

CHAPTER I: DEPARTMENT OF BIOTECHNOLOGY

Bharat Immunologicals and Biologicals Corporation Limited

1.1.1 Underutilisation of Plant and Machinery

Inadequate planning and implementation of Oral Polio Vaccine project by the Bharat Immunologicals and Biologicals Corporation Limited resulted in continuous underutilisation of plant and machinery besides infructuous capital expenditure of Rs.7.80 crore.

Bharat Immunologicals and Biologicals Corporation Limited (Company) was incorporated (March 1989) under Department of Biotechnology (DBT), Ministry of Science and Technology with the objective of indigenous production of Oral Polio Vaccine (OPV) for National Immunisation Programme under National Technology Mission on Immunisation and Research & Development of new vaccines. The project was envisaged as an integrated project including formulation and blending (Phase-I) as well as indigenous production (Phase-II) of OPV. As per Detailed Project Report (DPR), the estimated cost of the project was Rs.28.70 crore¹. The commercial production was to start from imported bulk vaccine formulation (raw material) by way of blending and indigenous production of raw material was to be started concurrently. The production of OPV was to be switched over to indigenous production (raw material and OPV) completely based on domestic facility. Production from imported bulk vaccine formulation and indigenous production was to be commenced from 1990-91 and 1991-92 respectively, which was revised (July 1992) to 1993-94 and 1994-95.

The commercial production of OPV through imported bulk formulation started in 1995-96, after a delay of six years. The production capacity was 100 million doses for indigenously produced OPV and 600 million doses², if OPV is produced through blending of imported formulation. Indigenous production (Phase-II) could not take off due to the conditions imposed by Ministry of Environment and Forests that monkeys required for production and testing should not be procured from contractors and should only be procured from Central Drug Research Institute (CDRI), Lucknow or the Company should have its own breeding house. CDRI expressed its inability to supply required number of monkeys and the Company had not planned for any breeding house in initial project proposal. Since indigenous production of OPV could not take off, the Company continued blending process of imported bulk vaccine formulation to produce OPV.

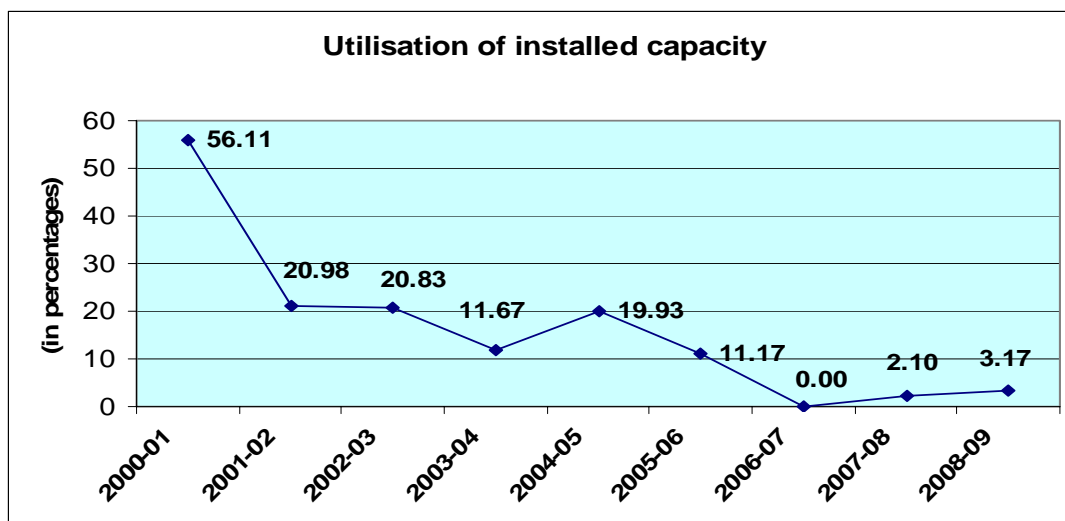
In October 2002, World Health Organisation (WHO) revised criteria for Vaccine Supplier Qualification (VSQ). This was to be completed by the end of 2005. To meet WHO requirement the Company started (June 2006) upgradation of its infrastructure and completed the same in August 2007.

¹ Revised to Rs.37.70 crore in July 1992

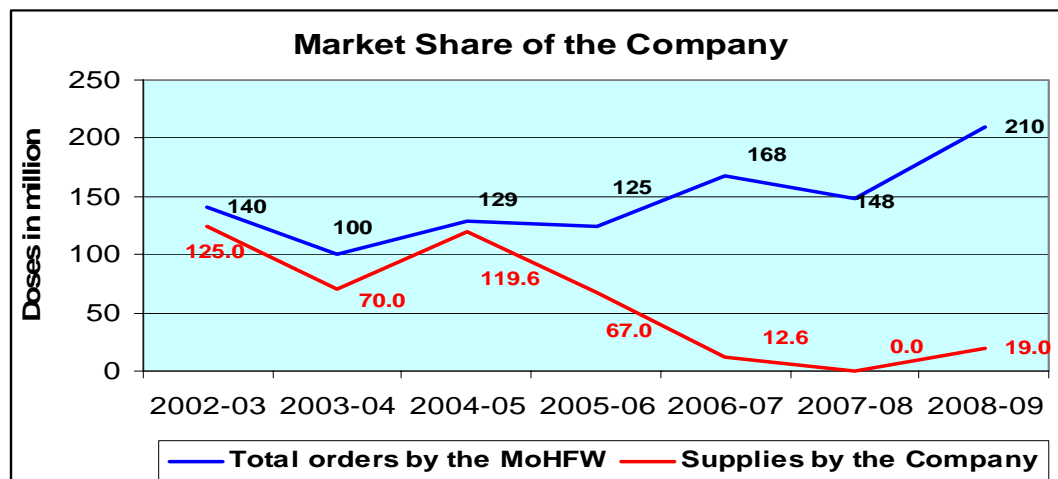
² From 2002-03 and it was 480 million doses from 1999-2000 to 2001-02

It was noticed in audit that:-

- The utilisation of the blending capacity had been declining since 2000-01. It fell to nil in 2006-07 and thereafter ranged between a meager two and three *per cent* as could be seen from the following chart: -



- The Company made an investment of Rs.44.33 crore (Gross Value of assets) in plant, machinery and other assets up to 31 March 2009 in both the phases including an expenditure of Rs.1.59 crore on construction of monkeys and animal houses in Phase-II, which was unfruitful, as Phase-II of the project could not begin.
- The up-gradation / modification of plant in line with the WHO requirement could only be completed in August 2007, after a delay of more than two years of deadline of 2005. Meanwhile, WHO removed OPV from its priority list of vaccines resulting in entire capital expenditure of Rs.6.21 crore on up-gradation of plant becoming infructuous.
- The Company was unable to get adequate supply orders from Ministry of Health and Family Welfare (MOHFW) even after fulfilling requirements of WHO and the Indian Drugs and Cosmetics Act, 1940 as could be seen from the following chart showing the total quantity of OPV purchased by the MOHFW and share of the Company which was declining from 2004-05:-



- The Company also failed to take timely action to diversify its product portfolio despite knowing the facts in March, 2000 that production of OPV was not viable because Polio virus was expected to be eradicated completely in next few years. Diversification of product portfolio was done after a delay of eight years in 2008, when it started producing dispersible Zinc tablets.

In response, the Ministry stated (September 2009) the following:-

- The Phase-II activity of bulk production of OPV could not be started because of conditions imposed by Ministry of Environment & Forests regarding procurement of monkeys for production and testing.
- At the time of establishment of the Company, there were no private OPV manufacturers. Subsequently, private OPV manufacturers entered the market and started competing with the Company. Further, due to mandatory tendering procedure laid down by Government of India, the supply orders for full capacity of the Company could not be obtained from MOHFW.
- To increase the viability and profitability of the Company and to impose technical and professional competence, the DBT was considering transfer of Management to HLL Lifecare Limited which was another Public Sector Undertaking (PSU) under the administrative control of MOHFW.

Reply of the Ministry is not convincing in view of the following:-

- There was lack of foresight on the part of the Company as well as Ministry as basic issues like availability of required number of monkeys and other animals for testing and development of bulk raw material for indigenous production and restriction, if any, from any other Ministry were not addressed properly in DPR, which not only resulted in abandonment of Phase-II, i.e., indigenous production of OPV but also non-achievement of the basic objective, for which the Company was incorporated.

- The OPV blending capacity of 480/600 million doses remained underutilised since inception of the Company. Besides delay in fulfilling WHO requirement, entire expenditure of Rs.6.21 crore incurred on this account became infructuous in view of the fact that WHO removed OPV from its priority list of vaccines in January 2007.
- The private players had entered the market in 1992-93 when the Company started producing OPV and to say that as a result of their entry supply orders for full capacity could not be obtained signifies that the Company was not able to produce OPV profitably even after so many years, and consequently, remained an inefficient producer of OPV. Also, diversification of product portfolio should have been done much earlier than the 8 years taken by the Company.

Thus, first due to lack of proper planning and implementation of the project for production of OPV, next due to delay in fulfilling WHO requirements and later, inability to procure adequate supply orders and lack of diversification of product portfolio; all led the plant to remain under-utilised since inception. This resulted in inefficient capital investment of Rs.44.33 crore, of which Rs.7.80 crore was infructuous expenditure on construction of monkey houses (Rs.1.59 crore) and up-gradation/modification of plants (Rs.6.21 crore).