

REVIVING THE WHITE TIGER

The 60 year old BCG Lab in Chennai, the 103 year old Central Research Institute (CRI) in Kasauli, and the 101 year old Pasteur Institute of India (PII) in Coonoor were closed down by the Government in January 2008 for failing to comply with good manufacturing practices (GMP) laid down by the WHO. The government planned to convert them into testing facilities; with vaccines to be produced in a proposed unit at Chennai, expected to be functional by 2012. This has resulted in a short supply of vaccines as the entire BCG for the country was being produced in the BCG lab and CRI was the only production center for the yellow fever vaccine in South East Asia. Other vaccines including DPT, anti rabies vaccine, typhoid vaccine are also hit. In view of the crisis, an expert committee headed by the Drug Controller General of India has submitted its recommendations for the revival of the 3 companies.

The current Indian market for vaccines is around Rs 1000 crore with a projected growth rate of 25%. But the space is dominated by vaccine majors like Glaxo SmithKline Beecham, Merck, Aventis Pasteur, Chiron and Hoescht. What went wrong with indigenous vaccine manufactures in India? The story is interesting. To protect their soldiers in India, the Britishers had established the above mentioned institutions in the early 1900's for development and manufacture of vaccines. In fact, David Semple first developed the anti rabies vaccine in CRI Kasauli. Post Independence, we lost the early advantage; research and development was neglected, and vibrant institutions became mere production units.

PII which had initially started producing OPV from seed virus procured from Sabin, abruptly stopped production. Today we import bulk OPV which is being bottled entirely by the private sector. In 1987, the Department of Biotechnology (DBT) established a modern vaccine production unit, Bharat Biologicals and Immunologicals Corporation Ltd. (BIBCOL) in Bulandshahar in Uttar Pradesh, a polio endemic area, to meet the

WHO's good manufacturing practices (GMP) norms. It began by packaging bulk obtained from Moscow and intended to produce indigenously within five years from the seed that was to be transferred from Russia. Until 2000, BIBCOL produced OPV and even supplied 70 million doses to UNICEF; it even made profits. But it was discontinued abruptly because the Moscow bulk was not WHO-pre-qualified and, as WHO regulations were now strictly enforced by importers, the product was rejected by international agencies. It was again revived and now the irony is that although BIBCOL is in the OPV business, it is merely repackaging bulk from the same source as the private players.

In 1989, the DBT established another state-of-the-art unit called Indian Vaccine Corporation Ltd. (IVCOL) in Gurgaon for the purpose of producing vero-cell-based IPV and measles vaccines using technology to be transferred by the French public sector unit, Institut Merieux, under the Indo-French Agreement. But, in spite of paying part of the fees for technology transfer, the project fell through because, in the meanwhile, the French government sold the company to a Canadian firm.

A 2005 paper in the journal PLoS Medicine states: "The inability of the Indian public sector to recover from its mounting failures to achieve self-sufficiency and self-reliance in primary vaccines is also related to liberalization and globalization of the Indian economy. It is no longer fashionable to produce vaccines in the public sector in India, let alone try and revive failing public sector units, even if essential vaccines are not available in the private sector".

The challenge remains — to transform tired government institutions into successful and internationally competitive units. (*The Economic Times* 7 January 2009, *The Times of India* 18 Dec 2008, *Frontline* April 11, 2008).

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