



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

Lok Sabha Question Dy.No.17035 for 20.08.2010 regarding procurement of BCG Vaccine

Question No. a: The vaccines being produced by the three public sector vaccine producing units and the steps taken/proposed to modernize them

DPT group of vaccines (DPT - Diphtheria, Pertussis and Tetanus Toxoid, DT- Diphtheria and Tetanus Toxoid and TT- Tetanus Toxoid) and Tissue Culture Anti Rabies Vaccine (TCARV) are being produced at Pasteur Institute of India, Coonoor.

This Institute has the proposal for new infrastructure prepared by 'Oversight Committee' as well as proposal for modification of the existing infrastructure prepared by committee consisting members from M/s. HLL Lifecare and M/s. NNE Pharmaplan. The Ministry of Health and Family Welfare, New Delhi vide letter No.V.11011/7/2010-VI dated 30th June, 2010 engaged M/s. HLL Lifecare Limited as Project Management Consultant for revival of Pasteur Institute of India, Coonoor.

Question No. b: Whether Government has procured/ considered to procure BCG vaccines which were well past their expiry date from the BCG Lab whose license was already suspended.

Not applicable to this Institute.

Question No. c: If so, the facts and the details thereof along with the reasons thereof;

Not applicable to this Institute.

Question No. d: Whether any probe has been carried out in this regards;

Not applicable to this Institute.

Question No. e: If so, the outcome thereof; and

Not applicable to this Institute.

Question No. f: The steps taken/ being taken by the Government to monitor the procedure which would ensure while procuring such vaccine?

Not applicable to this Institute.



Lok Sabha Prov. St. Question Dy. No.6256 for 19.11.2010 regarding Closure of three Public Sector Vaccine Units asked by S/Shri Gajanan D. Babar, Nikhil Kumar Choudhary, M.K. Raghavan, Dushyant Singh, S.S. Ramasubbu, Ravindra Kumar Pandey, MPs

(a) Whether the Drug Controller General of India (DCGI) has suspended the manufacturing licenses of three public sector vaccine unit;

Yes.

(b) If so, the details thereof and reasons therefor;

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.

(c) Whether the Government has constituted to investigate the reasons for closure of three public sector vaccine manufacturing units in the country;

Not applicable to this Institute.

(d) If so, whether the aforesaid committee has submitted its report to the Union Government;

Not applicable to this Institute.

(e) If so, the main reasons for suspending the manufacturing licenses of these three public sector vaccine units;

Not applicable to this Institute

(f) The recommendations made by the aforesaid committee regarding the revival of these public sector vaccine units; and

Summary of the Recommendations of the Interim Committee to set up to determine the reasons for the suspension of the manufacturing licenses of CRI, Kasauli, PII, Coonoor and BCGVL, Guindy is reproduced below:

- (i) The Ministry of Health and Family Welfare consider revoking the suspension orders issued against the three public sector vaccine manufacturing units in response to the appeals filed under Rule 85 (3) of the D&C Rules. The revocation may be made subject to the condition that the new production line, fully compliant with GMP standards, be installed and commissioned within a period of three years.



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- (ii) The Ministry of Health and Family Welfare consider directing the units holding finished products to confirm their quality standard and then supply and use them under the UIP before the date of their expiry of the products.
- (iii) The Ministry of Health and Family Welfare urgently make funds available to the units to complete the remaining upgradation works on the existing production lines.
- (iv) The Core Committee piloting the upgradation of the manufacturing units urgently intervene to resolve the existing deadlock between the management of the units and the contractors executing the upgradation works in the existing production lines.
- (v) The Core Committee be advised to urgently undertake the various responsibilities listed in Section 10 of the report for implementing the new production lines in the three units.
- (vi) The Ministry of Health and Family Welfare consider the recommendations of reviving/filling up the vacant posts in the units through the summary procedure suggested in Section 11 of the report, in order to expeditiously install the necessary manpower to effectively pilot the implementation of the new production lines. Also, the Ministry consider the recommended summary procedure for sanctioning the manpower for the new production line.

(g) The response of the Union Government thereto?

The Govt. of India, Ministry of Health and Family Welfare, New Delhi vide Order F.No.X.11035/2/2010-DFQC dated 26th February, 2010 revoked the suspension of licence for manufacturing vaccines.



Lok Sabha Admitted Unstarred Question No.3965 for answering on 3rd December, 2010 regarding WHO direction to vaccine manufacturers asked by Shri Anto Antony, MP

(a) Whether the World Health Organisation (WHO) has given any direction to vaccine manufacturers such as the Central Research Institute at Kasauli in Himachal Pradesh, Pasteur Institute in Kerala and BCG Vaccine Lab in Chennai;

No.

(b) If so, the details thereof and if not, the reasons therefor;

Not applicable

(c) The steps taken by the Government to revamp these institutions;

- The Govt. of India constituted an Expert Committee under the chairmanship of Dr. Surinder Singh, Drug Controller General (India), New Delhi visited Pasteur Institute of India, Coonoor during the period 10th to 12th July 2008.
- The Govt. of India constituted an Oversight Committee under the chairmanship of Dr. Surinder Singh, Drug Controller General (India) and with the following members visited this Institute on 15.09.2009 & 21.10.2009
 - Dr. Anil Kumar Chawla, WHO GMP Expert
 - Dr. V.G. Somany, Deputy Drug Controller
 - Mr. Avinash Mishra Director, MoHFW
 - Dr. Paul Francis, WHO Consultant
 - Mr. B. Banerjee, Consultant
 - Ms. Chandrani, Microbiologist
- As per the direction of the Govt. of India, Ministry of Health and Family Welfare, New Delhi a committee to review the reasons for suspension of licenses and to review the road map for revival of the Institutes, a committee consisting of Shri. Javed Chaudhary, Chairman and Dr. Salhan, Member constituted by Govt. of India, Ministry of Health and Family Welfare, New Delhi visited this Institute on 19th and 20th December 2009.
- The Govt. of India, Ministry of Health and Family Welfare, New Delhi has constituted a committee for the upgradation of existing facilities of DPT manufacturing facility, a team from M/s. HLL Lifecare along with experts from M/s. NNE Pharmaplan have visited this Institute during 16th and 17th January, 2010.
- The Govt. of India, Ministry of Health and Family Welfare, New Delhi vide Order F.No.X.11035/2/2010-DFQC dated 26th February, 2010, in exercise of its powers under Sub-rule (3) of Rule 85 of the Drugs and Cosmetics Rules, 1945 revoked the suspension of licence bearing 12 in Form 28. As such, the production activities are commenced with



immediate effect.

(d) Whether the World Health Organisation (WHO) has made any direction regarding these institutions; and

- Yes. The Oversight committee constituted by the Govt. of India, Ministry of Health and Family Welfare, New Delhi with WHO GMP Expert Dr. Anil Kumar Chawla, has visited this Institute on 14th and 15th September 2009 and provided the guidelines for new project proposals along with drawings for new infrastructure.

(e) If so, the details thereof?

The Oversight committee constituted by the Govt. of India, Ministry of Health and Family Welfare, New Delhi visited this Institute on 14th and 15th September 2009 and recommended new infrastructures for the following projects:

- TCARV lab
- Diphtheria and Pertussis lab- (with provision for Pentavalent vaccine production)
- Tetanus lab
- Formualtion and filling unit
- Antisera unit
- Animal House (for small and large animals)

The following facilities are available at Pasteur Institute of India, Coonoor for the revival plan suggested by the Oversight Committee:

- Vacant land of 5 acres available and an additional 3 acres can be reclaimed by demolishing old non- heritage buildings.
- Adequate water and electricity available.
- Adequate man power available

WHO has provided the structural drawings for all the facilities recommended by the Oversight Committee.

Tentative Budget Proposed for the new infrastructure by the Oversight Committee:-

Sl. No.	Name of the project	Estimated Amount (` in Crores)
1.	Tissue Culture Anti Rabies Vaccine (TCARV)	50.00
2.	Diphtheria and Pertussis production laboratories	50.00
3.	Tetanus Toxoid production	50.00



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	laboratories	
4.	Formulation and Filling (2 units – live & inactivated vaccines)	50.00
5.	Antisera project	20.00
6.	Animal House (2 buildings – one for large animals (stable) and other for small animals)	50.00
	TOTAL	280.00



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Lok Sabha Unstarred Question No.5147 for 10.02.2010 regarding Closing of Vaccine Manufacturing Unit

Prior to the suspension of our Drug Licence by DCG (I), New Delhi, this Institute has supplied the following quantities of DPT group of vaccines under EPI programme during the year financial year 2006-07.

Sl. No.	Name of the Vaccine	Quantity supplied (in lakh doses)	Value (Rupees in lakhs)
1.	DPT	380.52	449.01
2.	DT	207.55	193.61
3.	TT	471.34	292.23
	TOTAL		934.85 (or) 9.35 Crores

After the receipt of the suspension order in respect of our Drug Licence this Institute could not produce any DPT group of vaccines. If the licence is not suspended, we could have supplied the following quantities of vaccines approximately during 2007-08 to 2009-10 under EPI programme.

Sl. No.	Name of the Vaccine	Installed capacity (in lakh Doses)	2007-08	2008-09	2009-10
			Value (Rupees in lakhs)	Value (Rupees in lakhs)	Value (Rupees in lakhs)
1.	DPT	400.00	472.00	472.00	472.00
2.	DT	150.00	144.00	144.00	144.00
3.	TT	300.00	186.00	186.00	186.00
	TOTAL		802.00	802.00	802.00

As such, it is stated that there is a revenue loss of Rs.802.00 lakhs (8.02 crores) apprx. every year in view of non-supplying of DPT group of vaccines under EPI programme due to suspension of our Drug Licence.

In addition to the above, the details of the loss incurred by this Institute by way of intermediate stocks which could not be used due to the suspension of Drug Licence of this Institute are given below:

Sl. No.	Name of the Item	Quantity (in lakh doses)	Value (in lakhs rupees)
DPT COMPONENTS			

To Strive to seek to find and not to yield



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1.	Purified Diphtheria Toxoid	131.62	28.96
2.	Purified Tetanus Toxoid	23.67	4.97
3.	Pertussis Component	83.20	19.14
4.	Tetanus Toxoid Bulk	5.00	3.10
5.	Diphtheria and Tetanus Bulk	5.00	4.80
6.	Aluminium Phosphate Gel	420.00	1.68
	I. TOTAL		62.65
TISSUE CULTURE ANTIRABIES VACCINE (TCARV)			
1.	Lyophilised (Ready for supply but CDL test is to be completed)	0.30	61.50
2.	To be filled	0.26	53.30
3.	Concentrated stage	0.50	102.50
	II. TOTAL		217.30
	GRAND TOTAL (I + II)		279.95 (or) 2.80 Crores

To Strive to seek to find and not to yield



Lok Sabha Prov. St. Question Dy. No.2795 for 25.02.2011 regarding Production of Vaccine asked by Shri Abdul Rahman, MP.

(a) Whether the two public sector vaccine units have not been able to produce vaccines even after 10 months since lifting of suspension of production licenses and spending crores of rupees forcing the Central Government to purchase vaccines from the private vaccine manufacturers for its National immunization Programme

Pasteur Institute of India, Coonoor is yet to release the first batch of DPT vaccine as the component preparation like Diphtheria Toxoid, Tetanus Toxoid and Pertussis are underway.

(b) If so, the details thereof;

There were certain problems encountered in the production of tetanus component, although Diphtheria and Pertussis components were produced. Hence the supply of DPT vaccine could not be made as per the committed schedule.

(c) The reasons for not producing vaccines for the National Immunization Programme by these two units

This is mainly due to the problem in the tetanus seed. Action has been taken to procure the Tetanus seed from CRI, Kasauli.



Lok Sabha Prov. St. Question Dy. No.2771 for 25.02.2011 regarding DPT vaccine for Children, asked by Shri Anand Prakash Pranjpe, MP

(i) Whether 300 lakh doses of DPT vaccine for children have been reported to the rendered unusable recently

The Times of India dated 30.12.2010 published a false news captioned as '300 lakh doses of DPT vaccine down the drain' at Pasteur Institute of India, Coonoor. The factual position was clarified to the Ministry of Health and Family Welfare, New Delhi vide letter No.PII/ADMN/2010-11/5906 dated 17th January, 2011 (copy enclosed for ready reference). As of now no final vaccine has been prepared; only 40 lakh doses were formulated to test the quality and are yet to be filled. The usability of these 40 lakh doses of DPT vaccine will be decided only after the out come of the quality control tests which are under process are known.

(ii) If so, the reasons thereof

The analysis of the usability of 40.00 lakh doses of formulated DPT vaccine is under process.

(iii) the name and the place of the institution that prepared this vaccine

Pasteur Institute of India, Coonoor.

(iv) the extent of loss to the exchequer on this account

Not applicable at this juncture.

(v) whether Government has to pay high price to buy this vaccine from other sources

Not applicable to this organization.

(vi) whether any enquiry has been conducted in this regard

The factual position was clarified to the Ministry of Health and Family Welfare, New Delhi vide letter No. PII/ADMN/2010-11/5906 dated 17th January, 2011.

(vii) If so, the outcome thereof

Not applicable at this juncture.



Lok Sabha Unstarred Question No.798 for 25.02.2011 regarding Shortage of vaccines

(d) Whether the three vaccine producing units in Kasauli, Chennai and Coonoor have restarted producing vaccines after revoking their suspension in the country;

Yes.

(e) If so, the details thereof

The Ministry of Health and Family Welfare, New Delhi vide order number F.No.X.11035/2/2010-DFQC dated 26.02.2010 revoked the suspension of licence. Accordingly, productions of DPT vaccine at different component level are underway. As of now no final vaccine has been prepared; only 40 lakh doses were formulated to test the quality and are yet to be filled. The analysis of the usability of 40 lakh doses of formulated DPT vaccine is under process. There were certain problems encountered in the production of tetanus component, although Diphtheria and Pertussis components were produced. Action has been taken to procure the Tetanus seed from CRI, Kasauli.



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Lok Sabha Prov. St. Question Dy. No.10736 for 11.03.2011 regarding Unusable Vaccines asked by Dr. Sanjeev Ganesh Naik, MP.

(a) Whether a large quantity of doses of diphtheria, pertussis and tetanus vaccines meant for children, costing several crores of rupees, have been found unusable recently during an internal inspection;

The Times of India dated 30.12.2010 published a false news captioned as '300 lakh doses of DPT vaccine down the drain' at Pasteur Institute of India, Coonoor. The factual position was clarified to the Ministry of Health and Family Welfare, New Delhi vide letter No.PII/ADMN/2010-11/5906 dated 17th January, 2011 (copy enclosed for ready reference). As of now no final vaccine has been prepared; only 40 lakh doses were formulated to test the quality and are yet to be filled. The usability of these 40 lakh doses of DPT vaccine will be decided only after the out come of the quality control tests which are under process are known.

(b) If so, the details thereof;

The analysis of the usability of 40 lakh doses of formulated DPT vaccine is under process.

(c) Whether the Government had to purchase these from private manufacturers to meet the urgent demand;

Not applicable to this organization.

(d) If so, the details therefor

Not applicable.



Lok Sabha Starred Question Dy.No.17964 for answering on 26-8-2011 regarding production of vaccines asked by Dr. Baliram, MP

(a) Whether production of some vaccines including anti-rabies vaccine by some Public Sector Units has been suspended by the Drugs Controller General of India (DCGI).

Yes. The Drugs Controller General (I) & Central License Approving authority vested with the powers under Sub Rule (1) of Rule 85 of D&C Rules, suspended the whole licence bearing number 12 in form 28D held by Pasteur Institute of India, Coonoor vide their letter No.X-11026/1/06 D dated 15th January, 2008. Followed by this order, the productions of DPT group of vaccines and Tissue Culture Anti-rabies Vaccine have been suspended at PIIC.

(b) If so, the details thereof and the reasons therefor;

In the suspension of licence it has been stated that the Pasteur Institute of India has failed to comply with the conditions of licence in respect of

- i) Condition (a) (i) of Rule 78 in not maintaining adequate staff and adequate premises and plant as provided in Drugs and Cosmetics Rules
- ii) Condition (p) is not complied as the good manufacturing practices as laid down in part 1 and part 1-A of Schedule M of Drugs and Cosmetics Rules are not followed/adapted in the manufacture and quality control of the drugs manufactured under licence number 12 in form 28D

(c) Whether the Government is aware that suspension of production of the vaccines has led to shortage of such vaccines in the market and subsequently increase in their prices by the private companies; and

Not applicable to this organization.

(d) If so, the details thereof and the corrective steps taken by the Government in this regard?

Not applicable.



Lok Sabha Prov. St. Question Dy. No.20515 for 04.05.2012 regarding Production of BCG Vaccine asked by Shri Kodikunnil Suresh and S.R. Jeyadurai, MPs – Reg.

(a) Whether the Central Research Institute, Kasauli, the BCG Vaccine Laboratory, Guindy and the Pasteur Institute of India, Coonoor are producing vaccines as per their capacity after Government revoked the order which suspended their licenses;

After the revocation of suspension order during February, 2010 the Pasteur Institute of India, Coonoor initiated commercial production of vaccines and it has proposed to supply 39.5 million doses of DPT vaccine from June 2012 to July 2013 although the installed capacity of DPT group of vaccines has not been achieved now.

(b) If so, the details thereof and if not, the reasons therefor;

- 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.
- The commercial production of the Tetanus component has been initiated in August, 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.
- It is proposed to supply 39.5 million doses (395.00 lakh doses) of DPT vaccine from June – July 2012 to June-July 2013.
- 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.

(c) Whether the Government had taken a decision to upgrade these units;

Yes.

(d) If so, the details thereof and the status of upgradation of these units

Answer in respect of Pasteur Institute of India, Coonoor:

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.



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- 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.
- 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)



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Lok Sabha Prov. St. Question Dy. No. 20801 for 04.05.2012 regarding Anti Venom Vaccines asked by Smt. Menaka Gandhi, MP

This Institute does not produce Anti Snake Venom.



Lok Sabha Prov. St. Question Dy. No.15731 for 18.05.2012 regarding procurement of BCG Vaccine asked by Shri Dushyant Singh, MP

(a) Whether the Central Research Institute, Kasauli, the BCG Vaccine Laboratory, Guindy and the Pasteur Institute of India, Coonoor are producing vaccines as per their capacity after Government revoked the order which suspended their licenses;

After the revocation of suspension order during February, 2010 the Pasteur Institute of India, Coonoor initiated commercial production of vaccines and it has proposed to supply 39.5 million doses of DPT vaccine from June 2012 to July 2013 although the installed capacity of DPT group of vaccines has not been achieved now.

(b) If so, the details thereof and if not, the reasons therefor;

- 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.
- The commercial production of the Tetanus component has been initiated in August, 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.
- It is proposed to supply 39.5 million doses (395.00 lakh doses) of DPT vaccine from June – July 2012 to June-July 2013.
- 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.

(c) The details of extra expenditure on procurement of vaccine during the closure of above units;

Not applicable

(d) Whether the Government had taken a decision to upgrade these units;

Yes.

(e) If so, the details thereof and the status of upgradation of these units

Answer in respect of Pasteur Institute of India, Coonoor:

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 of Rs.137.02 crore 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.
- As per the directions of the Ministry of Health and Family Welfare, New Delhi, a sum of Rs.5.00 crore was transferred to M/s. HLL Lifecare Limited on 31.03.2012 for revival and upgradation of DPT group of vaccine manufacturing facilities as per cGMP at Pasteur Institute of India, Coonoor.
- The layout and other related documents have been submitted to the local municipal authorities for recommendation of the AAA/HACA committees on 17.04.2012 and the required fee has been remitted.
- The Director and senior officers met District Collector, The Nilgiris on 02.05.2012 and gave a letter of request to expedite for convening the AAA committee.
- The Deputy Director, Directorate of Town and Country Planning, Tamilnadu visited for preliminary discussion to PII, Coonoor on 03.05.2012.
- 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: Lok Sabha Provisional admitted Starred Question Dy. No.4687 for answer on 17-08-2012 regarding 'production of BCG Vaccine'

(a) The reasons for suspension order of Manufacturing licenses of Coonoor and BCG Vaccine along with the reason of the Government on the above reasons:

As per the Office Memorandum No.X-11026/1/06-D dated 15.01.2008 of Directorate General of Health Services, (Drugs Control Division), Nirman Bhawan, New Delhi, the Pasteur Institute of India, Coonoor, Tamilnadu has failed to comply with conditions of licence in respect of

- (i) Condition (a) (i) of Rule 78 in not maintaining adequate staff and adequate premises and plant as provided in Drugs and Cosmetics Rules.
- (ii) Condition (p) it not complied as the good manufacturing practices as laid down in part 1 and part 1-A of Schedule M of Drugs and Cosmetics Rules are not followed/adapted in the manufacture and quality control of the drugs manufactured under licence number 12 in form 28D.

Therefore, the Drugs Controller General (India), Central Licence approving Authority, vested with the powers under Sub Rule (1) of Rule 85 of D & C Rules, suspended the whole licence bearing number 12 in form 28D held by Pasteur Institute of India, Coonoor, Tamilnadu till such time all the deficiencies are rectified.

(b) The details of production of Coonoor and BCG Vaccine by the firms after revoked of above suspension order, firm-wise.

In pursuance of the revocation of the suspension of licence by the Ministry of Health and Family Welfare, Govt. of India, New Delhi vide their letter No.X.11035/2/2010-DFQC dated 26th February, 2010 and the renewal of production licence by the Drugs Controller General (I), Govt. of India and the Director of Drugs Control, Tamilnadu vide letter dated 5-9-2011, the production of vaccines was made at PIIC in the existing facility by adopting all mandatory quality control testings. As per procedure, 6 consecutive batches of DTP 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 14-6-2012, six batches of DTP Vaccine consisting of 15 lakh doses was released to Bangalore, Belgaum and Hyderabad on 26-6-2012. The second consignment consisting of 19.72 lakh doses have been dispatched to Pune and Mumbai on 11-8-2012 after getting the final certification for release from the Central Drugs Laboratory, Kasauli vide their letter No.CDL/2012/4632 dated 6-8-2012.

(c) The reasons for revoke the suspension order of manufacturing licenses Coonoor and BCG Vaccine;

The Pasteur Institute of India, Coonoor preferred an appeal against the suspension order to the Central Government vide letter dated 14-6-2008 requesting revocation of the suspension



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order so as to restart the suspended manufacturing operations.

The entire matter has been carefully considered by the Government taking into account provisions of the Drugs and Cosmetics Act, 1940 and the Rules, the recommendations contained in the Interim Report of Shri Javid Chowdhury Committee, the substantial compliance status furnished by the appellant Institute, 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.

Therefore, the Central Government, in exercise of its powers under sub-Rule (3) of Rule 85 of the Drugs and Cosmetics Rules, 1945 ordered revocation, with immediate effect, the suspension of the licence bearing 12 in Form 28D vide order No.X.11035/2/2010-DFQC dated 26th February, 2010.



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Sub: Lok Sabha Unstarred Question Dy. No.250 for reply on 22.02.2013 asked by Shri Virender Kashyap, MP

a.	Whether the Govt. proposed to establish a few new research Institute in the country to produce more Bacterial and Viral vaccines and sera	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 non-expenditure amount of Rs.137.02 crores plus the Project Management Consultancy Fee for HLL. After establishing the new facilities at PIIC, the installation capacity will be increased from 85.00 Million doses to 130.00 Million doses as detailed below:- (in million doses)																		
b.	If so, the details thereof;	<table border="1"><thead><tr><th rowspan="2">Name of the Vaccine</th><th colspan="2">INSTALLATION CAPACITY</th></tr><tr><th>Existing Facility</th><th>New Facility</th></tr></thead><tbody><tr><td>DPT</td><td>40.00</td><td>60.00</td></tr><tr><td>DT</td><td>15.00</td><td>15.00</td></tr><tr><td>TT</td><td>30.00</td><td>55.00</td></tr><tr><td>Total</td><td>85.00</td><td>130.00</td></tr></tbody></table>		Name of the Vaccine	INSTALLATION CAPACITY		Existing Facility	New Facility	DPT	40.00	60.00	DT	15.00	15.00	TT	30.00	55.00	Total	85.00	130.00
Name of the Vaccine	INSTALLATION CAPACITY																			
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TT	30.00	55.00																		
Total	85.00	130.00																		
c.	Whether Central Research Institute (CRI), Kasauli is not in a position to produce various vaccines due to shortage of staff;	Not applicable																		
d.	If so, the details thereof and the reasons therefore;	Not applicable																		
e.	The steps taken/being taken by the Govt. in this regard?	Not applicable.																		



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Sub: Lok Sabha Unstarred Question Dy. No.S 2102 for reply on 05.03.2013 asked by Shri K.N. Balagopal, MP.

(a) Whether the Government agencies are procuring vaccines from sector?

Not applicable

(b) If so, the percentage of vaccines private sector to the total use and the details thereof?

Not applicable

(c) Whether all the PSUs Vaccines Units are now functioning with full capacity?

With regard to PII, Coonoor, Ministry has allocated 380.60 lakh doses of DPT vaccine vide amended Supply Order No. S.12011/5/2012-VPC/DPT(2012-13)/SO/PII dated 18.01.2013.

(d) If so the details thereof?

Out of 380.60 lakh doses of DPT vaccine, PII, Coonoor has supplied 199.41 lakh doses as on date.



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)



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Sub: Lok Sabha Unstarred Question Dy. No.12750 for 15.03.2013 regarding Production of Vaccines asked by Smt. Rama Devi, Shri Neeraj Shekhar and Shri Yashvir Singh, MPs

- (a) The details of production of vaccines produced by Pasteur Institute of India, Coonoor, Central Research Institute, Kasauli and BCG Vaccine Laboratory, Chennai during each of the last three years and current year, institute wise and vaccine wise:

Details of production of vaccines produced by Pasteur Institute of India, Coonoor during each of the last three years

2009-11	2010-11	2011-12	Current year 2012-13
Nil	Nil	Nil	199.41 lakh doses of DPT vaccine

- (b) Whether the vaccines for Universal Immunization Programme (UIP) are currently being procured from private sources at higher prices due to inability of the public sector units to supply required quantity of vaccines:

Not applicable

- (c) If so, the details thereof and the reasons therefore

Not applicable

- (d) The steps taken by the Government to scale up the vaccine production in public sector units to meet the demand and also check their price?

In the new GMP complaint manufacturing facility to be established at Pasteur Institute of India, Coonoor it is proposed to scale up the vaccine production as follows:

(in million doses)

Vaccines	Current installation capacity	Proposed installation capacity
DPT	40.00	60.00
TT	30.00	55.00
DT	15.00	15.00
TOTAL	85.00	130.00



Sub: Lok Sabha Starred Question Dy. No.13435 for 30-8-2013 regarding Production of Vaccines asked by Smt. Rajkumari Ratna Singh, Shri S.S. Ramasubbu and Dr. Sanjay Sinh, MPs

(a) controlled units engaged in production of vaccines along with the production of each unit during each of the last three years and current year, vaccine and unit-wise

The details of production of vaccines by Pasteur Institute of India, Coonoor during each of the last three years and current year are given below:-

2010-11	2011-12	2012-13	Current year 2013-14 (upto 22-8-2013)
Nil	Nil	199.41 lakh doses of DPT Vaccine	153.00 lakh doses of DPT vaccine

(b) whether there is any shortage of certain vaccines against the usual requirements under various health programmes including the Universal Immunisation Programme (UIP);

Not applicable to this Institute

(c) if so, the details of the demand and supply during the above said period and its impact on various health programme run by the Government;

Not applicable to this Institute

(d) The quantum and types of vaccines imported as well as purchased from private companies for various health programme along with the funds spent for the purpose during the above said period, vaccine-wise;

Not applicable to this Institute

(e) The steps taken/ being taken by the Government to ensure adequate availability of all the vaccines for the UIP and also their availability in market at affordable prices in the country?

Not applicable to this Institute



Lok Sabha Starred Question Diary No. 1066 for 06.12.13 regarding "Shortage of Vaccines" asked by Shri C. Rajendran and Shri Virendra Kumar, MPs

-
- a. The number of the Government controlled units engaged in the production of various types of vaccines along with the production of each unit during each of the last three years and the current year, vaccine and unit-wise;

The details of production of vaccines by Pasteur Institute of India, Coonoor during each of the last three years and current year are given below:-

2010-11	2011-12	2012-13	Current year 2013-14 (upto 30-11-2013)
Nil	Nil	199.41 lakh doses of DPT Vaccine	181.19 lakh doses of DPT vaccine

- b. Whether there is any shortage of certain vaccines against the usual requirements under various health programmes including the Universal Immunisation Programme (UIP) due to poor response from private pharmaceutical companies;

Not applicable to this Institute

- c. If so, the details of the demand and supply during the above said period and its impact on various health programmes run by the Government

Not applicable to this Institute

- d. The quantum and types of vaccines imported as well as purchased from private companies for various health programme along with the funds spent for the purpose during the above said period, vaccine-wise;

Not applicable to this Institute

- e. The steps taken/ being taken by the Government to ensure adequate availability of all vaccines for the UIP and also their availability in market at affordable prices in the country?

Not applicable to this Institute



Sub: Lok Sabha Starred Question Diary No. 12908 for 13.03.2015 regarding "Shortage of Vaccine" asked by Shri Nimmala Kristappa, MP

Sl. No. a) The number of the Government controlled units engaged in the production of vaccines along with the production of each unit during each of the last three years and current year, vaccine and unit-wise;

Pasteur Institute of India is an autonomous body functioning under the Ministry of Health and Family Welfare, Government of India, New Delhi engaged in the production and supply of DPT group of vaccines to Universal Immunization Programme.

The details of production and supply of DPT vaccine by Pasteur Institute of India, Coonoor during each of the last three years and current year are given below:-

DPT Vaccine			
2011-12	2012-13	2013-14	2014-15 (current year)
Nil	199.41 lakh doses	188.19 lakh doses	106.70 lakh doses

Sl. No. b) whether there is any shortage of certain vaccines against the usual requirements under various health programmes including the Universal Immunisation Programme (UIP)

Not applicable to this Institute

Sl. No. c) if so, the details of the demand and supply during the above said period and its impact on various health programmes run by the Government;

Not applicable to this Institute

Sl. No. d) the quantum and types of vaccines imported as well as purchased from private companies for various health programmes along with the funds spent for the purpose during the above said period, vaccine-wise;

Not applicable to this Institute

Sl. No. e) The steps taken/being taken by the Government to ensure adequate availability of all the vaccines for the UIP and also their availability in market at affordable prices in the country?

The Govt. proposed to create Green Field GMP facility for manufacturing DPT group of 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 ₹137.02 crores plus the Project Management Consultancy Fee for HLL.



- Civil work for the new GMP project was initiated in the month of June, 2013.
- The project schedule is as follows:
 - Mechanical completion of facility will be February, 2016.
 - Facility validation (IQ & OQ) will commence by February 2016 and expected to be completed by August 2016
 - Performance qualification, Process validation GMP audits and trial batches production activities will commence from September 2016 onwards.
 - The trial batch of vaccine production will be commenced from the month of September, 2016 after the completion of facility validation (IQ & OQ) in the month of August, 2016. This requires a minimum period of 9 months. Accordingly, trial batch of vaccine production can be completed in the month of June, 2017. Later, the consistency/commercial production can be commenced from the month of July, 2017.

In the new GMP compliant manufacturing facility to be established at Pasteur Institute of India, Coonoor it is proposed to scale up the vaccine production to 130 million doses of DPT group of vaccine.

For the Financial year 2015-16, D, P,T components will be produced in the existing facility of around 20 lakh doses/per month of each, on receipt of licence for components from DCG(I).



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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: Lok Sabha Starred Question Diary No.22590 for 24.04.2015 regarding "VACCINE PRODUCTION" asked by Shri P.K. Biju, Dr. A. Sampath and Shri R.P. Marutharajaa, MP

- a) Whether there is a huge shortage of various types of vaccines in the country, if so, the details thereof;

Not applicable to this Institute.

- b) Whether the Government has taken any steps to boost the vaccine production, if so, the details thereof;

The Govt. proposed to create Green Field GMP facility for manufacturing DPT group of vaccines at PIIC. In this regard, HLL Lifecare Ltd., Trivandrum has been appointed as Project Consultant. EFC has recommended for a total estimated non-recurring expenditure of ₹137.02 crores plus the Project Management Consultancy Fee for HLL.

- Civil work for the new GMP project was initiated in the month of June, 2013.
- The project schedule is as follows:
 - Mechanical completion of facility will be February, 2016.
 - Facility validation (IQ & OQ) will commence by February 2016 and expected to be completed by August 2016
 - Performance qualification, Process validation GMP audits and trial batches production activities will commence from September 2016 onwards.
 - The trial batch of vaccine production will be commenced from the month of September, 2016 after the completion of facility validation (IQ & OQ) in the month of August, 2016. This requires a minimum period of 9 months. Accordingly, trial batch of vaccine production can be completed in the month of June, 2017. Later, the consistency/commercial production can be commenced from the month of July, 2017.

In the new GMP compliant manufacturing facility to be established at Pasteur Institute of India, Coonoor it is proposed to scale up the vaccine production to 130 million doses of DPT group of vaccine.

- c) Whether the Government proposes to restart the closed vaccine manufacturing companies in the country, if so, the details thereof indicating the time by which the said companies are likely to be reopened along with the safety norms being implemented in those units?

- 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 and subsequently this Institute has produced the vaccine in the existing facility and supplied the following quantities of vaccine to the UIP.



DPT Vaccine		
2012-13	2013-14	2014-15 (current year)
199.41 lakh doses	188.19 lakh doses	106.70 lakh doses

- The new GMP facility will be commissioned from July, 2017.



Sub: Lok Sabha Provisional Question (Diary No.15419) for 07.04.2017 regarding
“Renovation of national laboratories”

(a) whether any proposal is under consideration of the Government to resume the functioning and renovate Government run national laboratories, namely, BCG Vaccine Lab, Chennai and Pasteur Institute, Coonoor.

The Govt. proposed to create Green Field GMP facility for manufacturing DPT group of vaccines at PIIC. In this regard, HLL Lifecare Ltd., Trivandrum has been appointed as Project Management Consultant (PMC).

(b) if so, the details along with the proposed functions, the estimated renovation cost and capacity thereof;

- Government of India has sanctioned a estimated non-recurring expenditure of 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. As on Jan. 2017, 99.29% of civil work was completed.
- The timeline proposed by the PMC as on Jan. 2017 is as follows:
 - Mechanical completion of facility will be completed by June, 2017.
 - Facility validation (IQ & OQ) will be completed by September, 2017 except for IQ & OQ for ETP & STP i.e. 31.12.2017.
- Followed by IQ & OQ, the Performance qualification and Process validation will be commenced by PII, Coonoor from January, 2018 onwards.
- It is proposed to manufacture 130 million doses (Mld) of DPT group of vaccine i.e. DPT- 60 Mld; TT -55 Mld; DT- 15Mld, in the new GMP compliant manufacturing facility to be established at Pasteur Institute of India, Coonoor.

(a) The time by which the above two units are likely to start its functioning full-fledged?

The trial batch of vaccine production will be carried out from the month of April, 2018 to December, 2018. After that the commercial production will be commenced from the month of Jan. 2019.



Sub: Lok Sabha Provisional Question (Diary No.9389) for 28.07.2017 regarding
“SHORTAGE OF VACCINES”

(a) Whether the Government is aware of the huge shortage of vaccines in the county;

Not applicable to this Institute.

(b) If so, whether the Government have any proposal to restart the functioning of three vaccines laboratory units BCG Vaccine Laboratory, Chennai, Pasteur Institute of India, Coonoor and the Central Research Institute, Kasauli

- Government of India has proposed to establish cGMP facility for manufacturing DPT group of vaccines at PIIC. Govt. of India has sanctioned Rs.137.02 crores towards project cost plus the Project Management Consultancy Fee of Rs.9.59 crores. M/s. HLL is nominated as Project Management Consultant.
- Civil work for the new GMP project was initiated in the month of June, 2013.

(c) If so, the details thereof and the safety norms being implemented in those units;

- Civil construction is nearing completion and the cGMP compliant facility would be fully completed 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; which is more than 85 Mld of the old facility.
- This will ensure the vaccine security of the country.
- The cGMP facility will cover safety norms for product, person and premises.

(d) the time by which above units are likely to be started functioning?

- Followed by IQ & OQ, the Performance qualification and Process validation will be commenced by PII, Coonoor from January, 2018 onwards.
- The trial batch of vaccine production will be carried out from the month of April, 2018 to December, 2018. After that the commercial production will be commenced from the month of Jan. 2019.



Lok Sabha Starred Question Diary No.5036 for 09.02.2018 regarding “Private Sector in Immunization Programme”

a) & (b) Whether the public sector units producing essential vaccines such as DPT, BCG and TT have been making any contribution to the Government Universal Immunization Programme:

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 and subsequently this Institute has produced the vaccine in the existing facility and supplied the following quantities of vaccine to the UIP.

DPT Vaccine		
2012-13	2013-14	2014-15 (current year)
199.41 lakh doses	188.19 lakh doses	106.70 lakh doses

- Govt. of India proposed to establish cGMP facility for manufacturing DPT group of vaccines with a project cost of 137.02 crores at PII, Coonoor. The establishment of cGMP is underway.
- The current project completion schedule for its operationalization submitted by the PMC i.e. HLL was placed before the Governing Body meeting of PIIC held on 08.12.2017 wherein the Project Management Consultant proposed to complete the mechanical completion by December 2017 and the validation activities (IQ&OQ) by March 2018.
- As such, NRA inspection & PQ will be initiated by PII, Coonoor from April 2018 onwards. This will be followed by process validation and trial batch preparation from July 2018 onwards. Further the commercial batch production will be initiated after the completion of trial batch production, process validation and CDL, Kasauli clearance i.e. from April 2019 onwards.

The current progress of the GMP project is as follows,

S. No.	Activity	Timeline placed before GB on 08.12.2017	Status as on 31-Dec-2017
1.	Civil Work	31-Dec-2017	99.94 % of overall civil construction works have been completed.



2.	Mechanical Completion (including ETP & STP)	31-Dec-2017	99.82 % of overall mechanical completion of HVAC & BAS, Modular, Water System, Fire Safety, mechanical piping & insulation, electrical and process equipment of various blocks completed.
3.	Validation Activities (IQ & OQ) (including ETP & STP)	31-Mar-2018	47.14 % of validation activities have been completed.

Proposed supply of DPT group of vaccines to UIP

- The proposed Green field facility for manufacturing of DPT group of vaccines which is being established will have total annual installed capacity of 1300 Lds. The following are the installed capacities for individual vaccines that are planned to be produced in the new GMP facility,

Sl. No.	Name of the Vaccine	Installed Capacity	Operational Capacity (80% of installed capacity)
1.	DPT Vaccine	600 LDs	480LDs
2.	DT vaccine	150 LDs	120LDs
3.	TT vaccine	550 LDs	440LDs

(a) Whether the Government has sought the help of private sector in the immunization drive;

Not applicable to this Institute

(b) If so, the terms and conditions on which the Government Universal Immunization Programme have been assigned to private sector;

Not applicable to this Institute

(c) The role played by the Government to ensure proper implementation of the Universal Immunization Programme across the country?

Not applicable to this Institute



Sub: Lok Sabha Starred Question Diary No.17181 for 23.02.2018 regarding “Production of Vaccines”

(a) Whether the Government proposes to take steps to increase production of vaccine by public sector companies under the Ministry to encourage disrupted supply of vaccines and if so the details thereof;

- 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 be completed the validation by April, 2018. Based on the timelines proposed by HLL, the Performance Qualification (PQ) for all critical equipments will be carried out from May, 2018 onwards by PII, Coonoor. This will be followed by process validation and trial batch preparation from August, 2018 onwards. Commercial production will be initiated from August, 2019 onwards.
- After establishing the proposed facilities at PIIC, the installation capacity will be increased from 85.00 Million doses to 130.00 Million doses of DPT group of vaccine i.e. i.e. DPT- 60 Mld; TT –55 Mld; DT- 15Mld;

(b) Whether the private sector account for over 90 percent of the requirement of essential vaccines in the county ever through three PSUs also manufacture them, if so, the details thereof and reason therefor;

Not applicable to this Institute.

(c) Whether the country’s UIP is largely dependent on private sector with PSUs share miniscule or nil during 2014-15 and 2015-16 and if so, the details thereof vis-à-vis total requirement met, year wise and

Not applicable to this Institute.

(d) The steps taken by the Government to upgrade the facilities in PSUs so that the dependency on private vaccine manufacturing units can be reduced?

- 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;



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Name of the vaccine	Installed capacity (per annum)	Operational capacity (per annum)
	(in lakh doses)	
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.

Once the PII, Coonoor is made fully functional with the installed capacity of 130 million doses, which is one and half times more than the installed capacity of the old facility, supply to UIP will be initiated. This Institute has also submitted a proposal on the development and production of Pentavalent Vaccine at PII, Coonoor for UIP for approval. When PII, Coonoor starts functioning with its full capacity, it will reduce the dependency on private manufacturing units.



Sub: Lok Sabha admitted starred Question No.406 for answer on 23.03.2018 regarding
“Production of Vaccines”

I write with reference to the Ministry’s letter No. H.11016/02/2018-VI dated 19.03.2018 on
the above subject and to furnish below the details, in respect of **Pasteur Institute of India,
Coonoor:**

**(a) Whether the Government proposes to take steps to increase production of vaccine
by public sector companies under the Ministry to encourage disrupted supply of
vaccines and if so the details thereof;**

- The Drugs Controller General (I) & Central License Approving authority vested with the powers under Sub Rule (1) of Rule 85 of D&C Rules, suspended the whole licence bearing number 12 in form 28D held by Pasteur Institute of India, Coonoor vide their letter No.X-11026/1/06 D dated 15th January, 2008. Followed by this order, the productions of DPT group of vaccines and Tissue Culture Anti-rabies Vaccine have been suspended at PIIC.
- As per the direction of the Govt. of India, Ministry of Health and Family Welfare, New Delhi, a committee to review the reasons for suspension of licenses and to review the road map for revival of the Institutes, a committee consisting of Shri. Javed Chaudhary, Chairman and Dr. Salhan, Member constituted by Govt. of India, Ministry of Health and Family Welfare, New Delhi visited this Institute on 19th and 20th December 2009.
- The Govt. of India, Ministry of Health and Family Welfare, New Delhi had constituted a committee for the upgradation of existing facilities of DPT manufacturing facility, a team from M/s. HLL Lifecare alongwith experts from M/s. NNE Pharmaplan had visited this Institute during 16th and 17th January, 2010.
- The Govt. of India, Ministry of Health and Family Welfare, New Delhi vide Order F.No.X.11035/2/2010-DFQC dated 26th February, 2010, in exercise of its powers under Sub-rule (3) of Rule 85 of the Drugs and Cosmetics Rules, 1945 revoked the suspension of licence bearing 12 in Form 28. As such, the production activities were commenced with immediate effect in the existing facility.
- After the revocation of suspension of manufacturing licence, this Institute had produced and supplied the following quantities of DPT vaccine to Universal Immunization Programme, Govt. of India:

DPT Vaccine			
2011-12	2012-13	2013-14	2014-15
Nil	199.41 lakh doses	188.19 lakh doses	106.70 lakh doses



Establishment of Greenfield GMP facility at PIIC:

- HLL Lifecare Ltd. has been entrusted the responsibilities of establishing the Green Field GMP facility for manufacturing DPT vaccines at PIIC.
- M/s. HLL had submitted the Detailed Project Report (DPR) 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.
- 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 complete the validation by April, 2018. Based on the timelines proposed by HLL, the Performance Qualification (PQ) for all critical equipments will be carried out from May, 2018 onwards by PII, Coonoor. This will be followed by process validation and trial batch preparation from August, 2018 onwards. Commercial production will be initiated from August, 2019 onwards.
- After establishing the proposed facilities at PIIC, the annual installed capacity for manufacturing DPT group of vaccines will be increased from 85.00 Million doses to 130.00 Million doses of DPT group of vaccine i.e. i.e. DPT- 60 Mld; TT -55 Mld; DT- 15Mld;

(b) Whether the private sector account for over 90 percent of the requirement of essential vaccines in the county ever through three PSUs also manufacture them, if so, the details thereof and reason therefor;

Not applicable to this Institute.

(c) Whether the country's UIP is largely dependent on private sector with PSUs share miniscule or nil during 2014-15 and 2015-16 and if so, the details thereof vis-à-vis total requirement met, year wise and

Not applicable to this Institute.



(d) The steps taken by the Government to upgrade the facilities in PSUs so that the dependency on private vaccine manufacturing units can be reduced?

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.

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, the supply to UIP will be initiated. This Institute has also submitted a proposal on the development and production of Pentavalent Vaccine at PII, Coonoor for UIP for approval and is under perusal at the Ministry. Once PII, Coonoor starts functioning with its full capacity it will reduce the dependency on private manufacturing units thereby strengthening the vaccine security of the country.



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Sub: Assurance given in respect of Lok Sabha Unstarred Question No.6030 on 04.04.2018 regarding "Appointment of Senior Counsel" - information requested by Department of Law and Affairs, Ministry of Law and Justice.

(a) whether the Government has appointed new senior counsels and special advocates for various Ministerial departments, their allied offices, autonomous bodies and PSUs etc;

No.

(b) if so, the details thereof and if not, the reasons thereof;

The Branch Law Secretariat, Chennai vide letter No.0646/2015/CAT/CHN dated 24.08.2015 has nominated Shri Kishore Kumar, Additional Central Government Standing Counsel, Chennai to defend the case on behalf of this Institute. Accordingly the above ACGSC has been appointed in the subsequent cases also.

(c) whether the Government is following any transparent system in the appointment of Associate Solicitor Generals, Assistant Solicitor Generals and Panel Advocates to various High Courts in the country; and

Not applicable to this Institute.

(d) if so, the details thereof

Not applicable to this Institute.



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Assurance in respect of Lok Sabha Unstarred Question No. 1965 regarding Inter Ministerial Litigation raised by Dr. Udit Raj, MP

No such cases available with this Institute. Hence the information may be treated as 'Nil'.



Lok Sabha Question (Diary No. 3717) for 12.07.2019 regarding "Shortage of Vaccines" –

a) The number of the Government controlled units engaged in the production of vaccines along with the production of each unit during each of the last three years and the current year, vaccine and unit-wise;

PII, Coonoor was a major contributor of quality DPT group of vaccines to the UIP since 1982 till 2016. The production was stopped for the creation of new GMP infrastructure for production of DPT group of vaccines as directed by Ministry which is completed. Now the qualification works are being carried out at different level. Hence PII, Coonoor is unable to contribute to the UIP from the year 2016 onwards.

b) Whether there is any shortage of certain vaccines against the usual requirement under various health programmes including the Universal Immunisation Programme (UIP), if so, the details of the demand and supply during the above said period and its impact on various health programmes run by the Government.

Not applicable to this Institute.

c) The quantum and types of vaccines imported as well as purchased from private companies for various health programs along with the funds spent for the purpose during the above said period, vaccine-wise; and

Not applicable to this Institute.

d) The steps taken/being taken by the Government to ensure adequate availability of all the vaccines for the UIP and also their availability in market at affordable prices in the country?

Government of India proposed to establish cGMP facilities 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 installed 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 (in lakh doses)	Installed capacity (per annum)	Operational capacity (per annum)



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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 for its approval.

Once the PII, Coonoor is made fully functional with the installed capacity of 130 million doses, there will be a substantial increase in vaccine supply to UIP.



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Assurance in respect of Lok Sabha Unstarred Question No. 3833 regarding contempt cases against Government raised by Shri Tarthagata Sapathy, M.P.

No such cases available with this Institute. Hence the information may be treated as 'Nil'.



Lok Sabha Admitted Unstarred No. 5582 for answer on 26.07.2019 regarding “Shortage of Rabies Injection” – regarding

a) Whether there is an acute shortage of rabies injection across the country and if so, the reaction of the Government thereon;

Not applicable to this Institute.

b) The number of deaths reported in the last two years due to shortage of rabies injection;

Not applicable to this Institute.

c) The further steps being taken by the Government to supply the said injections?

The production of Tissue Culture Anti Rabies Vaccine is stopped due to non-availability of facilities with GMP compliant norms.



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Sub: Lok Sabha USQ No.4353 (Dy. No.11661) for 13.08.2021 - Reg.

(a) *the details of Public Institutions available to produce vaccines indigenously in India as on date, State/UT-wise;*

Pasteur Institute of India, Coonoor is an autonomous body under the Ministry of Health and Family Welfare, Govt. of India.

(b) *The quantum of vaccine production capacity and its actual production as on June 30, 2021, year/institution-wise;*

The installation capacity is 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.

The actual production as on 30.06.2021 is Nil. At present, the qualification activities are underway in the newly established GMP facility for the production of DPT group of vaccines. Due to the establishment of above facility, there are no vaccines supplied between the financial year 2015-16 to till date.

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.

(c) *Whether these institutions are exporting the vaccine globally;*

No.

(d) *If so, details thereof?*

Not applicable to this Institute.



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Sub: Lok Sabha Unstarred Q. No.6158 due for answer on 08.04.2022 regarding "Allowances to Health Care Professionals" asked by Shri Rajveer Singh (Raju Bhaiya), Dr. Jayanta Kumar Roy, Hon'ble MPs - Reg.

S. No.	Name of the Autonomous Body/Central University	Whether allowances viz. Annual Allowance, Post Graduate allowance, conveyance allowance, etc., the same are being paid to doctors and other healthcare workers	If yes, the details thereof along with current status	If not, the reason for disparity	The remedial steps taken/ being taken
1.	Pasteur Institute of India, Coonoor	Yes	Non-medical Group 'A' officers - Annual Allowance of Rs.1350/- p.m. for those who acquired PG degree and Rs.2250/- p.m. for those who acquired Ph.D. qualification are being paid. For Medical Officers - having PG qualification - Rs.2250/- p.m, without recognized PG qualification - Rs.1350/- p.m.*	Not Applicable	Not Applicable

*At present there are no regular Medical Officers and Health care workers available in this Institute. Further the Post Graduate and Conveyance Allowances are not being paid at this Institute.

To Strive to seek to find and not to yield



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To Strive to seek to find and not to yield