PARLIAMENT OF INDIA

RAJYA SABHA

43

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

FORTY-THIRD REPORT

ON

ACTION TAKEN BY THE DEPARTMENT OF HEALTH AND FAMILY WELFARE ON THE RECOMMENDATIONS/ OBSERVATIONS OF THE COMMITTEE CONTAINED IN ITS THIRTY-EIGHTH REPORT ON MAJOR ISSUES CONCERNING THE THREE VACCINE PRODUCING PSUs, NAMELY, THE CENTRAL RESEARCH INSTITUTE (CRI), KASAULI, THE PASTEUR INSTITUTE OF INDIA (PII), COONOOR, AND THE BCG VACCINE LABORATORY (BCGVL), CHENNAI.

(PRESENTED TO THE RAJYA SABHA ON 4th AUGUST, 2010)
(LAID ON THE TABLE OF LOK SABHA ON 4th AUGUST, 2010)

RAJYA SABHA SECRETARIAT
NEW DELHI

AUGUST, 2010/SRAVANA, 1932 (SAKA)

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COMPOSITION OF THE COMMITTEE (2009-2010)

RAJYA SABHA

1. Shri Amar Singh - **Chairman**
2. Shrimati Viplove Thakur
*3. Dr. Radhakant Nayak
4. Shri Janardan Dwivedi
5. Shri Balbir Punj
6. Dr. Prabhakar Kore
7. Shrimati Brinda Karat
8. Shrimati Vasanthi Stanley
@9. Dr. M.A.M. Ramaswamy
#10 Dr. Anbumani Ramadoss

LOK SABHA

11. Shri J. M. Aaron Rashid
12. Shri Ashok Argal
13. Shrimati Sarika Devendra Singh Baghel
14. Shri Vijay Bahuguna
15. Dr. Chinta Mohan
16. Shrimati Tabassum Hasan
17. Dr. Sanjay Jaiswal
18. Shri S. R. Jeyadurai
19. Dr. (Shrimati) Kruparani Killi
20. Shri N. Kristappa
21. Dr. Tarun Mandal
22. Shri Datta Meghe
23. Dr. Jyoti Mirdha
24. Shrimati Jayshreeben Patel
25. Shri R.K. Singh Patel
26. Shri M. K Raghavan
27. Dr. Anup Kumar Saha
28. Shrimati Meena Singh
29. Dr. Arvind Kumar Sharma
30. Shri Pradeep Kumar Singh
31. Shri Ratan Singh

SECRETARIAT

Shrimati Vandana Garg, Additional Secretary
Shri R.B.Gupta, Director
Shrimati Arpana Mendiratta, Joint Director
Shri Dinesh Singh, Assistant Director
Shri Satis Mesra Committee Officer

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* ceased to be a member w.e.f 01/7/2010
@ ceased to be a member w.e.f 30/6/2010
# ceased to be member w.e.f 29/6/2010

PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorised by the Committee on its behalf, do hereby present this Forty-Third Report of the Committee on the action taken by the Department of Health and Family Welfare on the recommendations/ observations of the Committee contained in its Thirty-Eighth Report on 'Major issues concerning the three vaccine-producing PSUs, namely, the Central Research Institute (CRI), Kasauli, the Pasteur Institute of India (PII), Coonoor and the BCG Vaccine Laboratory (BCGVL), Chennai.'

2. The Committee had made an extensive study on the Functioning of the three vaccine-producing PSUs, namely, the Central Research Institute (CRI), Kasauli, the Pasteur Institute of India (PII), Coonoor and the BCG Vaccine Laboratory (BCGVL), Chennai', the reasons for their closure in the 34th Report. Thereafter, the Committee also considered the Action Taken Note on the Report received from the Department of Health and Family Welfare and finding that a number of important issues still remained unanswered, the Committee presented its 38th Report highlighting those major issues on which the Committee wished to make further emphasis and obtain the Government's response. Keeping in view of the adverse impact of the closure of the three vaccine-producing units on the vaccine availability in the country, and consequently the Universal Immunization Programme, the Committee had recommended revival of the three vaccine producing PSUs at the earliest in both its aforesaid Reports. Like in the previous instance, the Ministry furnished a much delayed Action Taken Note on the 38th Report of the Committee.

1. The Committee had also taken note of the fact that a Committee had been set up under the Chairmanship of Shri Javed Chaudhary, former Secretary under the Ministry of Health and Family Welfare, to determine the reasons for the suspension of the manufacturing license of the three vaccine producing units and to draw a road-map for their revival. An Interim Report had been presented by this Committee to the Ministry

on the 5th February, 2010. The Committee had the opportunity to go through this report and found that it *inter-alia* confirmed the apprehensions highlighted and the conclusions arrived at by the Committee in its 34th and 38th Report.

4. The Draft Report, prepared on the basis of the feedback received from the Department, was considered and adopted by the Committee on the 6th July 2010.

5. For facility of reference and convenience, observations and recommendations of the Committee have been printed in bold letters in the body of the Report.

NEW DELHI
***6th July*, 2010**
15 Asadha, 1932 (Saka)

AMAR SINGH
Chairman,
Department-related Parliamentary
Standing Committee on Health and Family Welfare

Report

I INTRODUCTION

1.1 During the course of scrutiny of Demands for Grants, 2008-09 of the Department of Health and Family Welfare, the Department-related Parliamentary Standing Committee on Health and Family Welfare had taken note of suspension of manufacturing license of the three vaccine producing PSUs, namely, the Central Research Institute (CRI), Kasauli, the Pasteur Institute of India (PII), Coonoor, and the BCG Vaccine Laboratory (BCGVL) Chennai. In view of the adverse impact of such a move on the vaccine availability in the country, and consequently the Universal Immunization Programme, the Committee had recommended revival of the three vaccine producing PSUs at the earliest. Since then, the Committee has been vigorously pursuing with the Ministry the issue of making these units functional at the earliest. An extensive analysis of the background leading to closure of these units, which have remained major contributors of life-saving vaccines for our new-born children for decades, inherent constraints being faced by them, adverse fallout of their closure, specially on the Universal Immunization Programme and the very apparent lack of initiative on the part of the Central Government made by the Committee resulted in an exhaustive report, i.e. 34th Report presented to Parliament on the 18th February, 2009. However, instead of a pro-active follow-up action on the part of the Ministry, it took seven months for it to come out with its Action Taken Note.

1.2 The Action Taken Note confirmed Committee's apprehensions that there was sheer lack of will on the part of the Ministry for reviving the three vaccine producing PSUs. Major part of the Action Taken Note seemed to display a lack of commitment on the Ministry's part. The Committee strongly felt that presenting an Action Taken Report in the routine manner would serve no purpose as quite a few pertinent issues had remained unanswered. The Committee, accordingly, interacted with the Secretary, Health and Family Welfare at its meeting held on the 26th October, 2009. A detailed questionnaire covering all conceivable aspects was also forwarded to the Ministry by the Committee. Based on the analysis of the Action Taken Note furnished

by the Ministry, deposition of the Secretary and the response to its questionnaire, the Committee presented to the Parliament its 38th Report on major issues concerning the three vaccine producing PSUs, namely the Central Research Institute (CRI), Kasauli, the Pasteur Institute of India (PII), Coonoor, and the BCG Vaccine Laboratory (BCGVL) Chennai on the 18th December, 2009.

1.3 The Action Taken Note on a Parliamentary Committee Report is to be submitted by the administrative Ministry within a period of three months of its presentation to the Parliament. However, as in the case of 34th Report, the Ministry took more than five months to furnish its ATN on the 38th Report, which was received in the second week of June, 2010 and that too, after constant reminders by the Committee at different levels. **The Committee had hoped that the Department would come out with follow-up action in the true sense along with clear cut plan of action for the future. Unfortunately, the Committee is surprised to observe that the feedback furnished by the Ministry belies the very idea of Action Taken Note. The Committee's pointed recommendations/observations on quite a few pertinent and crucial issues have either simply remained unanswered or are circumlocutory in nature and lack conviction. Not only has this, in response to a number of recommendations/observations on entirely different aspects, the Ministry has simply repeated the same reply.**

1.4 The Committee would take the opportunity to recall the interaction which took place with the Secretary, Health and Family Welfare on the 17th February, 2010. The Committee was informed that based on its 38th Report on the subject, orders for revocation of suspension of manufacturing license of the three vaccine-producing units had been issued by the Minister so as to allow them to use the existing finished as well as the raw material for production of vaccines, subject to their being fit for consumption. The Committee was further informed that the case for revoking the suspension on a formal basis for three years and to restore full-scale production was under consideration. The Secretary also assured the Committee that CRI, Kasauli would be operational by June, 2010. With regard to PII, Coonoor, no final decision had

been taken at that point of time. Lastly, the BCG Vaccine Laboratory, Guindy was proposed to be shifted to the new Vaccine Complex coming up in Chennai. The Committee's attention was also drawn to the Interim Report given by the Javed Chowdhary Committee, recommending three years' time for the three units to start production. It was emphatically pointed out that vaccines could not be allowed to be produced in sub-standard institutes which were to be made GMP compliant. Also, the Vaccine Complex going to be constructed at Chennai at the cost of Rs. 700 crore would be meeting global standards. The Committee had then directed the Secretary to submit the Action Taken Note without further delay in view of emerging shortage of vaccines and their increasing prices.

1.5 Against this background, an attempt has been made to analyse the much-delayed Action Taken Note submitted by the Ministry on the 38th Report of the Committee. The Committee also had the opportunity to study the Interim Report submitted by the Javed Chowdhary Committee on the 5th February, 2010. This Committee was set up by the Government on the 25th September, 2009 to review the reasons for the suspension of manufacturing licenses of the three units and also to review the road map for their revival. The Committee was to give its Report within three months. However, only an Interim Report could be submitted by it on the 5th February, 2010, with a request to submit its final report by the 25th March, 2010. The Committee is not aware about any further report given by this Expert Committee. **However, on a perusal of the Interim Report, the Committee is somewhat surprised to observe that the conclusions drawn by the four-member Expert Committee (including two technical members having expertise in the product/ manufacturing standards of drugs and pharmaceuticals), are not only similar to its findings but also emphatically establish that the decision to suspend the manufacturing licence of the premier vaccine-producing institutes was not only ill-advised but has also resulted in acute shortage of vaccines, - the most essential component of Universal Immunisation Programme. The Committee has the following observations/ recommendations to make in the succeeding paragraphs.**

II. REVIVAL OF VACCINE -PRODUCING PSUs

2.1 The Committee had made an attempt to analyse the sequence of events so as to understand whether any initiative worth-mentioning had been undertaken for the revival of the three vaccine-producing units after the Drug Controller General's orders for suspension of their manufacturing license coming into force w.e.f. 15th January, 2008. However, the feedback furnished by the Ministry clearly indicated a bleak future for the three units. The only positive development was the setting up of the Javed Chowdhary Committee on the 25th September, 2009. The Committee had made the following observations in its 38th Report:

> The above sequence of events since the suspension of manufacturing licenses of the three units in January, 2008 clearly establishes the fact that their revival is not envisaged by the Government in the near future. Rather every attempt has been made to create hurdles so as to ensure that the process of making them GMP compliant continues for long and manufacturing process of major vaccines of UIP at these age-old PSUs remains suspended. The Committee takes note of the fact that the Expert Committee headed by the Drug Controller General of India, the supreme authority for quality control of drugs in the country has expressed its inability at arriving at a decision about the status of the three units inspite of persistent efforts by the Ministry. The Committee wonders how the Director General Health Services who is directly under the control of the Ministry could simply negate the report of the Expert Committee. The Committee is not aware of the fate of the latest Committee (Javed Chowdhary Committee) set up by the Ministry. But, the fact remains that the time is running out for the three vaccine producing units. (Para 2.3)

Action Taken by the Ministry

Invoking provisions of the Drugs and Cosmetics Act, 1940 and Rules, the recommendations contained in the Interim Report of Shri Javed Chowdhary Committee and taking into account substantial compliance status furnished by the appellant Laboratory, evaluation of impact on the post-suspension era in terms of the availability and prices of these vaccines on the Universal Immunization Programme and the above all public interest involved in generating maintaining its own captive production capacity in the Government sector, revocation of suspension of the licenses of the Institutes have been ordered on 26th February, 2010. These Institutes have also been asked to ensure that the production line is made fully compliant with GMP standards within three years.

Central Research Institute (CRI), Kasauli has planned the schedule for supply of DPT group of vaccines during 2010-11 as follows:-

Month	Name of the Vaccines (In lakh doses)		
	DPT	TT	DT
April	30	20	-
May	30	30	-
June	-	60	-
July	-	60	-
August	-	60	7
September	-	80	-
October	-	80	-
November	50	20	-
December	50	20	-
January	50	20	-
Feburary	50	20	-
March	50	20	-
Total	310	490	7

Pasteur Institute of India (PII), Coonoor has also anticipated following schedule for supply of DPT vaccine by December,2010 onwards. In the meantime, some technical activities like Calibration, validation of functional equipments, repairing of defective equipments, procurement of raw material, chemicals etc. would be completed:-

Name of Vaccine	Name of Month	Quantity(In Million Doses)
DPT Vaccine	December, 2010	8.00
	January, 2011	8.00
	February, 2011	8.00
	March, 2011	8.00
	TOTAL	32.00

2.2 Before giving its observations on the action taken by the Ministry for revival of the three units, the Committee would like to draw the attention to the Interim Report of Javed Chowdhary Committee which has expressed serious reservations on the very motive behind such a move, in the following manner:

"1.10 From the records it appears that the final decision to suspend the license was taken by the DCGI after extended consultations with the Ministry. The examination of the issue in the Ministry was extremely circumlocutory and scattered over several files. An explicit decision has not been recorded at any place based on an analysis of the issues. At one point of the record it is cryptically stated that the Minister, Health and Family Welfare has approved the issuance of the show cause notices for suspension of the licenses. This note is signed by everyone in the administrative line-of-command including the Minister. However, as stated earlier, there is nothing substantial on record analyzing the grounds on which the decision was taken".

2.3 The above observations clearly indicate that the decision for discontinuance of vaccine production was not guided by sound reasoning. The Committee observes that finally the three vaccine producing PSUs i.e. CRI, Kasauli, PII, Coonoor and BCGVL, Guindy, which have been the mainstay of vaccine production and supply in the country, have been conferred a new lease of life. The Department has informed that production of DT and TT vaccines at CRI, Kasauli was to start from the month of April, 2010. The Committee would have appreciated if specific feedback about the actual production had been furnished by the Ministry. Similarly, production of DPT vaccine at PII, Coonoor is anticipated to begin from December, 2010. The Committee, however, finds that although suspension of manufacturing license of BCGVL, Guindy also stands revoked, the Ministry has remained silent as regards the revival of production schedule at this unit. The Committee would have appreciated if production had started here also.

2.4 The Committee would like to quote from the Interim Report with regard to the status of manufacturing facilities at the three units:

> "7.1 The last detailed inspection report was submitted in early January, 2008, after the receipt of the reply from the units to the show cause notice, and immediately prior to the suspension of the manufacturing licenses. Out of the total of 129 deficiencies raised in the reports, about 71 observations are of a minor nature, not significantly affecting the manufacturing standards. Some 58 others require improvement or upgradation - walls not having a smooth surface; junctions, corners, window/ door frames not being smooth and dust free; animal house requiring minor improvement; SOPs requiring revision; need for introduction of new documentation; need for calibration of different equipments; separation of different work areas; etc. About 60% of this second category of work has already been completed. The remaining work in this category can comfortably be completed within two months.
>
> 7.3 The existing production lines in the three units, as upgraded after completion of some incomplete works, can safely be used till the new production lines are commissioned. The Committee are of the considered view that it would be absolutely safe and in public interest, to restart the manufacturing activities in the existing production lines with immediate effect. More explicitly, it is the considered view of the Committee that the

operation of the units would, in the totality of the prevailing circumstances, be in compliance with the GMP standards."

2.5 The above analysis is self-explanatory about the present status of the three vaccine-producing units and establishes beyond doubt their manufacturing capacity. The Committee is happy to note that its assessment about the circumstances leading to the closure of the premier vaccine-producing units and urgency for their revival has been emphatically endorsed by the fact-finding Committee appointed by the Ministry. The Committee would have appreciated if the Ministry was more forthcoming while furnishing details regarding the progress made in the manufacturing status and quantum of vaccines produced from February onwards. Mere statement about planned and anticipated schedule of vaccine supply at these units not only falls much below the expectation but also indicates that the Ministry has failed to show any pro-active action so far. The Committee, therefore, once again reiterates that the Ministry has to vigorously monitor the functioning of these units so as to ensure the optimum utilization of their manufacturing capacity.

INTEGRATED VACCINE COMPLEX, CHENGALPATTU.

2.6 The Committee had made the following observations in its 38th Report in the context of the proposed Vaccine Complex at Chengalpattu:

> What gives credence to Committee's apprehensions is the background for setting up the Integrated Vaccine Complex at Chengalpattu (TN) and progress made so far. On a specific query, the Committee was informed that capability of HLL Lifecare Limited, a 'Mini Ratna' Public Sector Enterprise in implementing Healthcare projects, technology assimilation and expertise in vaccine business were the criteria for entrusting the company with the project. The Committee is, however, surprised to note that the only expertise of HLL Lifecare Limited in vaccine business so far has been marketing of Hepatitis B and Typhoid vaccines from 2005, followed by recent entry into marketing for Rabies Vaccine (Human) and sourcing agent for Government of India for the import and supply of JE vaccines since 2006. Technology transfer discussions with Denmark, Korea and Belgium based Institutes and positioning of a project team are the technology assimilation credited to the company. (Para 2.4)

The Committee has also been informed that the first phase of the IVC project focusing on formulation facilities is expected to start in January, 2010 and to be completed in December, 2012. The second phase on bulk production units is expected to start in September, 2010 and to be completed in December, 2012. The Committee can, therefore, only conclude that at least for the next three years, supply of vaccines as per the requirements of the entire country will be met mainly by the private sector. Not only this, the quantum of manufacturing of UIP vaccines like DPT (100 million doses), TT (200 million doses), BCG (100 million doses), Measles (100 million doses), Hepatitis B (40 million doses) and Pentavalent combination vaccines (100 million doses) establishes the fact that the fate of the existing PSUs is sealed. (Para 2.5)

Action Taken by the Ministry

Other than the three vaccine manufacturing Institutes which were manufacturing vaccines for the Govt. Programmes, there are no Institution other than M/s HLL Lifecare Ltd under the Ministry of Health and F.W. capable of taking up the assignment for establishing of IVC and revival of CRI, Kasauli. HLL Lifecare Ltd has also engaged M/s NNE Pharmaplan, a reputed International Consultant based in Copenhagen, Denmark for setting up of IVC and revival of CRI, Kasauli.

Central Government in exercise of its powers under Sub rules (3) of Rule 85 of the Drugs and Cosmetics Rules, 1945 have ordered revocation of suspension of the licenses of these Institutes vide order No. X.11035/2/2010-DFQC dated 26/2/2010. The Institutes may start functioning and produce the relevant vaccines which they were producing earlier before suspension of the license. Necessary schedule has been planned for DPT group of vaccines to be supplied during 2010-11 by CRI, Kasauli.

2.7 The Committee notes that as per the information furnished by the Department, HLL Lifecare Ltd is the only agency in the country capable of executing the ambitious project of Integrated Vaccine Complex at Chengalpattu and presently, it has engaged M/s NNE Pharmaplan, a reputed International Consultant based in Copenhagen, Denmark for setting up of IVC and revival of CRI, Kasauli.

2.8 The Committee would like to point out that it has no objection to establishment of well-equipped vaccine manufacturing units meeting international standards in the country. However, that cannot be at the cost of our age-old premier units fulfilling the vaccine requirements of the country for the past hundred years or so. The foremost objective before the Committee is to ensure availability of

cheap and affordable health care for the infants and children in the country, - in this case availability of vaccines at affordable prices which was being accomplished by these units so far. The Committee would like to point out that PII, Coonoor had been issued the ISO 9001:2000 Certificate in February, 2003 which was valid till 2006. Similarly, BCG Vaccine Laboratory, Guindy had obtained a certificate under ISO 9001:2000 in October, 2001 which was extended upto January, 2007. Nobody would deny the fact that ISO certification implies recognition of a high standard of management systems in the establishment. With the limited experience and exposure to implementing health care projects in the country, the Committee has had its own apprehension regarding HLL Lifecare Ltd's ability to give a final shape to the Integrated Vaccine Complex project. The Committee is not aware whether the selection of M/s NNE Pharmaplan has been based on its experience and expertise in the field of setting up of scientific infrastructure as required under the IVC project. The Ministry has chosen to remain silent on the progress made in the first phase of the IVC project which was to take off in January, 2010. From the time-line projected by the Ministry about the completion of this complex, it is anticipated to be completed by December, 2012.

2.9 As pointed out by the Committee earlier, vaccine requirements of the country will be mainly met by the private sector at least during this period of three years. This position has been further complicated by the three units remaining shut during the last two years. Not only this, it cannot be guaranteed that the proposed Integrated Vaccine Complex will be completed within the prescribed time-limit, specially due to lack of experience/ expertise of the implementing agency, i.e. HLL Lifecare Ltd. The Committee, therefore, is of the firm view that priority should be making the three vaccine-producing units fully functional by restoring their production capacity. Simultaneously, the process of making them GMP compliant may also continue. Besides that, the Committee would like to emphasize once again, that there is a need for review of the ambitious project of Integrated Vaccine Complex. If all the required support of every kind,- be it infrastructure, manpower,

technical expertise, modern equipment and machinery is placed at the disposal of all the three units, the requirement of the proposed complex may perhaps not arise.

VACCINE-PRODUCING PSUs *vis-à-vis* VACCINE POLICY

2.10 The Committee made the following observations on the above issue in its 38th Report:

> Committee's worst fears are confirmed by the assessment about the three units given by the Ministry. According to the Ministry, what these units are going to produce is to be determined by a vaccine policy, yet to be formulated by the Government. Secretary, Health Research has been requested to organize a discussion with all concerned. Only thereafter, the policy on what the three units should manufacture for ensuring vaccine safety would be developed. It has also been pointed out that the three units, given their heritage status have inherent capacity constraints to undergo the requisite modernization. Consequently, their product mix can never be as dynamic as envisaged in the case of IVC. (Para 2.6)
>
> The Committee is deeply disturbed by the conflicting signals emerging from the Government's side on the status of the three existing vaccine- producing PSUs. On the one hand it is being emphasized time and again at different fora that Government is determined for the revival of the three units and every effort is being made to ensure their becoming GMP compliant, on the other hand it is also being categorically pointed out that their fate is to be decided by a vaccine policy yet to be formulated and they can never equate with the proposed 'state of the art' IVC project. (Para 2.7)

Action Taken by the Ministry

Government stands by commitment made in the Presidential address to both houses of the Parliament and at different fora from time to time and is making every efforts to ensure their (these three Institutes) becoming cGMP compliant . Central Government in exercise of its powers under Sub rules (3) of Rule 85 of the Drugs and Cosmetics Rules, 1945 have ordered revocation of suspension of the licenses of the these Institutes vide order No. X.11035/2/2010-DFQC dated 26/2/2010. These Institutes have also been asked to ensure that the production line is made fully compliant with GMP standards within three years. These Institutes have been asked to submit quarterly progress report to the Ministry. IVC will network with PII, Coonoor, BCGVL, Guindy and CRI, Kasauli for the vaccines they are producing.

2.11 The Committee finds that no mention has been made about the proposed move to formulate a vaccine policy which would be the deciding factor about the kind of production to be carried out at the three units. The Committee was given to

understand that the Secretary, Department of Health Research had been requested to organize a discussion with all concerned. In the absence of any response from the Ministry in this regard, the Committee can presume that no such discussion has taken place so far. The Committee would like to point out that with the Interim Report of the Javed Chowdhary Committee establishing beyond doubt the manufacturing capacity of the three units, their viability i.e. continuing to fulfill the vaccine requirement of the country has already been confirmed. Vaccine policy, as and when formulated, can focus on the policy-related issues and not on which units are to be closed down or to start functioning.

III CENTRAL RESEARCH INSTITUTE, KASAULI

3.1 In its 34th and 38th Reports, the Committee had taken serious note of mishandling of a project for creating new facilities at CRI, Kasauli by M/s HSCC, Noida. Following recommendation for initiation of immediate corrective measures including action against the project agency was, accordingly, made by the Committee.

> The Committee observes that the reply of the Ministry regarding the action taken against M/s HSCC, Noida for its failure to build a GMP compliant structure at CRI, Kasauli is simply untenable. The Committee also raises serious doubts on the process of awarding the contract to M/s HSCC, Noida. The process of awarding contract for building a GMP complaint structure to an agency which did not have the technical competence to build such a unit itself speaks volumes of a faulty process of selection *ab initio*. The Committee observes that it seems that from 1997-98 until December, 2006 – the time when M/s HSCC, Noida expressed its inability in completing the project, monitoring as required was not done by the Ministry to assess the progress of work undertaken by the agency. (Para 3.3)

> The Committee also finds that the action initiated by the Ministry against M/s HSCC, Noida has been perfunctory in nature. Instead of pursuing the matter vigorously, the Ministry has moved at a snail's pace which is evident from the fact that action against the company has been initiated only after the matter was reported upon by the Committee in its 34th Report in February 2009, and thereafter also, it took the Ministry more than six months to reach a decision regarding referring the matter to CVC for advice and almost nine months to issue a notice to M/s HSCC. The reasons as to why the matter has remained pending from December, 2006 till date without any substantial action being initiated against the defaulter

company simply escapes the Committee's comprehension. The Committee also feels that the tardy pace of action taken so far clearly indicates dilatory tactic on the part of the Ministry. The Committee's apprehensions in this regard get reinforced from the fact that the records pertaining to this case, which were forwarded to the CVC on 31st August, 2009, were not furnished in the prescribed new reporting format. The Committee is simply not ready to buy the argument that it took more than two months for the CVO of the Ministry to come to know that the communication from the Ministry to CVC was not forwarded as per the new reporting format. The Committee is constrained to call into question the seriousness of the Ministry to take stringent action against those who were responsible for this mix-up. The Committee, therefore, recommends that the Departmental Inquiry under progress may be completed within a strict time frame and action may be initiated against those responsible without further delay. The Committee would like the Ministry to provide a copy of the enquiry report as well as the follow-up action taken thereon. (Para 3.4)

3.2 The Committee notes with surprise that the Department has not furnished any information regarding the action taken by the Ministry against M/s HSCC, Noida for breach of agreement nor has furnished any details regarding the action taken against those who were responsible for the mix-up. The Committee expresses its grave concern on the matter and observes that the Ministry has been perfunctorily pursuing the matter. From the information furnished to it during September last year, the Committee is aware that the matter was in the process of being referred to the CVC for further investigation. The Committee is also aware that the CVO of the Ministry had advised that since the case pertained to professional impropriety rather than financial impropriety, the administrative division should process the case for taking administrative action against the officers as deemed fit. However, the absence of any committed action on the part of the Ministry only reinforces the Committee's apprehensions that perhaps the Ministry is not keen to bring this issue of grave impropriety involving huge amount of public funds to a logical conclusion.

3.3 The Committee fails to comprehend the sheer lack of action on the part of the Ministry. It seems that the observations/ recommendations of a Parliamentary Committee do not evoke any sense of pro-active initiative in the Ministry. Ideal position would have been that the Ministry had taken all the corrective measures

on its own. Considerable time has passed since M/s HSCC, Noida was issued a notice for breach of their agreement and administrative division of the Ministry was advised by its CVO to process the case for taking administrative action against the officers as deemed fit. The very fact that the Ministry has chosen not to come forward with any further report speaks for itself that perhaps it is not keen to pursue the matter. The Committee strongly feels that such an approach of the Ministry is a fit case of a deliberate attempt to ignore the recommendations of a Parliamentary Committee. The Committee, therefore, calls upon the Ministry to expedite the required action with final disposal of the case and furnish a status report in this case as soon as the Committee Report is presented to Parliament.

3.4 Following observation was made by the Committee in its 38th Report with regard to HLL Lifecare Ltd. handling the revival project of CRI, Kasauli.

> The Committee takes serious objection to the state of affairs emerging after submission of a project proposal by CRI. The Committee wonders about the feasibility of the DPT unit at CRI becoming GMP compliant by June, 2010 as the process of selection of implementing agency is still continuing. Further, the rationale of inviting HLL Lifecare Ltd. for taking up the project by ignoring the names of experienced vendors suggested by WHO is also not known to the Committee. The Committee views with serious concern the involvement of HLL Lifecare Ltd., for Kasauli project when it is already set to start an ambitious Vaccine Park at Chengalpattu (TN). The Committee, accordingly, recommends that the approved layout plan for the DPT vaccine unit at CRI, Kasauli should be implemented in a transparent and time-bound manner. (Para 3.7)

Action Taken by the Ministry

To fulfill the commitment made at different fora and urgency involved in timely completion of the revival project, M/s HLL Lifecare Ltd was engaged as Project Management Consultant and M/s NNE Pharmaplan as their Detailed Engineering Consultant for developing DPT vaccine manufacturing facility at CRI, Kasauli and making it cGMP compliant. M/s HLL Lifecare Ltd has been directed to take up the work on fast track mode. The project is currently under execution and is being closely monitored. Various stakeholders, including the Vaccine Institutes at CRI, Kasauli, the WHO and DCG(I) have been involved in preparing its drawings and design, identification and selection of equipments and machinery.

3.5 The latest feedback of the Ministry simply indicates that the project of CRI, Kasauli becoming GMP compliant is currently under execution by M/s HLL Lifecare Ltd. which had been directed to take up the work on fast-track mode and is being closely monitored. In the absence of any specific time-bound Action Plan indicated by the Ministry, the Committee is not in a position to assess the progress made so far. The only authentic information available with the Committee is that the Javed Chowdhary Committee had visited the unit from 21st to 23rd November, 2009 which had found that out of the 65 deficiencies pointed out in the NRA Inspection Report, 44 deficiencies had been rectified and in 21 deficiencies, the upgradation work was under way. These remaining deficiencies in the existing line could be rectified in 3 months. After completion of the upgradation of the existing line, fresh production could start in 3 months. The Committee hopes that the full manufacturing capacity of CRI, Kasauli must have been restored by now.

3.6 On the issue of M/s HLL Lifecare Ltd. being engaged as the Project Consultant for making CRI, Kasauli GMP compliant, the Committee has a word of caution. Every conceivable step needs to be taken so as to ensure that the very discouraging experience of M/s HSCC, Noida is not repeated once again. Committee's apprehensions arise from the fact that experience and expertise of HLL Lifecare Ltd. is of the same level as of M/s HSCC, Noida commented upon by the Javed Chowdhary Committee also.

IV BCG VACCINE LABORATORY, CHENNAI.

4.1 The Committee had, in its 34th Report, taken note of the fact that out of the 55 deficiencies pointed out by the WHO-NRA inspecting team which visited BCGVL, Chennai in August, 2007, 45 major deficiencies had already been rectified by it. As regards the remaining 10 deficiencies, corrective action had either been already initiated or justification for the existing position had been given by the Institute. Subsequently, action was initiated by the Institute for renovation/upgradation of existing facilities for production of BCG vaccine. Attention of the Committee was also drawn to the fact that while the Inspection Team had observed 70 deficiencies, the

compliance statement of the then Director listed out only 55 deficiencies. Feeling not very satisfied with the subsequent developments, the Committee had made the following observations in its 38th Report:

> The Committee would like to point out that as per the status note of the Ministry, a proposal for upgradation/renovation of BCGVL, Chennai was submitted to the Drug Controller General of India on the 30th January, 2008. This was followed by a report of the Institute submitted to the Deputy Drugs Controller, South Zone on 26th February, 2008 and later on 20th March,2008 to the Ministry of Health and Family Welfare about the rectification work that it had carried out in the Institute. Not only this, the Institute had preferred appeals twice, - once on 24th January, 2008 against DCGI's decision to suspend its license, and again on 14th June, 2008 to the Ministry of Health and Family Welfare to revoke suspension of the license. However, the ATN did not mention as to what action was taken on the part of the Ministry to consider their case in the light of the rectifications carried out by the Institute. (Para 4.2)
>
> The Committee would like to note here that the Ministry had furnished the Inspection Report of the WHO-NRA team that had visited BCG VL in August 2007 along with the status note vide its O.M. dated 24th July 2008 to the Committee for its consideration. The Committee would like to point out that the onus of furnishing vetted information to a Parliamentary Committee lies with the Ministry. The Committee finds it strange that the Ministry had not challenged the veracity of the report submitted by the Institute while forwarding the same to it. The Ministry continued to remain silent on this issue even in its Action Taken Note. It was only after a pointed query with regard to rectification of 45 deficiencies out of the 55 deficiencies pointed out by the WHO-NRA assessment team, that the Ministry has chosen to react. An attempt has been made by the Committee to make a comparative analysis of 55-deficiency and 70-deficiency Reports. The Committee has no hesitation in arriving at the conclusion that the so-called additional 15 deficiencies are duly reflected in the original report, the only difference being that some of the deficiencies are in the expanded form in the later report. The Committee is also not inclined to agree with the contention of the Ministry that the action taken information was not complete and did not indicate the manner of compliance/rectification of deficiencies**. (**Para 4.4)
>
> The Committee takes note of the fact that as per the Expert Committee constituted in April, 2008, the existing facilities had inherent problems for renovation and vaccines can be manufactured only on the construction of new facilities. Feasibility of BCGVL becoming GMP compliant has become more difficult in the light of the latest report given by the Oversight

Committee in October, 2009. Although, WHO GMP expert has been requested to prepare the preliminary layout plan for the Institute, there is no land available for the same. A proposal is, therefore, in the pipeline to shift the work of the Institute along with its personnel to the upcoming Vaccine Complex at Chengalpattu. The Committee strongly feels that a pre-conceived view about there being no possibility of BCGVL becoming GMP compliant is very dominant. The very fact that persistent efforts made by the Institute authorities to rectify the deficiencies pointed out in the WHO-NRA assessment report and succeeding in removing the majority of the same with the remaining ones being the responsibility of the Ministry have been of no avail, confirms Committee's observations. (Para 4.5)

Action Taken by the Ministry

Invoking provisions of the Drugs and Cosmetics Act, 1940 and Rules, evaluation of impact on the post-suspension era in terms of the availability and prices of these vaccines on the Universal Immunization Programme and taking into account substantial compliance status furnished by the appellant Laboratory and the paramount public interest involved in generating maintaining its own captive production capacity in the Government sector, revocation of suspension of the licenses of the Institutes including BCG VL, Guindy have been ordered on 26th February, 2010. These Institutes have also been asked to ensure that the production line is made fully compliant with GMP standards within three years.

4.2 The Committee had observed that the basis for suspension of manufacturing license of BCGVL, Guindy, like the other two public sector vaccine producing units by the DCGI was the inspection reports of the WHO-NRA inspecting team that had physically visited these institutes and found several deficiencies in pursuance to cGMP. The Committee had also observed that the Institute had initiated all the required steps for rectification of deficiencies. The Institute had also preferred appeals to both the DCGI and the Ministry for revocation of suspension of its license. The Committee finds it very strange that the Ministry has not indicated any action whatsoever on their part inspite of the Institute approaching them time and again. The Committee takes note of the fact the Javed Chowdhary Committee after inspecting the premises of the Institute from 19th to 22nd December, 2009 has pointed out that out of the 23 deficiencies, 16 had been rectified or would need implementation only at the time of commencement of the operations. For the

remaining 7 deficiencies, work on 4 would be completed in two months and the rest in three months time. Fresh production could, accordingly, commence after a period of three months.

4.3 The Committee observes that consequent to submission of the Interim Report of the Javed Chowdhary Committee on the 5th February, the three months' time, as observed in the above Report, has already passed. The Committee can easily presume that work on a fast track mode had been initiated by the Department as per the assessment in the Interim Report. However, as no concrete information on the progress of work relating to BCGVL, Guindy has been furnished in the ATN, the Committee has no other alternative but to conclude that the rectification exercise - as envisaged to make these units fully functional, has not been completed. The Committee, therefore, apprehends that if such is the case then production of vaccines by the unit is bound to be stalled further.

4.4 The Committee was given to understand that due to non-availability of land for making BCGVL GMP compliant, it was proposed to shift the production work along with the manpower to the upcoming vaccine complex at Chengalpattu. However, from the perusal of the Interim Report of the Javed Chowdhary Committee, it has become abundantly clear that there should not be any problem in building multi-floored structure compliant to international standards at BCGVL, Guindy as there is ample scope for additional construction at the plot of land on which the institute is situated. The additional permissible construction would not merely cover the requirement for the new production line but would also be available for subsequent expansion of the unit. In view of the factual position at the ground level and rectification of all the deficiencies, the only line of action on the part of the Ministry in co-ordination with the Institute authorities is to take all the required measures for restructuring the Institute. The Committee, accordingly, urges the Department to take utmost care and remain vigilant so that the revival of the institute is not trapped in the labyrinths of procedural formalities resulting in undue delays and cost-escalations. The Committee would also appreciate if the proposed move of shifting the Institute along with its

manpower to the Vaccine Complex at Chengalpattu is reviewed objectively and the correct decision taken.

V PASTEUR INSTITUTE OF INDIA, COONOOR

5.1 The Committee in its 38th Report had examined in detail the progress made with regard to the work on the new facility for production of TCARV with GMP compliant facility at PII, Coonoor. The Committee had noted that the lay-out plans for construction of Tissue Culture Anti Rabies Vaccine (TCARV) facility were finalized on 20th February, 2006, followed by submission of drawings prepared by HSCC (I) to the Coonoor Municipality during September 2006, and payment of fee for land development immediately after the assessment in October 2006. Thereafter, correspondence continued with the Coonoor Municipality during 2007, 2008 and 2009 for completion of various procedural formalities. Additional set of drawings were submitted for approval for the construction of facility as per the layout plan without any deviation in the height limit. The matter was taken up with the Collector of Nilgiris District to grant approval to the construction of the manufacturing facility on 29th March, 2009 and again on 17th July, 2009. The matter rested with the submission of the drawings to the Assistant Director of Town Planning, Coimbatore on 10th September, 2009 for examination and recommendations to the Hill Area Conservation Authority (HACA) for forwarding to the Dept. of Town & Country planning, Govt. of Tamil Nadu, Chennai for final approval. However, after a visit of the Oversight Committee comprising of WHO-GMP Expert, the DCGI and officials from the Ministry to the Institute on 14th and 15th September 2009, the conceptual layout plans of all the proposed buildings/blocks of PII, Coonoor were modified and finalised by the Committee at its second meeting held on 21st October, 2009.

5.2 The Committee made the following observations on this issue in its 38th Report:

> The Committee observes that till the 10th September, 2009 the issues surrounding the commencement of the construction work at PII, Coonoor

were yet to be finalized even after three years, of the initial layout plans for the construction of TCARV facility being finalized on the 20th February 2006. Another disturbing fact which came to the notice of the Committee was that M/s HSCC (I), which had failed to build a GMP compliant structure at CRI, Kasauli after spending nearly 12 crore of public money, was involved by the Department to prepare the drawings of TCARV facility at PII, Coonoor. The Committee fails to understand as to how the services of an agency which expressed its inability to construct a GMP compliant structure in another Institute could be retained by the Ministry in the case of a second unit again. The Ministry has informed that the layout plan was originally submitted to the local body i.e. Coonoor Municipality during September, 2006. In November, 2008 another set of drawings was submitted for approval for the construction of the facility. Subsequently, the Oversight Committee visited the Institute in September, 2009 and the conceptual layout plans of all proposed buildings/blocks of PII were modified and finalized by it in October, 2009. Thereafter, the revised layout plan was again resubmitted to the local authorities for approval. The Committee is constrained to observe that a gap of almost three and a half years between the submission of the first layout plan and the last revised layout plan not only reflects poorly on the decision making process in the Ministry but also shows a lack of urgency on the part of the Ministry for reasons best known to it, in addressing this vital issue in a proactive manner. The Committee apprehends that given the pace with which the approval of the previous plan had progressed, a similar situation may arise for the revised plan. The Committee, therefore, suggests that the Ministry should, henceforth, leave no stone unturned to expedite the approval of the revised plan so that it is not inordinately delayed. (Para 5.5)

5.3 The Committee is deeply disturbed to note that once again the Department has no action taken report to offer. Reasons for such an approach by the Ministry are beyond the comprehension of the Committee. The Committee is forced to conclude that no progress worth mentioning has been made inspite of its very critical observations. Not only this, the Committee finds that the Javed Chowdhary Committee, after its inspection of the Institute from 19th to 22nd December, 2009, was of the view that the existing production line could resume operations for fresh production in 6 months. The Committee is not aware whether the requisite funds for the upgradation/ modification work on the existing production line, as recommended by the Javed Chowdhary Committee, have been made available to the Institute so far. If not, the Committee can only conclude that this is a sorry state of affairs. The Committee would also take the opportunity to point out that this

very Committee had also given its considered opinion about the viability of setting up a new production line at the Institute due to the availability of enough naturally terraced land, ideal for such a requirement. The Committee would appreciate if the Department plays the role of a nodal authority for initiating the preparation of a detailed project report in this regard, if not already done so far.

VI VACANCY POSITION IN THE VACCINE-PRODUCING UNITS

6.1 The Committee had taken note of acute shortage of manpower, specially those having technical expertise in the three units, in its 34th Report presented to Parliament on the 18th February, 2009. Serious concerns about the vacancy position in CRI, Kasauli had also been expressed by it in its 38th Report presented to Parliament on the 18th December, 2009, as indicated below:

> The Committee is not happy with the status of duly sanctioned posts at CRI remaining vacant for so long leading to some posts getting lapsed. The fact that as many as 27 Group 'A' posts and 10 Group 'B' Non-Gazzetted Posts are still vacant at CRI requires the matter to be pursued vigorously and persistently. Not only this, action also needs to be initiated without any delay for reassessment of requirement of manpower at CRI in accordance with the GMP norms and the revival plan. (Para 3.9)

6.2 The Committee is somewhat surprised to observe that no response has been forthcoming from the Ministry on such a vital issue. It seems that Committee's repeated efforts to draw the attention of the Ministry in this regard during the last two-three years have gone unnoticed. The Ministry has not considered it important enough to initiate any action so far. This is the case when two of the units, i.e. CRI, Kasauli and BCG VL, Guindy are subordinate offices of DGHS while PII, Coonoor is an autonomous body under the Ministry.

6.3 The Committee has no other alternative but to draw the attention of the Ministry to the following recommendations made in the Interim Report of the Javed Chowdhary Committee, constituted by the Ministry itself:

> "10.1 For close to a decade now, these three vaccine manufacturing units have been tottering with poor continuity in the tenure of the Directors. A large section of the vacant posts are those that lapsed after remaining vacant

for over one year under the economy orders of the Ministry of Finance. The staff in these establishments have been so comprehensively depleted that they do not even retain the critical mass of man-power required to implement a revival programme. The filling up of vacant posts is urgently required.

10.2 The new manufacturing lines, which will be for much larger capacities, will no doubt, require a package of additional posts. In order to kick-start the revival process, the Committee would urge that the creation of new technical posts for the new production lines not be processed in the conventional manner. For this category of posts, the Committee would recommend that the authority to create new technical posts be entrusted to an Empowered Group headed by a reputed scientist-administrator. Only such a modality will ensure that the additional staff required for the new production lines will be approved in reasonable time with well-informed objectivity. For the additional administrative posts for the new production lines, the normal procedure adopted in government would serve the purpose adequately.

10.3 As for the vacant posts linked to the existing production lines, government should consider a 'single-shot' revival methodology. These posts have fallen vacant only because there was no one to even plead the case for their continuance to run the units. The processing of these posts through the normal procedure applicable to new posts would take anything up to two years. Any plan of the Ministry to implement the new projects would be critically handicapped as a result of such a large vacancy position. The posts had lapsed because of neglect after all it is no one's case that the manpower requirement for the existing production line has diminished over time. It is in these circumstances that the Committee makes the unconventional recommendation that Government as a special case (not to be treated as a precedent), revive the vacant posts with immediate effect and to hasten the selection process, contractual appointments should be considered. It is felt that this would go a long way in strengthening the team that will have to implement the new projects."

6.4 The purpose of the Committee for quoting from the Javed Chowdhary Committee Report is only to emphatically impress upon the Ministry to initiate immediate action for making available the required manpower for the existing production lines. Similar exercise is required to be initiated for the new production lines also. The Interim Report was submitted by the Javed Chowdhary Committee on the 5th February, 2010. The Committee would be happy if the sense of urgency for making available the required manpower at the three units reflected in the

Report has not escaped the attention of the Ministry and some corrective exercise has already started. The Committee would appreciate if a Status Note in this regard is submitted to it at the earliest.

VII PROCUREMENT PRICE OF VACCINES

7.1 The Committee has been drawing the attention of the Ministry towards the adverse impact on the procurement price of vaccines as a result of closure of the three Public Sector Units which have been the mainstay in fulfilling the vaccine requirement of the country and contributing to the successful implementation of the Universal Immunization Programme. Committee's apprehensions were confirmed by the following details about the increasing trend in the vaccine prices noticed since the closure of the three PSUs.

Vaccine Procurement Price

BCG			
Years	2007-08	2008-09	2009-10
Rate (per vial of 10 doses in Rs.)			
Vaccine Institutes		-	-
Other Public/ Private Sector	13.00 13.50	17.50	27.85 (SII)
DPT			
Years	2007-08	2008-09	2009-10
Rate (per vial of 10 doses in Rs.)			
Vaccine Institutes	11.80	-	-
Other Public/ Private Sector	13.50	13.40(IIL, 14.37(serum), 16.88(BE)	23.59 (IIL & BE), 23.49 (Shantha)
DT			
Years	2007-08	2008-09	2009-10
Rate (per vial of 10 doses in Rs.)			
Vaccine Institutes	9.60		--
Other Public/ Private Sector	9.14	12.00(IIL),13.85 (BE)	--
TT			
Years	2007-08	2008-09	2009-10
Rate (per vial of 10 doses in Rs.)			
Vaccine Institutes	6.20	--	--
Other Public/ Private Sector	--	8.40 (IIL),11.85 (BE)	17.69(IIL, BE & SII)

7.2 On this alarming trend, the Committee had made the following observations/ recommendations in its 38th Report.

The Committee observes that from the year 2004-05 onwards the prices of the four vaccines namely BCG, DPT, DT and TT remained stable until 2007-08. However, in the year 2008-09, and especially in 2009-10, the prices of vaccines have nearly doubled with the price of BCG rising from Rs. 13.00 per vial of 10 doses in 2007-08 to Rs 17.50 in 2008-09 and to Rs 27.85 in 2009-10. Similarly, in the case of DPT vaccine which was earlier procured from the other public/private sector units at the rate of Rs 13.50 per vial of 10 doses to Rs 13.40 for the quantities procured from Indian Immunological Limited (IIL), Rs 14.37 from Serum Insitute of India (SII), Pune and Rs 16.88 from Biological E. (BE) Ltd, Hyderabad during 2008-09. While, in 2009-10 the price per vial of 10 doses for DPT rose to Rs 23.59 for supplies procured from IIL and BE, and Rs 23.49 from Shanta. Similarly, the price of the DT vaccine rose from Rs 9.14 per vial of 10 doses in 2007-08 to Rs. 12.00 (IIL) and Rs 13.85 (BE) for the quantities procured for the year 2008-09. For TT vaccine, the price per vial of 10 doses was Rs 6.20 in 2007-08 which rose to Rs 8.40 (IIL) and Rs 11.85 (BE) for the quantities procured for the year 2008-09 which again shot up to Rs 17.69 for the quantities procured from IIL, BE and SII for the year 2009-10. (Para 6.4)

The Committee observes that within two years of the closure of the three PSUs, the competitive prices of vaccines have shot up to more than double the figures. The Committee notes that with the rising prices of vaccines, the expenditure incurred in the implementation of the Universal Immunization Programme in the country would surely add to the burden of the Public Exchequer and the very objective of providing highly essential drugs like vaccines to the targeted population at affordable prices would stand defeated. Thus it is beyond doubt that the Ministry's argument that the vaccines have been procured at relatively fair prices is not factually correct. It is also evident that after the closure of the captive units, the challenge to the private sector to provide vaccines at competitive prices has been nullified. Hence, the prices of vaccines have been spiraling upwards. The Committee has been given to understand that the Integrated Vaccine Complex at Chengalpattu, Tamil Nadu would be completed by the year 2012 and until then the vaccines required under UIP would be procured through the process of tendering as has been continuing since the last two years. The Committee apprehends that given the present trend of price rise, the prices of vaccine may rise manifold in the coming years which would hit hard the general public as well as the Government Exchequer. The Committee, therefore, observes, even at the cost of repetition, that for stabilizing the prices of vaccines, there may be no other alternative than revoking the suspension of the manufacturing license of the three vaccine Institutes to enable them to start production forthwith. (Para 6.5)

Action Taken by the Ministry

Invoking provisions of the Drugs and Cosmetics Act, 1940 and Rules , substantial compliance status furnished by the appellant Laboratory and taking into account evaluation of impact on the post-suspension era in terms of the availability and prices of these vaccines on the Universal Immunization Programme and the paramount public interest involved in generating maintaining its own captive production capacity in the Government sector, revocation of suspension of the licenses of the Institutes have been ordered on 26th February, 2010. These Institutes have also been asked to ensure that the production line is made fully compliant with GMP standards within three years.

7.3 The Committee notes that the reply of the Department to very specific observations regarding rising prices of vaccines since the closure of three public sector vaccine producing institutes is completely evasive. The Committee would like to make it abundantly clear, even at the cost of being repetitive, that the foremost objective before the Committee is to ensure availability of cheap and affordable vaccines for infants and children in the country. It is for this reason that stabilization of the prices of vaccines in the country is critical and the role of public sector units in ensuring low and stable prices acquires utmost importance. It is an undisputed fact today that since the closure of CRI, Kasauli, BCGVL, Guindy and PII, Coonoor - the three vaccine producing units, the prices of vaccines supplied under UIP have shot up. Committee's analysis of the rising procurement prices of vaccines and observations thereto have been bolstered by similar findings in the Interim Report of the Javed Chowdhary Committee which has pointed out that between the years 2007-08 and 2009-10, the prices of vaccines purchased per vial have increased by 30 per cent (2008-09) and by 59 per cent in 2009-10 on a year-on-year basis over the prices of 2007-08 for BCG, between 25 to 63 per cent for DPT for the same time periods.

7.4 Since it is not clear as to what quantum of vaccines have been procured during 2010-11 from the private sector vis-à-vis the public sector, the Committee apprehends that the prices of vaccines would have increased further over that of the past year. The Department has informed that CRI, Kasauli would be supplying DPT and TT vaccine since April, 2010, and also supply of DPT by PII, Coonoor from December 2010. Under the above circumstances, the cost of supply of the

various vaccines by the private sector units which were being supplied earlier by the three vaccine producing public sector units would remain a matter of concern.

7.5 The Committee is in full agreement with the observation of the Javed Chowdhary Committee that by closing down the existing public sector vaccine production units in advance, the country would be exposing itself to vaccine insecurity for five years or possibly, even a much longer period. The Committee, therefore, once again impresses upon the Ministry that keeping in view the public interest at large the three vaccine producing units are made fully functional without any further delay. The Committee foresees no hindrances in accomplishment of this task due to the very specific and foolproof assessment made by the Javed Chowdhary Committee about the inbuilt capacity of the three premier units. With constant monitoring and availability of required funds and manpower, the Ministry - the nodal authority in this crucial area, can very well succeed in achieving this social responsibility.

VII SHORTAGE OF VACCINES

8.1 Following observations were made by the Committee in its 38th Report on the shortage of vaccine in the country:

> Asked to comment on the shortfall of 11.22 crore doses of UIP vaccines in the year 2008-09 and 17 crore doses in the year 2009-10 as admitted by the Ministry itself in reply to an RTI application, the Ministry in a written reply has tried to explain away the shortage by stating that the actual requirement of vaccines for any particular year for which procurement order is placed during the year may be more or less than the projected requirement shown by the states as the actual requirement depends on a number of factors such as balance reported by States/ GMSDs as on 1st April of that year, pipeline supplies of previous year etc. The Department has further stated that no shortage is anticipated during the year 2009-10. (Para 7.1)
>
> The Committee is not inclined to agree with the explanation given by the Ministry about the actual requirement and the projected requirement of vaccines under UIP. The Committee wonders as to how the Ministry could deny the information submitted by it under RTI. Fact of the matter is that somewhere something is gravely wrong. Either the categorical information

given under RTI supplemented by the fact that requirement details of some states were yet to be received is wrong or the subsequent clarification given by the Ministry is misleading. Either way, position seems to be very disturbing. Besides that, requirements projected being not judiciously made or non-utilization of available vaccines in a year cannot be considered an ideal situation. The Committee, accordingly, recommends that necessary steps may be taken for assessment of actual requirements of vaccines by different states followed by monitoring of their timely utilization. The Committee would also like to point out that inspite of overall coverage of states under UIP being satisfactory, very low coverage in some of the crucial states is a cause of serious concern. Committee's attention has been drawn by the below- 50 per cent coverage of vaccines under UIP in Delhi in 2008-09, showing a downward trend when compared with 2007-08 figures. When this is the state of affairs in the capital city of the country, factual position in respect of other states is likely to be different from what is shown on paper. (Para 7.2)

Action Taken by the Ministry

The observation has been noted for compliance.

8.2 The Committee notes that the recommendation of the Committee for assessing the actual requirements of vaccines by different States followed by monitoring of their timely utilization has been acknowledged by the Department for future compliance. However, this alone would not serve the purpose. That the Committee's apprehensions in this regard were not baseless have been proved by the findings of Javed Chowdhary Committee contained in its Interim Report. While analysing the impact of the closure of the three pubic sector vaccine producing units on the UIP, it has been stated that a number of States like Orissa, Bihar, Jharkhand, Madhya Pradesh, Assam, Punjab, West Bengal and Kerala did face shortfall of BCG, DPT, TT, OPV and Measles vaccine during 2008-09. As a result, the Ministry had to draw on the buffer stock available with these States.

8.3 The Committee would like to point out that many of the above States that have faced shortages have been placed under the category of High Focus States by the Department of Health and Family Welfare on the basis of their health indicator performance. Hence, shortage of vaccines in these States is bound to have an

adverse impact on their immunization programme. In any case, the act of drawing upon buffer stock to mitigate shortfalls can never be termed as a healthy practice. The Committee would like to add here that the reason for price spiral of vaccines owes its origin to shortages in its supply at the outset. The Committee, therefore, advises the Department to bear this in mind for all future references relating to making available critical healthcare component such as vaccines/ sera under various national healthcare initiatives.

IX GENERAL OBSERVATIONS

9.1 Committee's attention has been drawn by critical analysis of three pertinent issues, directly and indirectly connected with the closure of the three vaccine producing units made by the Javed Chowdhary Committee in its Interim Report.

9.2 As per the analysis made in the Interim Report, the three public sector vaccine-producing units have been subjected to selective scrutiny under the law. DCGI has the jurisdiction over all drugs and pharmaceutical manufacturing units in the country (nearly 10,000 units) including those categories for which the registration powers are with the State Governments. Central drug inspectors are carrying out inspection of only certain categories – vaccine & sera, large volume parenterals, notified medical devices, blood banks and units applying under WHO-GMP Certification Scheme. Drug manufacturing units are being inspected only on request. The three vaccine producing units have been inspected by State and Central Drug Control authorities time and again, with NRA inspections being conducted in 2001, 2004 and 2007. Total number of inspections by the Central Drug Inspectors compared to the number of manufacturing units in the country is self-revealing. View of the Interim Committee was that the three vaccine-producing units have been given exceptional degree of attention by the regulatory authorities. **The Committee is inclined to agree with the inference drawn by the Javed Chowdhary Committee. While inspection per se is a commendable course of action specially to ensure the quality of products related to the life of infants, it is also required to be followed by the requisite corrective measures. In units under Government control, this should become the priority of**

all concerned. Unfortunately, this did not happen in the case of these three units. Track-record of the last decade is ample proof. The Committee, therefore, strongly feels that review and revamping of our drug regulatory machinery should be taken up at a priority level.

9.3 Second critical issue analysed by the Javed Chowdhary Committee is the scope of the provisions of the GMP standards notified under the Drugs and Cosmetics Act, 1944 and Rules made thereunder. Following facts are self-revealing:

- GMP standards for drug manufacture are largely identical to the WHO-GMP standards.
- A large number of standards set out in Schedule 'M' of the Rules cannot be met to the fullest extent by every manufacturing facility.
- Assessment of compliance of many of the standards spelt out in descriptive language would depend on the subjective perspective of the inspector.
- Legal compliance does not require each norm to be met to the fullest extent, but overall compliance of various norms.
- A shortcoming in some of the areas does not automatically call for the suspension/ cancellation of the license.
- Deficiencies had been pointed out in the statutory inspections of the public sector vaccines units carried out in the past but suspension/ cancellation of license was not recommended.

9.4 The Javed Chowdhary Committee had rightfully concluded that it needs to be recognized that the sudden-death approach to the implementation of the GMP standards would serve no public purpose; it would only bring about a crisis, as the operations of a larger portion of the domestic drug sector would come to a halt. The above facts clearly indicate that so far judicious applicability of Drugs and Cosmetics Rules has been lacking. The case of the three public sector units is a classic example of total lack of accountability of all concerned. It is time that a fool-proof mechanism for regulating the manufacturing units of all categories- both in the private and public sector, is evolved. Simultaneously,

review of infrastructure and manpower of the drug regulatory body also needs to be taken on a priority basis.

9.5 The last but the most important issue highlighted in the Javed Chowdhary Report relates to the jurisdiction of WHO Inspection team and the NRA team of India. Responsibilities of the Central License Approval Authority (Indian NRA) are not in any circumstances to be jointly discharged with the WHO. Accordingly, WHO was not permitted to join the Indian NRA team in its inspections carried out in 2001 and 2004. However, request of WHO was accepted by the Ministry in 2007 inspection. Secondly, WHO in its capacity as a consultant to multi-lateral agencies (UNICEF, WB) which purchase drugs/ pharmaceuticals for their interventions in international health programmes, sets certain norms for pre-qualifying manufacturers bidding for these contracts. As a result, WHO is entitled to exclude the public sector vaccine units from their pre-qualified lists of manufacturers for international health interventions. However, NRA in India can take a differing view of the status of compliance for the very same units for its own purposes. Since WHO does not have any authority of superintendence over the Indian NRA, there can be no question of it de-recognising NRA.

9.6 The Committee is of the firm view that the in-depth analysis of all the critical issues related to the viability and manufacturing capacity of the three premier public sector vaccine producing units clears all the ambiguity, complexities and contradictions involved. The Committee can only say that the administrative Ministry which is the nodal authority for all such policy matters/ as well as objective interpretation of statutory powers simply failed to come up to the rightful expectations. The Committee is not aware of the final report to be given by the Javed Chowdhary Committee by 25th March, 2010. However, since the Interim Report of the Javed Chowdhary Committee given on the 5th February, 2010, sufficient time has passed for the Government to take all the required corrective measures. The Committee believes that follow-up action on the Interim Report and recommendations made by the Committee in its present

Report in the real sense will make available the required vaccines - both qualitative and cheap, for the infants. Status Note on the follow-up action taken on the Javed Chaudhary Committee Report as well as the recommendations made in the present Report may be submitted to the Committee at the earliest.