



4.6 Replies to questions asked in the parliament [Section 4(1)(d)(2)]

4.7.1 Details of questions asked and replies given

Rajya Sabha Question Dy.No.U69 for 10.08.2010 regarding Vaccine Manufactured by Closed Vaccine Units

1. *The detailed reasons for suspending India's oldest vaccine manufacturing units namely BCG Vaccine Laboratory (Chennai), Pasteur Institute of India, (Coonoor) and the Central Research Institute (Kasauli); producing 80-90 percent in one year and reducing the production to 15 percent in the next year;*

The Drugs Controller General (India), Central Licence approving Authority, Drugs Control Division, DGHS, New Delhi has vide Office Memorandum No.X-11026/1/06-D dated 15.01.2008 informed that the Drug Licence has been suspended till such time all the deficiencies pointed out by the Inspection team of NRA Assessment are rectified.

2. *Whether Government has investigated into nexus between these public sector units and private sector units;*

Not applicable to this Institute.

3. *If so, details thereof; and*

Nil

4. *What is the shortest period involved in reviving these public sector units in commencing the production of vaccines to meet the needs of population at an affordable price?*

After revocation of the suspension of the production licence vide Govt. of India, Ministry of Health and Family Welfare, New Delhi vide Order F.No.X.10035/2/2010-DFQC dated 26th February, 2010, the Pasteur Institute of India, Coonoor vide letter No.PII/ACCTS//DPT/2009-10/5345 dated 16th March, 2010 committed to produce and supply 32.00 million doses of DPT vaccine (8.00 million doses will be supplied every month from Dec 2010 to March 2011) and 50000 doses of Tissue Culture Anti Rabies Vaccine by March, 2011.



Rajya Sabha Question Dy. No. S 676 for 09.11.2010 regarding Vaccine Manufacturing in the country asked by Shri Prabhat Jha, MP.

Question No. a: The name of the agency which has been entrusted with the manufacturing of vaccines of different diseases by the Central Government

Pasteur Institute of India, Coonoor has been producing Anti Rabies Vaccine since 1907 for rabies/dog bite treatment and DPT, DT and TT vaccines are being manufactured since 1983 and supplied under EPI programme of Govt. of India, Ministry of Health and Family Welfare, New Delhi.

Question No. b: Whether it is a fact that between the period January 2010, the Central Government was wholly dependent on the private sector companies for BCG, DPT, DT and TT vaccines

No comments

Question No. c: If so, the details thereof; and

Not applicable

Question No. d: If not, the details thereof

Not applicable



Rajya Sabha Question Dy. No.S1314 for 01.03.2011 regarding Supply of vaccine seeds to private companies

1. *Whether it is a fact that Government vaccine units supplied vaccine seeds to private companies*

No.

2. *If so, under what terms and conditions the seeds were supplied*

Not applicable.

3. *What is the total cost of vaccine procured from private companies in India and abroad for the past five years*

Not Applicable.



Rajya Sabha Prov. Starred question No.3742, 3735 for answering on 27-3-2012 regarding Reopening of closed vaccine units asked by Shri R.C.Singh & Shri D. Raja, MPs

- a) **Whether it is a fact that the Central Research Institute (CRI) at Kasauli, one of the major vaccine manufacturing public sector undertaking has restarted production;**
b) **If so, the details thereof;**

Not applicable to this Institute.

- c) **The measures being taken for restarting the other two vaccine manufacturing unit i.e., the Pasteur Institute of India at Coonoor in Tamilnadu and the BCG Vaccine Laboratory at Chennai which were closed due to not complying with Good Manufacturing Practices (GMP); and**
d) **If so, the details thereof?**

Answer in respect of Pasteur Institute of India, Coonoor:

Progress MADE after revocation of suspension of licence IN THE PRODUCTION OF VACCINES IN THE existing FACILITIES

- After the receipt of the revocation of suspension order No.X.11035/2/2010-DFQC dated 26th February, 2010, servicing & calibration of critical equipments were carried out and the vaccine production was initiated in each production sections with the seed lots held in the stock at PIIC.
- Seed copies of Diphtheria and Pertussis could be revived and put up for further production processes. As the Tetanus seed in the stock of PIIC was observed to be not optimally functioning, request for supply of Tetanus seed sent to CRI, Kasauli, in December 2010. Tetanus seed from CRI was received in April, 2011.
- Seed lot preparation and standardization carried out. The commercial production of the Tetanus component has been initiated in August, 2011.
- Initial formulation of the three components (0.75 million doses) of DPT vaccine has been completed in the month of December 2011.
- After quality control testing, filling and inspection, samples of 6 consecutive batches of the DTP vaccine (about 15.00 lakh doses) has been sent to CDL, Kasauli for testing on 7th March, 2012.
- After the validation and certification for the release of vaccine by CDL, Kasauli, the first batch of DPT will be supplied in June/July 2012.
- It is proposed to supply 39.5 million doses (395.00 lakh doses) of DPT vaccine from June – July 2012 to June-July 2013.

CREATION OF GREEN FIELD PROJECT FOR DPT PRODUCTION

- HLL Lifecare Ltd. has been entrusted the responsibilities of establishing the Green Field GMP facility for manufacturing DPT vaccines at PIIC.
- The required infrastructure is available at PIIC as follows:-



- Vacant land of 5 acres available.
- An empty hall of 3000 Sq.ft. and other usable buildings are available.
- Adequate water and electricity available.
- A detailed geo technical investigation of the land for constructing the manufacturing facility was done by HLL and submitted Project Cost Estimation Report in March, 2011.
- In Nilgiris, the height of new building is restricted to 7 mts and any proposal above 7 mts.requires approval of Architectural & Aesthetics Aspects (AAA) Committee and Hill Area Conservation Authority (HACA) committee.
- The proposal submitted by HLL has indicated the building height including the technical floor around 14 meters. As suggested by PIIC/ Ministry, HLL has submitted the revised Project Cost Estimation Report in July 2011.
- First project meeting for finalizing the technical requirements for DTP group of vaccine manufacturing facility was held on 2nd & 3rd September, 2011.
- Second project meeting for developing the facility layout was held on 21st & 22nd September, 2011.
- The Detailed Project Report and the conceptual lay-out has been prepared and submitted by HLL in December, 2011.
- The Expenditure Finance Committee (EFC) meeting under the Chairmanship of Shri P.K. Pradhan, Secretary (HFW) was held on 1st March, 2012 for considering the expenditure proposed to be incurred during 2011-2015 for revival of DPT group of vaccines manufacturing facilities as per cGMP norms at Pasteur Institute of India, Coonoor.
- Approval of the competent authority for the estimated cost for the revival of DPT group of vaccine manufacturing facilities as per cGMP norms at Pasteur Institute of India, Coonoor was received from the Ministry of Health and Family Welfare, New Delhi on 22nd March, 2012.
- The PIIC is processing for the layout approval by AAA/HACA committees.
- HLL has proposed to complete the construction of GMP establishment in 30 months after the initiation of the construction - i.e., by the end of 2014 - till then production of vaccines shall continue from the old facilities.
- After that Equipment Validation takes 6 months and Process validation takes 6~9 months. Then production of vaccine from the new facility will be initiated and completed with the certification of initial 3 consecutive bulks by CDL, in 12 months
- The proposed annual supply from the new facility will be : DPT- 60Mld; TT -55 Mld; DT- 15Mld- (Total- 130 Mld)



Demand for Grant (2012-13) pertaining to the Department of Health and Family Welfare (Health sector)

(i) Reasons for delay in production of vaccine after revocation of licences for manufacturing vaccines:

- After the receipt of the revocation of suspension order No.X.11035/2/2010-DFQC dated 26th February, 2010, servicing & calibration of critical equipments were carried out and the vaccine production was initiated in each production sections with the seed lots held in the stock at PIIC.
- Seed copies of Diphtheria and Pertussis could be revived and put up for further production processes. As the Tetanus seed in the stock of PIIC was observed to be not optimally functioning, request for supply of Tetanus seed sent to CRI, Kasauli, in December 2010. Tetanus seed from CRI was received in April, 2011.
- Seed lot preparation and standardization carried out. The commercial production of the Tetanus component has been initiated in August, 2011.
- Initial formulation of the three components (0.75 million doses) of DPT vaccine has been completed in the month of December 2011.
- After quality control testing, filling and inspection, samples of 6 consecutive batches of the DTP vaccine (about 15.00 lakh doses) has been sent to CDL, Kasauli for testing on 7th March, 2012.
- After the validation and certification for the release of vaccine by CDL, Kasauli, the first batch of DPT will be supplied in June/July 2012.
- It is proposed to supply 39.5 million doses (395.00 lakh doses) of DPT vaccine from June – July 2012 to June-July 2013.



Sub: Rajya Sabha Starred/Unstarred Question Dy. No.S5692 for answer on 04-09-2012 regarding 'Vaccine Procurement from PII, Coonoor' – Reg.

(a) *Whether it is a fact that procurement of vaccine has been stopped from the Government unit, Pasteur Institute of India (PII), Coonoor that makes vaccine to save children from dangerous diseases like Goitri, Pertussis and Tetanus vide a Government decision in the year 2008*

PII, Coonoor manufactures and supplies DPT group of vaccines to immunize against diseases like Diphtheria, Pertussis and Tetanus. The manufacturing licence has been suspended vide letter No.X-11026/1/06 D dated 15th January, 2008 by the Drugs Controller General (India), Central Licence approving Authority, Drugs Control Division, DGHS, New Delhi.

(b) *The price at which PII was providing these vaccine and the price at which private companies have sold them*

The price of DPT group of vaccines supplied by PII, Coonoor before the suspension in 2008 is DPT – Rs.11.80 per vial of 10 doses, DT – Rs.9.60 per vial of 10 doses and TT – Rs.6.20 per vial of 10 doses.

(c) *The official who took this decision and the date and the reasons therefore;*

The Drugs Controller General (India), Central Licence approving Authority, Drugs Control Division, DGHS, New Delhi has vide Office Memorandum No.X-11026/1/06-D dated 15.01.2008 informed that the Drug Licence has been suspended till such time all the deficiencies pointed out by the Inspection team of NRA Assessment are rectified.

(d) *the steps taken by Government to revamp PII and BCG vaccine laboratory etc.*

(a) PROGRESS MADE AFTER REVOCATION OF SUSPENSION OF LICENCE IN THE PRODUCTION OF VACCINES IN THE EXISTING FACILITIES:

The Ministry of Health and Family Welfare, New Delhi vide letter No.X-11035/2/2010-DFQC dated 26th February, 2010 revoked the suspension of licence. The Drugs Controller General (I), Govt. of India and the Director of Drugs Control, Tamilnadu vide letter dated 05-09-2011 renewed the production licence and the production was made in the existing facility by adopting all mandatory quality control testings by PII, Coonoor. As per procedure, 6 consecutive batches of DPT vaccine were sent to Central Drugs Laboratory, Kasauli for final testing and certification of release.

After the final certification by Central Drugs Laboratory, Kasauli vide their letter No.CDL/2012/3629 dated 14.06.2012, six batches of DPT vaccine consisting of 15 lakh doses was released to Bangalore, Belgaum and Hyderabad on 26.06.2012. The second



consignment consisting of 19.72 lakh doses have been dispatched to Pune and Mumbai on 11.08.2012 after getting the final certification for release from the Central Drugs Laboratory, Kasauli vide their letter No.CDL/2012/4632 dated 06.08.2012. The third consignment consisting of 19 lakh doses have been dispatched to Chennai, Vizag and Bengaluru on 27.08.2012 after getting the final certification for release from the Central Drugs Laboratory, Kasauli vide their letter No.CDL/2012/4798 dated 14.08.2012.

It is proposed to supply 395 lakh doses of DPT vaccine from Jun-Jul 2012 to Jun-Jul 2013.

(b) CREATION OF GREEN FIELD PROJECT FOR DPT PRODUCTION

- HLL Lifecare Ltd. has been entrusted the responsibilities of establishing the Green Field GMP facility for manufacturing DPT vaccines at PIIC.
- The required infrastructure is available at PIIC as follows:-
 - Vacant land of 5 acres available.
 - An empty hall of 3000 Sq.ft. and other usable buildings are available.
 - Adequate water and electricity available.
- After the extensive discussion of the officers of PIIC, M/s. HLL has prepared the Detailed Project Report and the conceptual lay-out in December, 2011.
- The Expenditure Finance Committee (EFC) meeting under the Chairmanship of Shri P.K. Pradhan, Secretary (HFW) was held on 1st March, 2012 for considering the expenditure proposed to be incurred during 2011-2015 for revival of DPT group of vaccines manufacturing facilities as per cGMP norms at Pasteur Institute of India, Coonoor.
- Approval of the competent authority for the estimated cost for the revival of DPT group of vaccine manufacturing facilities as per cGMP norms at Pasteur Institute of India, Coonoor was received from the Ministry of Health and Family Welfare, New Delhi on 22nd March, 2012.
- The layout has been submitted to the local municipal authorities for recommendation of the AAA/HACA committees.
- AAA Committee recommended and referred the proposal to HACA committee in its meeting held on 12.06.2012.
- HLL has proposed to complete the construction of GMP establishment in 30 months after the initiation of the construction - i.e., by the end of 2014 - till then production of vaccines shall continue from the old facilities.
- After that Equipment Validation takes 6 months and Process validation takes 6-9 months. Then production of vaccine from the new facility will be initiated and completed with the certification of initial 3 consecutive bulks by CDL, in 12 months
- The proposed annual supply from the new facility will be : DPT- 60Mld; TT -55 Mld; DT- 15Mld- (Total- 130 Mld)



Sub: Rajya Sabha Prov. Unstarred Question Dy. No.2871 for answering on 18/12/2012 regarding Revival of vaccine producing PSU's asked by Shri Ambeth Rajan, MP.

a) *Whether any road map had been drawn by the Government for revival of vaccine producing PSU's namely, the Central Research Institute (CRI), Kasauli, the Pasteur Institute of India (PII), Coonoor and the BCG Vaccine Laboratory (BCGVL), Chennai.*

Yes.

b) *If so, the details thereof?*

CREATION OF GREEN FIELD PROJECT FOR DPT PRODUCTION AT PII, COONOOR:

- HLL Lifecare Ltd. has been entrusted the responsibilities of establishing the Green Field GMP facility for manufacturing DPT vaccines at PIIC.
- The required infrastructure is available at PIIC as follows:-
 - Vacant land of 5 acres available.
 - An empty hall of 3000 Sq.ft. and other usable buildings are available.
 - Adequate water and electricity available.
- After the extensive discussion of the officers of PIIC, M/s. HLL has prepared the Detailed Project Report and the conceptual lay-out in December, 2011.
- The Expenditure Finance Committee (EFC) meeting under the Chairmanship of Shri P.K. Pradhan, Secretary (HFW) was held on 1st March, 2012 for considering the expenditure proposed to be incurred during 2011-2015 for revival of DPT group of vaccines manufacturing facilities as per cGMP norms at Pasteur Institute of India, Coonoor.
- Approval of the competent authority for the estimated cost for the revival of DPT group of vaccine manufacturing facilities as per cGMP norms at Pasteur Institute of India, Coonoor was received from the Ministry of Health and Family Welfare, New Delhi on 22nd March, 2012.
- The layout has been submitted to the local municipal authorities for recommendation of the AAA/HACA committees.
- AAA Committee recommended and referred the proposal to HACA committee in its meeting held on 12.06.2012.
- HLL has proposed to complete the construction of GMP establishment in 30 months after the initiation of the construction - i.e., by the end of 2014 - till then production of vaccines shall continue from the old facilities.
- After that Equipment Validation takes 6 months and Process validation takes 6~9 months. Then production of vaccine from the new facility will be initiated and completed with the certification of initial 3 consecutive batches by CDL, in 12 months
- The proposed annual supply from the new facility will be : DPT- 60Mld; TT -55 Mld; DT- 15Mld- (Total- 130 Mld)



Sub: Questionnaire pertaining to Action Taken Notes on the 54th Report of the Committee on Demands for Grants (2012-13) pertaining to the Department of Health and Family Welfare (Health & NRHM Sector)

Q.No. 55: What is the utilization status of funds (both Plan and Non-Plan) allocated in the 2012-13. What were the physical and financial achievements made under the head?

a) Utilization of funds during the year 2012-13:

(Rupees in Crores)

Sl. No.	Name of the Scheme	Budget Allocation 2012-13	Grant-in-Aid received during 2012-13	Expenditure as on 28-02-2013
1	Plan Scheme	38.00	Opening Balance 4.28 Grants received till Feb.2013 <u>23.75</u> TOTAL 28.03	27.00

b) Physical and Financial achievement during 2012-13.

Allocation of vaccines have been received from the Ministry of Health and Family Welfare, New Delhi for the supply of 380.60 lakh doses of DPT Vaccine for the period from June, 2012 to August, 2013, as detailed below:-

(Quantity in lakh doses)

Allocation received from June 2012 to August 2013	Vaccine supplied upto February 2013	Balance vaccine to be supplied till August 2013
380.60	199.41	181.19

Q.No. 56: By when the three vaccine manufacturing PSUs would start production of vaccines?

This Institute has already started manufacturing DPT vaccine in the existing facility and has initiated the supply since June, 2012. As on 28-2-2013, this Institute has supplied 199.41 lakh doses of DPT vaccines to the various consignees and the balance quantity of 181.19 lakh doses will be supplied to the consignees before the end of August, 2013.

- Further, the Govt. proposed to create Green Field GMP facility for manufacturing DPT



vaccines at PIIC. In this regard, HLL Lifecare Ltd., Trivandrum has been identified as Project Consultant. EFC has recommended for a total estimated non-recurring expenditure of Rs.137.02 crores plus the Project Management Consultancy Fee for HLL.

- In Nilgiris, the height of new building is restricted to 7 mts. and any proposal above 7 mts. requires approval of Architectural & Aesthetics Aspects (AAA) Committee and Hill Area Conservation Authority (HACA) committee. Accordingly, the layout has been submitted to the local municipal authorities for recommendation of the AAA/HACA committees. AAA Committee recommended and referred the proposal to HACA committee and the HACA has also approved in principle and the proposal has been forwarded to the Municipal Administration and Water Supply Department (MAWS) for final Orders. The MAWS have issued order relaxing the height restriction on 1-3-2013 and the final order is yet to be received from the Local Municipal Authorities, Coonoor.
- HLL has proposed to complete the construction of GMP establishment in 30 months after the initiation of the construction.
- After that Equipment Validation takes 6 months and Process validation takes 6-9 months. Then production of vaccine from the new facility will be initiated and completed with the certification of initial 3 consecutive batches by CDL, in 12 months.
- The proposed annual supply from the new facility will be : DPT- 60 Mld; TT -55 Mld; DT- 15Mld (Total- 130 Mld)



Sub: Questionnaire on Demands for Grant 2015-16 of Department of Health and F.W. in respect of Sera and Vaccine manufacturing Units -reg.

a) What is the actual expenditure (both plan and non-plan) in 2014-15 under this Head?

This Institute receives Grant-in-Aid under Plan scheme only. As on 11.03.2015, the actual expenditure under Plan scheme is 3442.84 lakhs.

b) What is the updated status of production of vaccines and sera by the three PSUs under reference?

About 106.70 lakh doses of DPT vaccine has been produced and supplied to the Universal Immunization Programme (UIP) in the current financial year 2014-15.

c) Whether the vaccine for UIP is being procured from private players? If so, the reason thereof? What is the cost of procurement of vaccine from private players vis-à-vis those supplied by Vaccine manufacturing PSUs.

Not applicable to this Institute.



Sub: Rajya Sabha Starred/Unstarred Dy. No.U2762, U2758, U2760 for 10.08.2017
regarding 'Return of examination fees'

(a) Whether it is a fact that the fees charged from candidates for examination to fill Government appointments published through advertisements by various departments is not refunded in case the recruitment for said posts are cancelled due to any reasons;

No. In the year 2012 due to administrative reasons, PII, Coonoor cancelled recruitment of the advertised posts. However, PII, Coonoor refunded the application fee collected from the candidates in the said Advertisement No. 01/2012.

(b) the number of cases in country wherein fee charged from candidates was not refunded in case of cancellation of appointment;

Not applicable.

(c) whether Ministry would consider a proposal to charge fee only from these candidates who get new Government appointments so that unemployed candidates are not put under a financial burden?

Not applicable to this Institute.



Sub: Rajya Sabha Questionnaire on Vaccine Policy and Immunization programme in India

Sl. No. 18: What is the present status of vaccine production units for producing DPT, BCG, Polio vaccine in the country? How much is the production capacity vis-à-vis actual output of each of these units? What efforts have been made by the government to step up the vaccine production by PSUs at Kasauli; Coonoor and Guindy? What are the reasons for poor capacity utilization of these units?

- Government of India has proposed to establish cGMP facility for manufacturing DPT group of vaccines at PIIC and nominated M/s. HLL as Project Management Consultant. Govt. of India has sanctioned Rs.137.02 crores towards project cost plus the Project Management Consultancy Fee of Rs.9.59 crores. .
- Civil work for the new GMP project was initiated in the month of June, 2013.
- Civil construction is mostly completed and the PMC proposed to completed the validation by December, 2017. Based on the timelines proposed by HLL, the Performance Qualification (PQ) for all critical equipments will be carried out from Jan. 2018 onwards by PII, Coonoor. This will be followed by process validation and trial batch preparation from April 2018 onwards.
- The proposed GMP facility for manufacturing DPT group of vaccine will have an installed capacity 130 million doses (Mld) of DPT group of vaccine i.e. DPT- 60 Mld; TT -55 Mld; DT- 15Mld;

Name of the vaccine	Installed capacity (per annum) (in lakh doses)	Operational capacity (per annum)
DPT	600.00	480.00
TT*	550.00	440.00
DT*	150.00	120.00

* A proposal for converting TT and DT vaccines into Td vaccine has been submitted to Ministry.

Sl. No.19: What is the demand and supply ratio for mandatory vaccines in India? Whether all public sector units producing these vaccines are producing vaccines as per the demand? How much is the demand supply gap for mandatory vaccines? What has been the contribution of private sector w.r.t. fulfilling the requirement of vaccines in the country? Names of all private companies manufacturing vaccines in the country may be given.



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At PII, Coonoor the commercial vaccine production of DPT group of vaccines will resume from the year 2019-20 as per the progress of the establishment of Greenfield DPT manufacturing unit at PII, Coonoor.

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Rajya Sabha Unstarred Question No.717 for 08.02.2019 on 'Cases pending before Tribunals'
by Shri K.C. Ramamurthy, MP

(a) the details of each of the different kinds of Tribunals functioning in the Country, State wise

- Central Administrative Tribunal (CAT)
- [Income Tax Appellate Tribunal](#) (ITAT)
- [Customs, Excise and Service Tax Appellate Tribunal](#) (CESTAT)
- National Green Tribunal (NGT)
- Competition Appellate Tribunal (COMPAT) and
- Securities Appellate Tribunal (SAT)

(b) the details of cases pending before each of the above mentioned Tribunal and details of cases that are pending for more than one year, two years, three years and five years and reasons for such pendency

Cases pending before Hon'ble Central Administrative Tribunal, Madras Bench are furnished below:

Sl. No	Case No.	Case filed by / Respondents	Present Status / Remarks
1.	OA No. 310/347/2015	Shri T.G. Irudayaraj Vs UOI, Secretary, MoH&FW (R-1), Director, PIIC (R-2) & Dr.B.Sekar, Director, PIIC (R-3).	The case adjourned to 02.04.2019.
2.	OA No. 310/00766/2015	Shri Raja Karthikeyan, Sr. Research Asst., PIIC Vs. UOI, Secretary, MoH&FW (R-1), Director, PIIC (R-2) & Dr. B. Sekar, Director, PIIC (R-3)	The case came on 07.02.2019 and adjourned.
3.	OA No. 310/00768/2015	Shri G. Chandramohan, Sr. Research Asst., PIIC Vs. UOI, Secretary, MoH&FW (R-1), Director, PIIC (R-2) & Dr. B. Sekar, Director, PIIC (R-3)	



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4.	O.A. No. 310/00381/2 016	Shri M. Madhavan & 29 Others Vs UOI, Rep. by Under Secretary to Govt. of India, MoH&FW (R-1) & Director, PII, Coonoor (R-2).	- The reply statement filed before the Hon'ble CAT. The case adjourned to 22.03.2019
5.	OA No. 310/817/201 6	Shri C. Muniandi Vs. UOI, Secretary, MoH&FW (R-1), Director, PIIC (R-2), Dr. B. Sekar, Director, PIIC (R-3) & Dr. K.N. Venkataramana, Former Asst. Director, PIIC (R-4)	- The reply statement filed before the Hon'ble CAT. - The OA Nos.310/817/2016 & 310/1471/2016 has been merged into a single case. Next date will be informed by Legal Counsel.
6.	OA No. 310/1471/20 16	Shri C. Muniandi Vs. UOI, Secretary, MoH&FW (R-1), Director, PIIC (R-2), Dr. B. Sekar, Director, PIIC (R-3) & Dr. K.N. Venkataramana, Former Asst. Director, PIIC (R-4)	
7.	OA No. 310/1647/20 16	Shri C. Muniandi Vs. UOI, Secretary, MoH&FW (R-1), UOI, Secretary, DoPT (R-2), Director, CLTRI (R-3) & Dr. B. Sekar, Director, PIIC (R-4).	- The reply statement filed before the Hon'ble CAT. Next date will be informed by Legal Counsel.
8.	OA No. 310/00004/2 017	Shri Balasubramani Vs. The Secretary (H) and Chairman of GB of PIIC (R-1), Director, PIIC (R-2), Dr. B. Sekar, Director, PIIC (R-3) & N.K.Subash, Inquiry Officer, Chennai (R-4)	- The reply statement filed before the Hon'ble CAT Next date will be informed by Legal Counsel.

(c) whether it is a fact that delay is due to huge vacancies in Tribunals

Not applicable to PII, Coonoor.

(d) whether inordinate delay has defeated the very purpose of establishing Tribunals, and

Not applicable to PII, Coonoor.

(e) if so, the steps taken/proposed to be taken to dispose the pendency in a time bound manner?

Not applicable to PII, Coonoor.

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Rajya Sabha provisionally admitted Starred/Unstarred Question Diary No.U1604 to be answered on 09.07.2019 regarding "VACCINE IMPORTS" raised by Shri Tiruchi Siva

(a) *Whether the dependence on vaccine imports has increased after the shutting down of State run PSUs in 2008*

Not applicable to this Institute.

(b) *Whether Government plans to revive or set up new PSUs for vaccine production*

Yes.

(c) *If so, the details thereof, and if not, the reasons thereof:*

Government of India proposed to establish cGMP facility for manufacturing DPT group of vaccines at PIIC, nominated M/s. HLL as Project Management Consultant. Govt. of India and sanctioned Rs.137.02 crores towards project cost plus the Project Management Consultancy Fee of Rs.9.59 crores.

The existing annual installed capacity of production of DPT group of vaccines at PII, Coonoor is 85.00 million doses. After establishing the proposed facilities, the installation capacity will be increased from 85.00 Million doses to 130.00 Million doses of DPT group of vaccine i.e. DPT- 60 Mld; TT -55 Mld; DT- 15Mld is as follows:

Name of the vaccine	Existing installed capacity	Installed capacity (per annum)	Operational capacity (per annum)
	(in lakh doses)		
DPT	400.00	600.00	480.00
TT*	300.00	550.00	440.00
DT*	150.00	150.00	120.00

* A proposal for converting TT and DT vaccines into Td vaccine was submitted to the Ministry and approval.

Once the PII, Coonoor is made fully functional with the installed capacity of 130 million doses, which is substantial increase in comparison with the existing installed capacity, will be supplied to UIP.

This is for your kind information.



Rajya Sabha provisionally admitted Starred/Unstarred Question Diary No.U1595 to be answered on 28.11.2019 regarding “High Expenses on government litigation” raised by Hon’ble Member Shri Amar Patnaik

(a) *The details of the expenditure on lawyers fees and other related expenses incurred by Government on litigation where Government is a party during the last three years:*

Year	Amount (in Rs.)
2016-17	59,000.00
2017-18	58,500.00
2018-19	55,000.00

(b) *The details of the expenditure on lawyers fees and other expenses incurred by Government on litigation initiated by it, as well as litigation for disputes inter-se Government Ministries, Departments and Public Sector Undertakings during the last three years*

Nil

(c) *The details of steps taken by Government to reduce expenditure on litigation?*



Rajya Sabha provisionally admitted Starred/Unstarred Question No.588 for 21.11.2019 regarding “Ongoing litigation Cases in courts” raised by Hon’ble Member Shri Amar Patnaik

(a) The number and percentage of ongoing litigation cases in courts where Government is a party to the dispute:

Out of 7 cases, the Government is party in 6 cases and the percentage for the same is 86%.

(b) The percentage of such litigation that has been initiated by Government

Out of 7 cases, 1 case has been initiated by Government and the percentage for the same is 14%.

(c) The number and percentage of such litigation for an inter-se dispute between Ministries/ Departments of Government and PSUs:

Nil

(d) Whether the Legal Information Management and Briefing System (LIMBS) platform comprehensively tracks all such litigation?

Yes.



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and Family Welfare, New Delhi, Government of India)



Rajya Sabha provisionally admitted Question No.S4405 for answer on 05.12.2019 regarding “Prosecution of Government employees” asked by Hon’ble Member Shri Binoy Viswam

no employees of this Institute prosecuted since 2014. Hence the information may kindly be treated as ‘Nil’.



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Assurance to Rajya Sabha USQ No.2652 on 17.03.2020 regarding innovative measures undertaken to Ministry - Reg.

(a) Whether any kind of new and innovative measures have been undertaken by the Ministry in general and/or its various departments or PSUs and autonomous bodies associated with it to improve work culture, bring more transparency and accountability and also enhance result orientation during the last five years, if so, the details thereof?

In order to improve the work culture of this Institute, external trainings have been imparted to all the staff members in various aspects like Good governance, 5Rs, RTI, various GMP related training/programmes and webinars. To bring more transparency, transparency audit was conducted in line with RTI Act. By which, many of the documents were published in the website of this Institute and accessible at our Library. Some of the photocopies of documents are given to staff members on written request.

With regard to accountability and result orientation, it will be fixed once the production of DPT group of vaccines commences at each laboratory.

(b) The impact of these efforts?

These trainings would bring more transparency, team work and better productivity in all the aspects.



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Rajya Sabha USQ No.1221 regarding vacant posts under Ministries - Reg.

(a) the cadre and grade-wise sanctioned and vacant posts in each agency and academic Institutions of the Ministries during the financial years 2017-18, 2018-19, 2019-20 and 2020-21

Group	Sanctioned Strength	As on 01.04.2018		As on 01.04.2019		As on 01.04.2020		As on 01.02.2021	
		No. in payroll	Vacant	No. in payroll	Vacant	No. in payroll	Vacant	No. in payroll	Vacant
A	15	8	7	8	7	7	8	6	9
B	46	30	16	25	21	22	24	19	27
C	242	132	110	113	129	104	138	94	148



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Sub: Rajya Sabha USQ No.923 regarding “Non utilization of vaccination manufacturing units” - Reg.

(a) reasons for not utilizing three vaccination manufacturing units at HLL Biotech, Chenagapattu, Tamilnadu, BCG Vaccine Laboratory, Chennai and Pasteur Institute of India, Coonoor, Tamilnadu for manufacturing COVID-19 vaccines despite requests from Chief Minister of Tamilnadu;

Since the BSL-III facility is not available at this Institute, this Institute is not in a position to manufacture COVID-19 vaccines.

(b) Details of COVID-19 vaccines distributed to all States, brand –wise, and total expenditure incurred in purchase of vaccines by Government till end of June, 2021, brand wise and cost of each vial for each brand;

Not applicable to this Institute.

(c) Steps taken by Government to get immediate EUL Clearance from WHO for Covishield and Covaxin so as to enable Indian citizens to move freely abroad?

Not applicable to this Institute.



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Sub: Rajya Sabha USQ No.2024 to be answered on 05.08.2021 raised by Shri, Iranna Kadadi, Hon'ble MP - Reg.

(a) *The number of tribunals functioning as on date;*

Not applicable to this Institute.

(b) *The total number of cases pending in various tribunals as on date, tribunal-wise;*

As on 03.08.2021, 4 Nos. of cases are pending in Hon'ble Central Administrative Tribunal, Madras Bench.

(c) *The present status of progress made with regard to the merger of various tribunals in the country;*

Not applicable to this Institute.

(d) *Whether the Government has consulted various Ministries under which the said tribunals are functioning and their responses in this regard;*

Not applicable to this Institute.

(e) *If so, the details thereof and the steps taken/proposed to be taken by the Government in this regard; and*

Not applicable to this Institute.

(f) *whether these tribunals have been successful in achieving their objectives and if not, the steps taken/being taken by the Government to review/improve their functioning?*

Not applicable to this Institute.



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Sub: Rajya Sabha Unstarred Question No.1057 for answer on 07.12.2021 by Dr. Vinay P. Sahasrabuddhe regarding "Institutions and manpower of the Ministry" - Reg.

(b) the number of employees, permanent, temporary and contract basis who are working in these Institutions/bodies;

The actual position of permanent and outsourced employees as on 01.12.2021 in this Institute is as follows:

Permanent employees:

S. No	Group	Total Sanctioned posts	No. in pay roll	Vacant posts
1.	A	15	5	10
2.	B	46	23	23
3.	C	113	49	64
4.	C (Erstwhile Group D) - Multi-Tasking Staff	129	21	108
	TOTAL	303	98	205

Outsourced employees:

S. No	Name of Post	Total sanctioned posts	No. in pay roll	Vacant posts
1.	Medical Officer	1	1	0
2.	Veterinary Assistant Surgeon	1	1	0
3.	Consultant (Admin/Accts)	1	1	0
4.	Highly Skilled Engineer	7	5	2
5.	Highly Skilled Science	56	56	0
6.	Skilled Engineer	12	12	0
7.	Skilled Clerical	11	9	2
8.	Skilled Nursing Staff	1	1	0
9.	Unskilled	58	58	0
	TOTAL	148	144	4



(c) whether the Ministry as a whole has done any manpower needs assessment of these institutions and autonomous bodies. If so the result of such assessment, if not the reason thereof?

Government of India established cGMP facilities for the manufacturing DPT group of vaccines at PII, Coonoor by the Project Management Consultant viz. M/s. HLL with an estimated cost of Rs.137.02 crores. Currently the Performance Qualification and trial batch production is in progress, followed by consistency batch production will be initiated.

EFC also recommended to rationalize the staff as per GMP (Good Manufacturing Practice) requirements. Further the Committee directed to submit the recurring expenditure due to rationalization of staffs as per GMP requirement subject to the requirement to be re-examined and finalized.

As per the above director, this Institute submitted the requirement of rationalized manpower to the Ministry and the same was duly approved by the Standing Finance Committee meeting of this Institute held on 27.07.2021 and Governing Body meeting held on 29.07.2021. The Governing Body approved the proposal of rationalization of manpower for the (i) creation of 66 Nos. additional manpower in Group A & B cadres (ii) engagement of 188 manpower on outsourced basis for the activities to be carried out by Group C cadre and (iii) engagement of 175 manpower on outsourced basis for the activities be carried out by erstwhile Group D cadre.

The above manpower is sufficient to run the GMP facilities for the production of DTP group of vaccines and its allied functional areas.



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Sub: Rajya Sabha Provisionally Admitted Question Diary No.S3886 due for answer on 22.03.2022 regarding "Vacancies in various institutions under the Ministry of Health and Family Welfare" asked by Dr. V. Sivadasan, Hon'ble MP for answer on 22.03.2022 - Reg.

S. No.	Name of the Institute	Number of Vacant Posts	Concerned JS/AS
1.	Pasteur Institute of India, Coonoor	Group A - 9 Nos. Group B - 25 Nos. Group C - 175 Nos.	Ms. Padmaja Singh, Joint Secretary to Govt. of India

Name of the Institute: Pasteur Institute of India, Coonoor

S. No.	Year (2010 onwards)	Total number of Recruitments done	Concerned JS/AS
1.	2010 onwards	Nil	Ms. Padmaja Singh, Joint Secretary to Govt. of India