

CHAPTER VIII : MINISTRY OF HEALTH AND FAMILY WELFARE

8.1 Unfruitful expenditure on construction of sub-standard laboratories

Even after nine years of award of work, Ministry failed to ensure renovation/upgradation of laboratories of Central Research Institute, Kasauli to meet the requirements of current Good Manufacturing Practices (cGMPs) for safe production and testing of vaccines. The facilities created at the cost of Rs. 11.86 crore could not be put to use due to sub-standard construction/not meeting cGMPs requirements, thus rendering the entire expenditure unfruitful. No action was taken against HSCC, the consultant and executing agency, for faulty execution of the project.

Ministry of Health and Family Welfare sanctioned a project for renovation/upgradation of laboratories of Central Research Institute, Kasauli (CRI) in December 1996 at a cost of Rs. 4.50 crore to meet the requirement of current Good Manufacturing Practices (cGMPs) for safe production and testing of immunobiologicals. In September 1997 Ministry appointed Hospital Services Consultancy Corporation (India) Ltd (HSCC) as the project implementation authority to carry out preliminary survey, prepare drawings through specialised agency and rendering project implementation services at a fee of 12 *per cent* of the project cost. An agreement was signed between CRI and HSCC in March 1998. The project started in April 1998 and was scheduled to be completed in 2½ years.

During the currency of the Project, CRI in November 1999 submitted a revised project 'Renovation/Upgradation of Triple Vaccine Manufacturing and Quality Control Facility' at a cost of Rs. 9.86 crore to provide for expansion of manufacturing for advanced version of Petrusis vaccine and incorporation of inbuilt quality control, research and development of laboratories which was approved by the Ministry in March 2000 without stipulating any specific date of completion.

In August 2001, an assessment of the upgradation of the facilities was made by the office of Drug Controller General (India) at the request of CRI. It reported that the building for the laboratory did not fulfil the requirement of cGMPs and noticed a number of shortcomings including non-construction of separate premises for the production of different vaccines, non/faulty provision of internal system of laboratories, etc. A committee consisting of Senior Officers of CRI in August 2002 also observed in their report a number

of shortcomings in the project apart from pointing out additional expenditure of Rs. 2.02 crore over and above the approved cost of Rs. 9.86 crore. To regularise the extra expenditure and remove the defects, Ministry issued a revised project sanction of Rs. 13.29 crore in August 2003 with stipulation to complete the work within six months. CRI had made a progressive payment of Rs. 11.86 crore to HSCC from April 1988 to March 2006 for this project. The work was held up after August 2004 as a result of deadlock between CRI and HSCC over sub-standard execution of work/non-completion of work and non-release of balance amount of Rs. 1.43 crore to HSCC. A committee of officers, constituted by Ministry of Health in November 2005 after visiting the building concluded that the premises built for triple vaccine production was not suitable for production as per cGMPs. The work was lying incomplete as of April 2007. The case points out a number of deficiencies in planning and execution of the project as discussed below:

- (i) No specific date was stipulated by the Ministry for completion of the revised project. This shows lax attitude of the Ministry towards early completion of the project.
- (ii) The Ministry had sanctioned the revised project at the cost of Rs. 9.86 crore. The executing agencies incurred additional expenditure of Rs. 2.02 crore over and above the sanctioned cost without obtaining prior approval. The additional cost had to be subsequently regularised by a sanction from the Ministry. This indicates lack of monitoring, ineffective financial control and poor accountability in the CRI which allowed executing authorities to incur expenditure much beyond the sanctioned costs.
- (iii) The defects were pointed out as early as August 2001 but it took a period of one year for CRI to take up the matter with the Ministry and another one year by the Ministry to approve the proposal for rectification of defects.
- (iv) The work is held up after August 2004 for last three years but neither CRI nor Ministry took concrete steps either to resolve the deadlock with HSCC or to get the work executed from another agency to achieve the cGMPs objectives.
- (v) There were serious slippages and failures on the part of HSCC to execute the project as per contract conditions. The contract signed with HSCC clearly stipulated that the upgraded facilities should comply with cGMPs requirements. Despite significant cost overrun from initial cost of Rs. 4.50 crore estimated in 1996 to Rs. 11.86

crore already incurred up to 2006-07, HSCC could not ensure execution of the project as per cGMPs requirements even after nine years of award of contract. The HSCC's failure to deliver services and execute work to comply with the cGMPs standards rendered the entire expenditure unfruitful and led to non-achievement of the objectives of the project.

Despite serious defaults on the part of HSCC to complete the project timely as per contract specifications, Ministry failed to initiate action against HSCC for rendering poor quality of services.

Thus, the objective of cGMPs remained unachieved even after ten years of sanction of the project due to inept planning and failure of CRI to get the defects in building removed inspite of incurring an expenditure of Rs. 11.86 crore. The matter needs investigation for fixing responsibility.

Ministry while admitting the facts (April 2007) stated that they were seized of the matter and steps were afoot for fixing the responsibility and holding the inquiry against the officers responsible for the lapse.