines, which are not included in the universal immunisation programme (UIP) but hold 60% of the market share, and DPT, which despite being under the UIP had, as of 2018-19, a market share of less than 29%.

While other manufacturers upgraded and complied, the PSUs continued to focus on older generation, conventional vaccines, and kept operating with outdated equipment and ageing infrastructure.

The dominance that once ensured stable pricing and reliable supply came to an abrupt halt in 2008, when three major PSUs-Central Research Institute (CRI), Kasauli; Pasteur Institute of India (PII), Coonoor; and BCG Vaccine Laboratory (BCGVL), Guindy-lost their manufacturing licences for non-compliance with good manufacturing practices (GMP). Most of these facilities had been established in or before the 1940s-1960s and were designed for high-volume production under earlier, more lenient good manufacturing norms.

By the early 2000s, however, good manufacturing practices requirements had become far more stringent, and the revised [Schedule M standards](#) (2001) mandated full compliance by 2005, including validated clean rooms, automated filling lines, upgraded equipment, robust documentation systems, and stringent quality controls.

While other manufacturers upgraded and complied, the PSUs continued to focus on older generation, conventional vaccines, and kept operating with outdated equipment and ageing infrastructure. Many lacked even basic clean-room environments to prevent cross-contamination; quality control was inadequate; documentation practices were weak; and data integrity failed to meet the ALCOA (attributable, legible, contemporaneous, original, accurate) requirements.

These technical shortcomings reflected deeper structural problems-chronic under-investment and delayed release of funds; limited managerial autonomy due to administrative rigidity; weak research and development (R&D) capacity; and minimal technology partnerships. Despite having been responsible for the bulk of India's essential vaccine supply, these units were ultimately unable to meet the good manufacturing practices benchmarks.

Self-reliance to Dependence

The shutdown of the three major PSUs triggered a sharp decline in domestic vaccine production capacity. Production of [BCG vaccine](#) fell from 923 lakh doses in 2004 to just [24 lakh doses](#) by 2021, and tetanus toxoid production dropped to 1.4% of national production before ceasing entirely in 2016. While demand within the UIP remained high, India increasingly relied on imports. [Vaccine imports](#) rose from 10.6% of total supply in 2007-08 to 62.5% by 2012-13, and the country's vaccine import penetration ratio (IPR) reached

17.23% by 2018-19 (Hooda 2023).

These setbacks underscored a broader structural vulnerability-when domestically owned public sector fallback capacity erodes, India's ability to secure uninterrupted supplies of essential vaccines is seriously compromised.

The fallout from the 2008 closure of PSUs was not only economic but also strategic. With the suspension of their manufacturing licences, India lost one of the major pillars of its sovereign vaccine capacity. The immediate impact was felt in the supply of Japanese Encephalitis (JE) vaccines. The Central Research Institute, which had earlier supplied JE vaccine doses to nine states, suddenly became unable to meet demand, and the resulting supply gap forced India to [import JE vaccines from China](#).

Over time, this dependence widened, extending to other essential vaccines as domestic supply continued to shrink. Even after licences were restored between 2010 and 2013, the PSUs struggled to regain their place in the vaccine market. The Central Research Institute, for instance, failed to secure procurement orders under the UIP because of inadequate fund allocation (Chaudhuri 2022) and slow upgrades to meet good manufacturing practices.

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Market Shift

To fill the vacuum, private manufacturers such as the [Serum Institute of India](#), Panacea Biotec, and Shantha Biotech stepped in. While this shift was essential to restore supply, it also created new vulnerabilities. One visible consequence was a sharp increase in the prices of vaccines covered under the UIP.

Following the 2008 closure of PSUs, in the subsequent years the price of the [BCG vaccine doubled](#) from Rs. 13 to Rs. 27-28 per dose; the price of the DPT vaccine rose from Rs. 11.80 to Rs. 23-23.5; the price of tetanus toxoid more than doubled; and the price of the Hepatitis B vaccine increased from Rs. 16-17 to Rs. 45-50 per dose, a rise of 100-200%. These surges strained government budgets and threatened the affordability of essential vaccines supplied under public programmes. Market-driven incentives also increased the risk that manufacturers would skew production towards high-value, non-UIP vaccines rather than essential routine immunisation needs.

The Covid-19 pandemic exposed the structural vulnerability created by over-reliance on private manufacturers. The Serum Institute of India, the largest vaccine supplier to the UIP, diverted much of its production capacity to Covid-19 vaccines, [delaying production of the human papillomavirus \(HPV\) vaccine](#). In the absence of a strong public sector counterpart, beneficiaries of routine immunisation were temporarily left unserved. This experience showed that a more balanced and resilient dual public-private ecosystem could have helped maintain continuity of non-Covid vaccines during such a crisis.

Revival Attempts

Reviving PSUs manufacturing vaccines is therefore not merely desirable but strategically essential. Public manufacturers help ensure the steady production of low-margin essential vaccines and maintain surge capacity. Their revival has the potential to bring long-term gains in public health security, equitable access to essential vaccines, price stability, and sovereign control during global disruptions.

Although modest, these achievements indicate that mission-mode programmes have the potential to catalyse the revival of PSUs making vaccines.

The government has attempted several revival initiatives over the past decade, but these have yielded only limited outcomes. One major step was the establishment of the Integrated Vaccine Complex (IVC) in 2012 at Chengalpattu, Tamil Nadu. With an investment of [around Rs. 800 crore](#) and a planned capacity of 585 million doses annually, it was a flagship effort to restore the public sector, yet the [facility failed to contribute](#) meaningfully to the surge in demand for Covid-19 vaccines.

By contrast, targeted efforts under [Mission Covid Suraksha](#), launched by the Department of Biotechnology, showed that carefully structured interventions can yield tangible gains. Through grants, technical support and collaborative arrangements, the programme enabled Haffkine Biopharma, Bharat Immunologicals, Biologicals Corporation Limited (BIBCOL), and Indian Immunologicals Limited (IIL) to augment their manufacturing capacity. It also facilitated good manufacturing practices-compliant pilot production at the Central

Research Institute and the BCG Vaccine Laboratory. Although modest, these achievements indicate that mission-mode programmes have the potential to catalyse the revival of PSUs making vaccines.

New Avenue

The [BioE3 policy](#) is a government initiative that provides a shared platform for small and medium enterprises, industry, and academic researchers to fast-track innovation. Its key features include promoting innovation-driven R&D, establishing biomanufacturing hubs, Bio-AI hubs, and biofoundries, and focusing on specific thematic areas to advance a green and sustainable bioeconomy. It also emphasises job creation and encourages public-private and multi-stakeholder collaboration, and is envisioned as an umbrella framework in which academia, small-scale private entities, and state-owned corporations can thrive, collaborate, co-develop solutions, and compete fairly.

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Under the BioE3 policy, the launch of high-performance biomanufacturing platforms across sectors such as biopharmaceuticals, bio-agriculture, bioservices, and bio-industrial applications presents an important opportunity for innovation in vaccine technology. This opportunity is particularly suitable for R&D and skill development within PSUs, which have been significantly weakened by unstructured and fragmented funding.

The planned biomanufacturing and Bio-AI hubs will provide access to cutting-edge infrastructure and open up opportunities for testing, validation, and pilot-scale manufacturing. R&D units can use these facilities for innovation, testing and small-scale initial production, allowing PSUs to avoid massive up-front infrastructure costs. These hubs can serve simultaneously as platforms for skill training and innovation, while existing government-supported schemes enable the building up of full-scale manufacturing capacity.

New Insights

These biomanufacturing hubs can be viewed as system-level infrastructure that supports the system building function policy of the BioE3 policy. Through the lens of the National Innovation System (NIS) framework (Kayal 2008), the BioE3 brings together actors like academic institutions, private sector firms, government missions, and public sector entities within a coordinated structure. The policy integrates R&D funding, infrastructure creation, skill development, and employment generation with innovation linkages like innovation centres and biomanufacturing hubs.

Such integration enhances knowledge diffusion, a core function of the National Innovation System framework, and addresses the historical isolation and capability gaps that had earlier limited PSU innovation.

This logic is further strengthened when examined through the quadruple helix innovation model (Schütz 2019), which emphasise collaborative overlaps between academia, industry, government, and civil society. The BioE3 design inherently promotes this configuration, where academia, industry (small, medium, and probably large) and government agencies are brought into shared platforms, while the visibility of national-level missions engages civil society through media.

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In this ecosystem, PSUs will shift from siloed producers to an integrated actor within a collaborative innovation network. The civil society engagement will enhance the legitimacy and outreach of vaccine-related innovations and technology, attracting investments and partnerships.

A useful precedent comes from the Netherlands, where the triple/quadruple helix model has been applied successfully in the agrifood sector. Here, Wageningen University & Research and Unilever work together on the Wageningen campus within a broader ecosystem supported by the government, knowledge institutions, non-governmental organisations, and start-ups to develop sustainable food production technologies. Such multi-actor collaboration can be cultivated for PSUs under the BioE3 policy.

Way Ahead

The BioE3 policy is a broad attempt to connect biotechnology with the economy, the environment, and employment. However, there is no dedicated institutional programme to link PSUs manufacturing vaccines with the BioE3 policy, which raises concerns about the sustainability of such partnerships.

Institutional models such as the Biotechnology Industry Research Assistance Council (BIRAC) illustrate what is possible through initiatives like the National Biopharma Mission and the BioNEST incubators, which have funded, trained, and enabled public-private consortia. Since the Department of Biotechnology is the main manager of the BioE3 policy, it could work with public sector units to develop collaborative projects focused on innovation in vaccine technology and skills development.

However, this will require prior institutional reforms, including modernising management policies, granting greater autonomy to boards, and strengthening mechanisms for retaining skilled talent. Once these structural issues are addressed, PSUs can integrate more effectively into the BioE3 ecosystem, make use of state-of-the-art infrastructure and forge strategic partnerships. By drawing on funding and grants such as Vigyan Dhara, these units will be better placed to attract private partners and to diversify their role beyond manufacturing essential vaccines under the UIP.

Soumya Kanti Ghosh is a NAST Fellow (2025-26) at the Takshashila Institution, and currently works as a Grants Adviser with the DBT/Wellcome Trust India Alliance.

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