42	STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2022-23) SEVENTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS

(2023-24)

FORTY-SECOND

सत्यमेव जयते

LOK SABHA SECRETARIAT

NEW DELHI

March, 2023/ Phalguna, 1944 (Saka)

CC&F.No. 170

FORTY-SECOND REPORT

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CHEMICALS & FERTILIZERS

(2022-23)

(SEVENTEENTH LOK SABHA)

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(DEPARTMENT OF PHARMACEUTICALS)

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Presented to Lok Sabha on 21 March 2023

Laid in Rajya Sabha on 21 March 2023

LOK SABHA SECRETARIAT

NEW DELHI

MARCH, 2023/ PHALGUNA, 1944 (Saka)

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2022-23)

Dr. Shashi Tharoor- Chairperson

MEMBERS

LOK SABHA

2. Shri Dibyendu Adhikari
3. Maulana Badruddin Ajmal
4. Shri C.N. Annadurai
5. Shri Deepak Baij
6. Shri Ramakant Bhargava
7. Shri Prataprao Patil Chikhalikar
8. Shri Rajeshbhai Naranbhai Chudasama
9. Dr. Sanjay Jaiswal
10. Shri Ramesh Chandappa Jigajinagi
11. Shri Kripanath Mallah
12. Shri Satyadev Pachauri
13. Smt. Aparupa Poddar
14. Shri Arun Kumar Sagar
15. Shri Muniyan Selvaraj
16. Dr. Sanjeev Kumar Singari
17. Shri Atul Kumar Singh
18. Shri Pradeep Kumar Singh
19. Shri Uday Pratap Singh
20. Shri Indra Hang Subba
21. Shri Parbhubhai Nagarbhai Vasava

RAJYA SABHA

22. Shri G.C.Chandrashekhar
23. Dr. Anil Jain
24. Shri Arun Singh
25. Shri Ram Nath Thakur*
26. Shri Vijay Pal Singh Tomar
27. Vacant
28. Vacant
29. Vacant
30. Vacant
31. Vacant

SECRETARIAT

1.	Shri Vinay Kumar Mohan	-	Joint Secretary
2.	Shri Nabin Kumar Jha	-	Director
3.	Smt. Geeta Parmar	-	Additional Director
4.	Ms. Sonia Sankhla	-	Executive Officer

** Nominated w.e.f. 13.02.2023 vide Lok Sabha Bulletin Part-II, Para No. 6251 dated 14.02.2023*

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals & Fertilizers (2022-23) having been authorized by the Committee do present on their behalf this Forty-Second Report (Seventeenth Lok Sabha) on 'Demands for Grants (2023-24)' pertaining to the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

2. The Committee considered the Demands for Grants (2023-24) pertaining to the Department of Pharmaceuticals for the Financial Year 2023-24 which were laid on the Table of the House on 10th February, 2023. Thereafter, the Committee took evidence of the representatives of the Department of Pharmaceuticals on 15th February, 2023. The Committee considered and adopted the Report at their sitting held on 20th March, 2023.

3. The Committee wish to express their thanks to the Officers of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers for tendering evidence and placing before the Committee all the requisite information sought for in connection with the examination of the subject.

4. The Committee also place on record their appreciation for the valuable assistance rendered to them by the officials of Lok Sabha Secretariat attached to the Committee.

5. For ease of reference and convenience, the Observations/ Recommendations of the Committee have been printed in bold letters in the body of the Report.

New Delhi;
20 March, 2023
29 Phalguna, 1944 (Saka)

DR. SHASHI THAROOR
Chairperson,
Standing Committee on
Chemicals & Fertilizers.

ACRONYMS/ABBREVIATIONS OF THE TERMS USED IN THE REPORT

APICF	Assistance to Pharma Industry for Common Facilities
APIs	Active Pharmaceutical Ingredients
BCPL	Bengal Chemicals & Pharmaceuticals Ltd.
BE	Budget Estimate
BIFR	Board for Industrial & Financial Reconstruction
BIL	Bengal Immunity Ltd
CAPPM	Consumer Awareness, Publicity and Price Monitoring
CEE	Committee for Establishment Expenditure
CIF	Common Infrastructure Facilities
CoEs	Centres of Excellence
CoM	Committee of Ministers
CPSEs	Central Public Sector Enterprises
DI	Drug Intermediates
DPCO	Drugs Prices Control Order
DPI	Development of Pharmaceutical Industry
EC	Empowered Committee
EFC	Economic finance Committee
FDI	Foreign Direct Investment
HAL	Hindustan Antibiotics Ltd.
IC	International Cooperation
ICPMR	Indian Council of Research & Development and Innovation in Pharma-MedTech Sector
IDPL	Indian Drugs & Pharmaceuticals Ltd.
IEC	Information, Education and Communication
IFCI	Industrial Finance Corporation of India
KAPL	Karnataka Antibiotics & Pharmaceuticals Limited
KSMs	Key Starting materials
MSME	Micro, Small & Medium Enterprises
NIMERs	National Institutes of Medical Devices Education and Research
NIPER	National Institute of Pharmaceutical Education &Research
NPAA	National Pharmaceutical Pricing Authority
NLEM	National List of Essential Medicines
PLI	Production Linked Incentive
PMA	Project Management Agency
PMBI	Pharmaceuticals and Medical Devices Bureau of India
PMBJP	Pradhan Mantri Bhartiya Janaushadhi Pariyojana
PMC	Project Management Consultant
PMPDS	Pharmaceuticals Promotion Development Scheme
PMRUs	Project Monitoring Resource Units
PoS	Point of Sale
PPDS	Pharmaceuticals Promotion Development Scheme
PRIP	Promotion of Research & Innovation in Pharmaceutical Sector

PSU	Public Sector Undertaking
PTUAS	Pharmaceuticals Technology Upgradation Assistance Scheme
QRR	Quarterly Review Report
RE	Revised Estimate
RDPL	Rajasthan Drugs & Pharmaceuticals Ltd.
SIAs	State Implementation Agencies
SIDBI	Small Industries Development Bank of India
SME	Small and Medium Enterprise
SoP	Standard Operating Procedure
SPI	Strengthening of Pharmaceutical Industry
SSC	Scheme Steering Committee
SSPL	Smith Stanistreet Pharmaceuticals Ltd
TMR	Trade Margin Rationalization
UC	Utilization Certificates
USFDA	United States Food and Drug Administration

REPORT

PART- I

I. INTRODUCTORY

The Department of Pharmaceuticals was created on the 1st July, 2008 under the Ministry of Chemicals & Fertilizers with the objective of giving greater focus and thrust on the development of pharmaceuticals sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to pharmaceuticals sector, which required integration of work with other ministries.

2. The work of the Department has been mainly divided into Pricing, Policy, Scheme, National Institute of Pharmaceutical Education & Research (NIPER), Public Sector Undertaking (PSU), Foreign Direct Investment (FDI), International Cooperation (IC) & Medical Device Divisions. The Department has the mandate to deal with the following broad subject matters: -

i. Drugs and Pharmaceuticals, excluding those specifically allotted to other departments.
ii. Medical Devices- Industry issues relating to promotion, production and manufacture; excluding those specifically allotted to other Departments.
iii. Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceuticals sector.
iv. Development of infrastructure, manpower and skills for the pharmaceuticals sector and management of related information.
v. Education and training including high-end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.
vi. Promotion of public- private-partnership in pharmaceutical related areas.
vii. International Co-operation in pharmaceuticals research, including work related to international conferences in related areas in India and abroad.
viii. Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.
ix. Technical support for dealing with national hazards in pharmaceutical sector.

x. All matters relating to National Pharmaceutical Pricing Authority including related functions of price control/monitoring.

xi. All matters relating to National Institutes of Pharmaceuticals Education and Research.

xii. Planning, development and control of, and assistance to all industries dealing with by the Department.

xiii. Bengal Chemicals and Pharmaceuticals Limited.

xiv. Hindustan Antibiotic Limited.

xv. Indian Drugs and Pharmaceuticals Limited.

xvi. Karnataka Antibiotics and Pharmaceuticals Limited.

xvii. Rajasthan Drugs and Pharmaceutics Limited.

3. The Vision of the Department is to promote Indian Pharma as the global leader for quality medicines; and to ensure availability, accessibility and affordability of drugs and medical devices in the country. The Mission is as follows:

- Investment for Make in India in Pharma sector,
- Make in India in critical APIs and medical devices,
- Industry expansion, skilling, R&D and innovation,
- Stable and effective price regulation, and
- Generic medicines by expanding Janaushadhi scheme

4. The main activities of the Department are policy-making, sectorial planning, promotion and Development of Pharmaceutical industries. The administrative and managerial control of the public sector undertakings engaged in the manufacturing of various pharmaceutical items and some other organizations are major functions of the Department.

5. The Department has five Central Sector Schemes, namely (a)National Institute of Pharmaceutical Education &Research (NIPER), (b) Production Linked Incentive (PLI) Schemes, (c) Development of Pharmaceutical Industry, an Umbrella Scheme (d) Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and (e)Consumer Awareness, Publicity and Price Monitoring(CAPPM). The PMBJP scheme is being implemented through Pharmaceuticals and Medical Devices Bureau of India (PMBI) which is an autonomous society registered under Societies Registration Act,1860. CAPPM is implemented through National Pharmaceutical Pricing Authority (NPPA) which is an attached office of the

Department. The remaining schemes namely NIPER scheme, PLI schemes and Development of Pharmaceutical Industry are operated by the Department directly.

6. As regards the performance of the Pharmaceutical Industry and medical device sector, the Secretary during evidence stated as under:

"About 20 per cent of the total global exports are from India. It is the third large just in volume but about 13th largest in value which shows that we are in low-cost generics more than in high end therapeutics……However, one indication of high equality is that in India, in the pharmaceutical sector, we have the largest number of United States Food and Drug Administration (USFDA) approved manufacturing sites outside of the US... In medical devices, it is a different story. Our imports are much higher than the exports. It is the exact reverse of what we have in pharma. It is so because it is a very new sector. It is known as a sunrise sector. But here also, I must say that it is 11 billion dollars' sector and there is an expectation that it will go up to 50 billion dollars. I must point out that although our exports are lower than imports, we are also able to export some of the electronic-based medical devices. We have a lot of strength in surgical, disposal syringes, implants, stent etc. We have 100 per cent FDI for greenfield pharma and 74 per cent in brownfield pharma. There has been a healthy growth in FDI inflows over the last four years, culminating to the amount of Rs. 12,000.00 crore inflows in 2021-22."

7. Elaborating on the broad strategy of the DoP for pharmaceutical and medical device sector, the Secretary stated as under :

"We look at the pharmaceutical sector not merely as an industry, but as a sector that also has societal goals in addition to economic strategic goals. Our strategic goals are to build the drug security and maintain global leadership. The societal goals are to maintain affordability and access to patients of good quality drugs. To build drug security, we need to secure our supply chain."

8. The detailed Demands for Grants (2023-24) of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers were presented to the Lok Sabha on 10 February, 2023. A Budget Estimate (BE) of Rs. 3160.06 crore has been made to the Department under **Demand No. 7** against the proposed demand of Rs. 5728.57 crore for the ensuing financial year 2023-24 which is 55.2 % of the proposed budgetary demand. During the previous year 2022-23 the BE allocation was Rs. 2244.15 crore. Thus, the budget

allocation of the Department has increased nearly 40.81%. Further, during the year 2022-23 the allocation was only 21.6 % of the proposed amount of Rs.10383.25 crore. The Committee have examined in-depth the detailed Demands for Grants of the Department for the year 2023-24.

II. PROPOSED AND APPROVED FINANCIAL OUTLAYS FOR THE DEPARTMENT OF PHARMACEUTICALS FOR THE FINANCIAL YEAR 2023-24

9. The scheme-wise breakup of the proposed and approved financial outlays for the Department of Pharmaceuticals for the year 2023-24 and the reason for variations are given in table below:

Sl. No.	Scheme/Non Scheme	Proposed BE 2023-24	Approved BE 2023-24	Percentage of approval and Reason for variations
1.	**Secretariat Economic Service MH 3451 (Non- Scheme)**	**25.00**	**21.10**	**-**
2.	**National Pharmaceuticals Pricing Authority MH 2852 (Non-Scheme)**	**23.50**	**18.90**	**-**
	Scheme			
3.	National Institute of Pharmaceutical Education and Research (NIPERs) MH2852	1226.00	500.00	The allocations are made under GIA-Capital, GIA- General and GIA – Salary heads for incurring expenditure for construction of campuses, up-gradation of laboratories, payment of salaries to faculty/ staff, award of fellowships and other academic/ administrative expenditure. The annual increase in allocation/ expenditure is mainly on account of construction of regular campuses of NIPERs (except Mohali and Guwahati), purchase of equipment, salary of regular faculties/ staff and fellowship to students. Department has proposed Rs. 500.00 crore and Rs. 60.00 cr for NIPERs (MH 2852+ MH2552), Rs.200.00 crore NIMERs, Rs. 233.00 crore for CoEs, Rs. 50.00 crore for R&D council and Rs. 243.00 crore for proposed Promotion of Research & Innovation in Pharmaceutical Sector (PRIP) for the FY 23-24.
	National Institute of Pharmaceutical Education and Research (NIPERs) MH2552	60.00	50.00	
	Total NIPERs (MH 2852+ MH 2552)	**1286.00**	**550.00**	
4.	**Development of Pharmaceuticals Industry MH 2852**			

Sl. No.	Scheme/Non Scheme	Proposed BE 2023-24	Approved BE 2023-24	Percentage of approval and Reason for variations
	Pharmaceuticals Promotion Development Scheme (PPDS) (now renamed as (i) (i) (i) (i)Pharmaceuticals Promotion Development Scheme (PMPDS)	5.00	4.00	80% Focus is to complete the studies already initiated on the thrust areas of the Pharma and MedTech sectors and also to support the major awareness programmes on the ongoing schemes of the DoP and also, to conduct the Annual Pharma and MedTech Event in 2023. If the requirement is more than the approved BE, the same will be sought in RE stage.
	(ii)Cluster Development(now renamed as 'Assistance to Pharma Industry for Common Facilities'(APICF))	61.90	51.00	82.4% So far, out of 3 projects approved before 2022, one is completed and remaining two are expected to be completed shortly. For the budget available during the scheme tenure, already 5 projects selected and in-principle approval letter is being issued and 1st instalment is likely to be released shortly.Funds in BE 2023-24 was proposed based on approval given for 7 projects and new projects expected to be approved in 23-24 towards release of 1st/2nd installments. If the requirement is more than the approved BE, the same will be sought in RE stage.
	(iii)Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)	104.30	95.00	91.1% Though extensive outreach was conducted on the benefits of the scheme, there were lukewarm response in FY 22-23 (four applications have been received in 2023 which is under scrutiny). It is expected that most of the applicants will be selected in this FY 23-24. Hence, a budget of 95.00 crore is proposed. If most of the applicants opt for capital subvention mode, then the amount will be paid at the end of the completion of the projects only. In that case, this projected amount will be appropriately

Sl. No.	Scheme/Non Scheme	Proposed BE 2023-24	Approved BE 2023-24	Percentage of approval and Reason for variations
				re-appropriated to other schemes.
	Total Strengthening of Pharmaceutical Industry (SPI) MH 2852 [(i)+(ii)+(iii)]	**171.20**	**149.00**	
	Promotion of Bulk Drug Parks	900.00	900.00	An amount of Rs. 900 crore has been proposed/allocated under the scheme for Promotion of Bulk Drug Parks in BE 2023-24. This amount will be used to give second instalment of Rs 300 crore each to the 3 selected states for creation of Common Infrastructure Facilities (CIFs) as grant-in-aid. Hence, no variation in the Gross budget allocation.
	Promotion of Medical Device Parks	207.563	200.00	Sufficient funds are available in and if required the same would be sought in RE stage/supplementary.
	Total Development of Pharmaceuticals Industry (DPI) MH 2852	**1278.763**	**1250.00**	
5.	**Production Linked Incentive (PLI) Scheme**			
	Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs	101.50	100.00	98.5% FY 2022-23 is the first year of production for chemical synthesis based bulk drugs. Funds for 2023-24 were proposed to provide the incentives to the applicants, as per the estimates given by the beneficiaries. If the requirement is more than the approved BE, the same will be sought in RE stage.
	Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device	102.00	100.00	98% FY 2022-23 is the first year of production for the PLI scheme for Medical Devices. Funds for 2023-24 were proposed to provide the incentives to the applicants, as per the estimates given by the beneficiaries.If the requirement is more than the approved BE, the same will be sought in RE stage.

Sl. No.	Scheme/Non Scheme	Proposed BE 2023-24	Approved BE 2023-24	Percentage of approval and Reason for variations
	Production Linked Incentive Scheme for Pharmaceuticals	2203.20	1000.00	45.4% FY 2022-23 is the first year of production for PLI scheme and hence, a RE of Rs.694.20 Cr is proposed to be utilized to process the interim-releases (75% of the eligible claims being filed within the FY). The PLI applicants have projected a total incentive claims of about 2200 Cr for FY 22-23 (most of which will be released in FY 23-24). Further, the interim release for the claims for the production in FY 23-24 is also factored in, while projecting a requirement of Rs.2203 CroreAgainst which, BE of Rs.1000 Cr is allocated. Any further requirement will be met out by supplementary demands.
	Total PLI MH 2852	**3514.263**	**1200.00**	
6.	**Jan Aushadhi(PMBJP) MH 2852**	105.00	105.00	There is no variation in fund allocation in case of Pradhan MantriBharityaJanaushadhiPariyojana (PMBJP).
	Jan Aushadhi(PMBJP) MH 2552	10.00	10.00	
	Total Jan Aushadhi (PMBJP) (MH 2852 + MH 2552)	**115.00**	**115.00**	
7.	**Consumer Awareness Publicity and Price Monitoring (CAPPM) MH2852**			
	Assistance to Project Monitoring Resource Units (PMRUs)	5.00	4.00	Sufficient funds are available in and if required the same would be sought in RE stage/supplementary.
	Advertising and Publicity for CAPPM	1.00	1.00	
	Total CAPPM (MH 2852)	**6.00**	**5.00**	
8.	**Assistance to Public Sector Undertakings (PSUs) MH6857**			
	Indian Drugs & Pharmaceuticals Ltd. (IDPL)	0.01	0.01	
	Hindustan Antibiotics Ltd. (HAL)	587.56	0.01	
	Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)	0.01	0.01	
	Bengal Immunity Ltd (BIL)	0.01	0.01	
	Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)	0.01	0.01	
	Smith Stanistreet Pharmaceuticals Ltd (SSPL)	0.01	0.01	

Sl. No.	Scheme/Non Scheme	Proposed BE 2023-24	Approved BE 2023-24	Percentage of approval and Reason for variations
	Total Loan	587.61	0.06	
	Grand Total	5728.573	3160.06	

MH 3451 Major Head for Secretariat Economic Services (non-scheme).
MH 2852 Major Head for NPPA, NIPERs, Jan Aushadhi Schemes, Development of Pharmaceutica Industry (DPI), CAPPM.
MH 2552 Major Head for North East Region - NIPERs, Jan Aushadhi Schemes.
MH 6857 Major Head for Assistance to PSUs Scheme.

10. The Committee desired to know whether budget allocations for the year 2023-24 is found to be adequate in order to achieve both the physical and financial targets in respect of various schemes/NPPA/PSUs. In reply, it has been stated that the amount allocated for PMBJP scheme is sufficient to achieve the targets of financial year 2023-24. For NIPER, in case of requirement of additional funds for expediting completion of construction of campuses, the same will be sought at RE stage. With respect to schemes under the promotion of Bulk Drug Parks scheme, the division has sought Rs 900.00 crore in BE 2023-24 in the scheme for Promotion of Bulk Drug Parks which is adequate to achieve the physical and financial targets as envisaged under the scheme. Financial year 2022-23 is the first year of production for all the 3 PLI Schemes. Funds for 2023-24 were proposed in all 3 PLI schemes, based on estimates of the projections of the claims that will be received during 2023-24, as submitted by Project Management Agency (PMA) that are Industrial Finance Corporation of India (IFCI) and Small Industries Development Bank of India (SIDBI). In respect of Pharmaceuticals Promotion Development Scheme (PMPDS)/ Cluster Development -Renamed as ‘Assistance to Pharma Industry for Common Facilities’ (APICF)/ Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) sub-schemes, the funds were proposed in BE 2023-24 based on estimated projects/schemes/seminars to be supported under the concerned sub-schemes. In all the schemes, if the requirement is more than the approved BE, the same will be sought in RE 2023-24. For NPPA, the allocation of funds for the year 2023-24 presently seems to be adequate to help the NPPA achieve both the physical and financial targets. However, if additional funds are required, the same will be requested at the RE stage. Lastly for PSU, no funds have been sought by any Pharma PSUs for the year 2023-24, only a token provision of Rs. 0.06 crore is allocated as loan for various PSUs in FY 2023.-24.

III. BUDGETARY ALLOCATION VIS-A-VIS UTILISATION DURING 2020-21, 2021-22 AND 2022-23

11. The details with regard to the total and scheme-wise Budget Estimate (BE), Revised Estimate (RE) and actual utilization of budget allocations during the years 2020-21, 2021-22 and 2022-23 under different budget heads are given in the table below:

(Rs in crore)

		2020-21			2021-22			2022-23		
No.	**Revenue Section**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual as on 20.02.2023**
	(Non-Scheme)									
1	Secretariat Economic Services **(MH 3451)**	15.50	14.45	14.40	16.73	15.98	15.54	18.56	18.56	14.93
2	National Pharmaceuticals Pricing Authority (NPPA) **(MH 2852)**	11.90	12.90	12.74	14.80	14.01	13.91	17.79	17.83	14.46
	(Schemes)									
3	National Institute of Pharmaceutical Education and Research (NIPERs) **(MH 2552 + MH 2852)**	202.45	333.83	333.83	234.34	372.00	372.00	395.00	422.00	231.05
i	Pharmaceuticals Promotic Development Scheme (PPDS)	1.00	0.50	0.49	2.00	2.00	1.20	2.00	3.00	0.52
ii	Cluster Development	12.00	7.23	7.22	18.00	15.61	9.89	36.00	32.00	8.18
iii	Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS)	0.02	0.01	-	0.01	0.01	-	62.00	1.00	0.00
iv	Assistance to Bulk Drug Industry for Common Facilitation Center	21.52	1.69	1.6815	36.24	36.24	2.24	-	-	-
v	Assistance to Medical Device Industry for Common Facilitation Cent	7.50	21.05	7.49	60.00	137.02	137.02	-	-	-
vi	Research and Developme in Pharma Sector	-	-	-	0.01	0.01	-	-	-	-
vii	Production Linked Incentive (PLI) Scheme fo Promotion of Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs	-	1.5550	1.55	2.79	2.79	2.18	-	-	-

		2020-21			2021-22			2022-23		
No.	**Revenue Section**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual as on 20.02.2023**
viii	Production Linked Incenti (PLI) Scheme for Promoti Domestic Manufacturing f Medical Device	-	2.005	2.005	2.36	3.31	3.31	-	-	-
	Production Linked Incenti Scheme for Pharmaceuticals	-	-	-	3.00	3.00	1.24	-	-	-
ix	Development of Pharmaceuticals Industry MH 2552	0.01	0.01	-	0.01	0.01	-	-	-	-
4	**Development of Pharmaceuticals Industry (MH 2852)**	**42.05**	**34.05**	**20.44**	**124.42**	**200.00**	**157.08**	**100.00**	**36.00**	**8.47**
i	Promotion of Bulk Drug Parks erstwhile Assistance to Bulk Drug Industry for Common Facilitation Center	-	-	-	-	-	-	900.00	900.00	526.49
ii	Production Linked Incentive (PLI) Scheme fo Promotion of Domestic Manufacturing of Critical KSMs/Drug Intermediates and APIs	-	-	-	-	-	-	390.00	14.61	0.50
iii	Promotion of Medical Device Parks erstwhile Assistance to Medical Device Industry for Common Facilitation Cent	-	-	-	-	-	-	120.00	32.93	0.90
iv	Production Linked Incenti (PLI) Scheme for Promoti Domestic Manufacturing f Medical Device	-	-	-	-	-	-	216.00	21.56	2.30
v	Production Linked Incenti Scheme for Pharmaceuticals	-	-	-	-	-	-	3.00	694.20	288.42
5	**Production Linked Incentive (PLI) Schemes (MH 2852)**	**-**	**-**	**-**	**-**	**-**		**1629.00**	**1663.20**	**470.93**
6	Jan Aushadhi Scher (PMBJP) **(MH 2552 + MH 2852)**	50.00	65.00	65.00	65.00	68.50	68.50	72.50	100.00	97.20
7	Consumer Awareness, Publicity and Price Monitoring (CAPPM)	4.50	3.00	2.60	6.00	4.50	2.82	6.00	3.75	1.48

		2020-21			2021-22			2022-23		
No.	**Revenue Section**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual**	**BE**	**RE**	**Actual as on 20.02.2023**
	(MH 2852)									
	Write Off/ Waiver losses in respect of Pharmaceutical In respect of IDPL (Rs. 889.50 crore a BCPL (193.71 cr) FY 21-22)	--								
	Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL) under Revenue Section in 1st SDG FY 22-23	-	-	-	-	-	-	-	1.80	
8	**Capital Section (MH 6857)**									
	(Assistance to PSUs)									
	Indian Drugs & Pharmaceuticals Ltd. (IDPL)	0.01	2.23	2.23	2.00	2.00	2.00	4.00	4.00	4.00
	Hindustan Antibiotics Ltd. (HAL)	4.74	2.52	2.52	4.09	122.09	122.09	1.26	1.26	1.26
	Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)	0.01	0.01	0.00	0.01	0.01	-	0.01	0.01	-
	Bengal Immunity Ltd. (BIL)	0.01	0.01	0.00	0.01	0.01	-	0.01	0.01	-
	Rajasthan Drugs & Pharmaceuticals Ltd. (RDPL)	2.40	2.40	2.40	3.00	24.00	21.00	0.01	0.01	-
	Smith Stanistreet Pharmaceuticals Ltd (SSPL)	0.01	0.01	0.00	0.01	0.01	0.00	0.01	0.01	-
	Total (Loan to PSUs)	**7.18**	**7.18**	**7.15**	**9.12**	**148.12**	**145.09**	**5.30**	**5.30**	**5.26**
	Grand Total	**333.58**	**470.41**	**456.16**	**470.41**	**823.11**	**774.94**	**2244.15**	**2268.54**	**843.78**

12. It has been observed that the total Budget Estimate (BE) allocation during 2022-23 was Rs.2244.15 crore which increased to Rs.2268.54 crore at Revised Estimate (RE), 2022-23. When asked whether the Department would be able to utilize the increased allocation for achievement of both the physical and financial targets kept during the year for various schemes/ NPPA. In reply, it has been stated that the physical and financial targets under PMBJP scheme will be achieved. Against allotted funds of Rs. 422.00 crore for NIPERs, an amount of Rs. 231.05 crore have been utilized till 31.01.2023. As tenders for construction of 4 campuses have been/ are at final stages of finalization, the allocated

funds will be utilized for construction and other expenses. Under the promotion of Bulk Drug Parks scheme, out of the Rs. 900 crore earmarked for 2022-23, three States are to be given Rs. 299.25 crore each and Rs. 2.25 is to be given to the PMA. The selection of 3 States under the Scheme has only been done in October/November, 2022. First installment has been released to one of the States and for the remaining two states, it will be done in the fiscal year. As regards PLI Schemes, for smooth implementation of the Schemes, the disbursement of interim claims/incentives was proposed to be released in last quarter of FY2022-23 against half yearly or three-quarters claims received up to Dec. 2022 subject to satisfaction of other eligible conditions such as minimum threshold sales/investments. Accordingly, so far, Rs.165.74 crore is released to the four eligible applicants under the PLI scheme for Pharmaceuticals. Funds for PLI schemes in 2023-24 were sought as per estimates of the claims, as projected by PMA. As regards PMPDS/APICF/PTUAS sub-schemes, the funds were revised in RE 2022-23 based on estimates for actual release for new selected projects. In respect of PMPDS/APICF/PTUAS sub-schemes, the funds were proposed in BE 2023-24 based on estimated projects/schemes/seminars to be supported under the concerned sub-schemes. In all the schemes, if the requirement is more than the approved BE, the same will be sought in RE 2023-24. NPPA has asked for less fund in RE 2022-23 viz. Rs.21.58 crore than what was asked for in BE 2022-23 that was Rs.23.79 crore. It is stated that NPPA would be able to achieve both the physical and financial target during the year within the said fund/allocation.

13. Regarding the procedural and financial reforms that the Department of Pharmaceutical has incorporated or is going to incorporate for enhancing effective budget utilization under various Scheme heads, it has been stated that under the Pradhan Mantri Bharitya Janaushadhi Pariyojana (PMBJP), for effective utilization of funds regular monitoring of the scheme is ensured by the implementing agency which is Pharmaceuticals and Medical Devices Bureau of India (PMBI) and the Department. Further, IFCI Ltd. is the Project Management Agency (PMA) to implement the PLI Scheme for Bulk Drugs and PLI Scheme for Medical Devices. Empowered Committee (EC) under the chair of CEO, NITI Aayog conducts periodic review of the schemes with respect to their investment, employment generation and production and release of eligible incentives to the PLI applicants under the Scheme. EC considers and approves the claims for disbursement of incentive based on the recommendation of the PMA. Then SIDBI is the Project Management Agency (PMA) to implement the PLI scheme for Pharmaceuticals. The

Scheme is monitored at the Department level, with a committee under the Chairmanship of Secretary, Department of Pharmaceuticals. This committee conducts periodic review of the schemes with respect to their investment, employment generation and production and release of eligible incentives to the PLI applicants under the Scheme. SIDBI is also the Project Management Agency (PMA) to implement the Scheme “Strengthening of Pharmaceuticals Industry”. This scheme with three components viz, Cluster Development - Renamed as ‘Assistance to Pharma Industry for Common Facilities’ (APICF), Pharmaceuticals Technology Upgradation Assistance Scheme (PTUAS) and Pharmaceuticals Promotion Development Scheme (PMPDS)/is monitored by the Scheme Steering Committee (SSC) under the chairmanship of Secretary, Department of Pharmaceuticals. SSC provide direction for effective implementation of the Scheme, which evaluates & recommends proposals for approval and take decisions on any deviations in approved projects. In 2022-23, Department held series of interactive sessions with the PMA & PLI beneficiaries at the level of Secretary / Jt. Secretary regarding status of incentive claims to be filed by the applicants and for specific government. intervention, if any, for smooth implementation of the Scheme and effective budget utilization. Similar interventions will be undertaken, if needed, in 2023-24 for effective budget utilization. The Department has engaged a professional Project Management Agency (PMA) for implementation of the schemes for Promotion of Bulk Drug Parks to ensure a professional approach both in procedural and financial matters.

IV. SCHEME-WISE ANALYSIS

(A) National Institutes of Pharmaceutical Education and Research (NIPER)-(Major Head 2552 + 2852)

14. National Institutes of Pharmaceutical Education and Research (NIPERs) are autonomous institutes of national importance, which have been established by an Act passed in Parliament in 1998, for imparting postgraduate and doctorate education and conducting research in various specializations of pharmaceutical science. With amendment of the 1998 Act in December, 2021, institutes are empowered to run undergraduate, integrated, diploma and online and offline courses.

15. Presently, there are seven functional NIPERs – set up at Mohali, Ahmedabad, Hyderabad, Hajipur, Guwahati, Raebareli and Kolkata. As per National Institutional

Ranking Framework (NIRF), 2022 of Ministry of Education for ‘Pharmacy’ category, three NIPERs are in top 10 and four in top 20 in the country viz. Hyderabad (2) Mohali (4), and Ahmedabad (10). Regular faculty and administrative posts sanctioned in all NIPERs have been filled up as per current needs. Campus construction of NIPER Guwahati is completed, about 60% construction has been completed at NIPER Ahmedabad, and Administrative Approval & Expenditure Sanction (AA&ES) for construction of campuses of NIPERs at Kolkata, Hajipur and Raebareli through CPWD and at Hyderabad through NPCC has been issued and the tenders are under finalization.

16. For the year 2023-24, the Department had proposed an amount of total Rs. 1286.00 crore for NIPER scheme which inter-alia is distributed into - Rs.500.00 crore and Rs. 60.00 crore for NIPERs under Major Head 2852 and Major Head 2552 respectively, then Rs.200.00 crore for National Institute of Medical Device and Education (NIMERs), Rs. 233.00 crore for Centres of Excellence (CoEs), Rs. 50.00 crore for R&D council that is an Indian Council of Research & Development and Innovation in Pharma-MedTech Sector (ICPMR) and Rs. 243.00 crore for proposed Promotion of Research & Innovation in Pharmaceutical Sector (PRIP) for the FY 23-24. However, only Rs. 550.00 crore has been allocated for the existing scheme of NIPERs.

17. As the Budget 2023-24, announcements have been made with respect to ‘(i) Pharma Innovation (Budget 2023-24, Para 30): A new Programme to promote research and innovation in pharmaceuticals to be taken up through Centres of Excellence(CoEs) to encourage industry to invest in research and development in specific priority areas, and (ii) Multidisciplinary courses for medical Devices (Budget 2023-24, Para 31): Dedicated multidisciplinary courses for medical devices will be supported in existing institutions to ensure availability of skilled manpower for futuristic medical technologies, high-end manufacturing and research.’

18. Pursuant thereto, the Department has sent a proposal for consideration of Economic Finance Committee (EFC) for the scheme for ‘Promotion of Research and Innovation in Pharma-MedTech sector (PRIP) having following two components, viz.,(i) Strengthening the research infrastructure by establishment of 7 CoEs at NIPERs and (ii) Promoting research in pharmaceutical sector by encouraging research in six moonshot areas like New chemical Entities, Complex generics including biosimilars, medical devices, stem cell therapy, orphan drugs, Anti-microbial resistance etc., wherein financial assistance will be provided for the companies working with government institutes and for

in-house R&D. The scheme has an outlay of Rs.7150.00 crore for a period of 5 years. Separately, in line of the budget announcement regarding supporting dedicated multidisciplinary courses for medical devices in existing institutions, the department is preparing a scheme, which will be placed for appraisal of the appropriate agency. Further, a proposal for setting up of Indian Council of Research & Development and Innovation in Pharma-MedTech Sector (ICPMR) is being referred to the Committee for Establishment Expenditure (CEE), before consideration by the Cabinet. These new initiatives will help in boosting research and innovation in pharmaceutical and MedTech sector thereby helping India become a leading power in development of new drugs and technologies, reduce import dependency, generate employment in the sector and help in realizing the vision of "AtamaNirbhar Bharat "in the sector of Pharmaceutical and Medtech sectors.

19. Regarding the budgetary challenges under this scheme during the ensuing year 2023-24, the Committee was apprised during evidence that as against Rs. 4300.00 crore sought for a period of 5 years from 2021-22 to 2025-26, Economic finance Committee (EFC) has approved Rs. 1500 crore only. Commenting on the reduction in the allocation, a representative of the DoP stated as under:

> *"Basically, challenges were about the provision of requisite funds. In the current Budget, as Secretary Madam has already indicated, two schemes are there. One is for the promotion of research and innovation in pharma sector; and the other is for running medical device courses in the existing institutions. One other proposal is that as per our mandate, the Department has assigned the responsibility of promotion and coordination of research. We also intend to set up a Council for Research and Development in Innovation in pharma and MedTech sector."*

20. In this regard, the Secretary, DoP also mentioned about the need for setting up of a Research & Development Council under NIPER scheme as under :

> *"Sir, this is the point. You said that there are so many institutions outside the administrative control of DoP which has pharmaceutical research whereas we have the mandate for Inter-Departmental coordination. We would appreciate the Committee's support. We want to set up the Indian Council of Research and Development and Innovation in Pharma MedTech on the lines of ICMR or ICAR."*

21. With respect to non-allocation of Rs. 200.00 crore at BE 2023-24 stage for creation of National Institutes of Medical Devices Education and Research (NIMERs) on lines of NIPERs, it has been replied that the Department is preparing a scheme, which will be placed for appraisal of the appropriate agency and based on the approval of the scheme, allocation/ disbursal of funds will be sought from the Ministry of Finance.

22. The details with regard to the Budget Estimate (BE), Revised Estimate (RE), actual expenditure during the last 3 years and the proposed and approved BE allocations under the scheme for the year 2023-24 are as under:

(Rs. in crore)

Year	BE	% increase	RE	% increase	Actual Expenditure
2019-20	150.00	-	160.01	-	160.01
2020-21	202.45	34.94	333.82	108.62	333.82
2021-22	234.34	15.75	372.00	11.43	372.00
2022-23	395.00	68.55	422.00	6.18	177.30*
2023-24	550.00#	-	-	-	-

*** Till 31.12.2022 # Proposed BE is Rs. 1286.00 crore**

23. During evidence, the Committee expressed their concern to observe that though NIPER institutes are of national importance, there has been underutilization of funds allocated to them, as out of Rs. 422.00 crore allocated during 2022-23, only Rs.177.30 crore has been utilised till 31.12.2022 and desired to know the reasons thereof. To this, the Secretary, DoP reacted as under:

> *"Firstly, in the current financial year, against the revised estimate of Rs. 422.00 crore, we have spent Rs. 231.00 crore that still leaves about Rs. 190.00 crore. Three NIPERs' tenders have to be awarded by CPWD. One has already been awarded. The next is going to be awarded in a couple of days. Third the tender, at Kolkata, will be awarded in March. So, about Rs.150.00 crore is for these NIPERs' construction, of which I said that one tender has been awarded, one is to be awarded this week or early next week, and the third will be awarded in March. So, we will be able to start the work and show the expenditure."*

24. In this context, the secretary further added as under:

> *"There was also a procedural delay this year as compared to last year because in the last three years, we have been spending something like Rs. 94 per cent, 96 per cent, and 98 per cent of our allocation. This year, the Finance Ministry has introduced new processes for release of grants to autonomous institutions like NIPERs. They are required to set up something called Central Nodal Accounts. That took some time. Now, that has been completed. We are in a position to continue the release of funds which was held up in the last two quarters. I am fairly confident that we shall be able to achieve the expenditure this year in a meaningful way."*

(B) Production Linked Incentive (PLI) Schemes- (Major Head2852)

25. The Committee have observed that the DoP implements three PLI schemes viz. a) PLI Scheme for promotion of domestic manufacturing of critical key Starting materials(KSMs)/Drug Intermediates (DIs)/ActivePharmaceutical Ingredients(APIs)in India; b) PLI Scheme for Promoting Domestic Manufacturing of Medical Devices; and c) PLI

Scheme for Pharmaceuticals as Central Sector Schemes under Major Head-2852. Among the three Production Linked Incentive (PLI) schemes, the PLI schemes for promotion of domestic manufacturing of API and Medical Devices were approved by the Government on 20 March 2020 and scheme guidelines were issued on 29.10.2020. As regards the third PLI scheme for Pharmaceuticals it was approved on 24.02.2021 and scheme guidelines were issued on 01.06.2021. The Department had sought Rs.3514.26 crore as budget allocations for 2023-24 for three PLI scheme but the Ministry of Finance has allocated only Rs.1200.00 crore.

26. The Committee were not happy to note almost nil utilization of BE allocations during the year 2022-23 on PLI schemes, resulting in downsizing of allocations at RE, 2022-23 by the Ministry of Finance in all the three PLI scheme and desired a clarification on the same. In reply, the Secretary submitted as under :

"Sir, in the PLI Scheme, there is a period for gestation, one year and two years and then there is a period of production and a period of incentive being released. We had made provisions for incentives to be released in 2022-23 whereas 2022-23 was the year of production. So, we could have actually made this provision next year."

27. In this context, the Secretary further elaborated as under :

"Sir, the scheme guidelines, initially, we had envisaged that they would complete production in a year, submit the documents including the audited statements, etc., then, we would release the incentives annually in the next year. What we have now done, taking the approach which you have just mentioned, Sir, we asked them to submit their claims for six months' period. It is for two reasons. One is that we had the provision which we should actually have made for next year but we had the provision so we could release money. Secondly, it was also a kind of pilot exercise so that they get used to this documentation, rigmarole and being able to submit the right documents, our PMA also handholds them, so that for a smaller amount, they clean the way they submit their claims. Having said that, however, we found that the sales and the production were lower in the bulk drugs than the amount provided for. So, we did some internal re-allocation. Now, in our re-allocation, as you can see in the second column, for PLI for bulk drugs, we have kept only Rs. 14 crore because this is their first year of production. In fact, for the fermentation based, it would be next year. Out of Rs. 14 crore, we will be able to release whatever claims we receive. As regards PLI for medical devices, again, we only took for the three companies that have met the threshold of Rs. 60 crore sales. Those are the three companies that I mentioned. They would be submitting their proposal amounting to Rs.8 crore per each company. So, we will be able to utilize. As regards pharmaceuticals, we already received claims of Rs. 538 crore, where we have a provision of Rs. 694 crore. We are asking for more claims for the third quarter also, whoever is in a position to submit the papers. However, since we will not have the fully audited statement, we will have the audit only of the claims. We plan to release about 75 per cent of the claims, and we have plans to achieve this amount of Rs. 694 crore."

28. The Secretary continued as under :

"Secondly, the reason for some delay was that we had to obtain exemptions from the Department of Expenditure for releasing those amounts in one go. Now, there is a new process in which we can release only 25 per cent of the annual outlay in one go. Since these are single releases, we have obtained that exemption in January. So, we are on the job."

(i) Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India-(Major Head2852)

29. The scheme provides for financial incentives to manufacturers selected 41 Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs). The 41products have to be among following four categories-

i. Target Segment I–Key Fermentation Based KSMs/DIs
ii. Target Segment II-Key Fermentation Based Niche KSMs/DIs
iii. Target Segment III–Chemical Synthesis Based KSMs/DIs
iv. Target Segment IV–Other Chemical Synthesis Based KSMs/DIs/APIs.

30. The tenure of the scheme is from FY 2020-2021 to 2029-30 with a total financial outlay of Rs. 6,940 crore. The financial incentive under the scheme will be provided on sales of 41 identified products for six (06) years at the rates given below:

i. For fermentation based products, incentive for FY2023-24 to FY 2026-27 would be 20%, incentive for 2027-28 would be 15% and incentive for 2028-29 would be 5%.
ii. For chemical synthesis based products, incentive for FY 2022-23 to FY 2027-28 would be 10%.

31. Further, the details with regard to Budget Estimate (BE), Revised Estimate (RE), actual expenditure and annual percentage increase in expenditure during the last 3 years and the proposed and approved BE allocations for the year 2023-24 is given as under:

(Rs. in crore)

Financial Year	Budget Estimate	Revised Estimate	Actual Expenditure	Percentage increase/decrease
2020-2021	00	1.55	1.55	155%
2021-2022	2.79	2.79	2.18	80%
2022-2023	390.00	14.61	0.50	423.65%
2023-2024	100.00#	N/A	N/A	584%

 # Proposed BE is Rs. 98.79 crore

32. When the Committee asked about the reasons for revising downward the allocation for the scheme from BE, 2022-23 of Rs. 390.00 crore to Rs. 14.61 crore at RE stage and abysmally low utilization of Rs. 0.50 crore, the Department in its reply has stated that the current FY 2022-23 is the first year of production for the chemical synthesis based Bulk drugs and FY 2023-24 is the first year of production for fermentation based bulk drugs. Under the PLI scheme for Bulk Drugs, as on date, 22 projects have been commissioned as per December 2022 Quarterly Review Report (QRR). The more plants are likely to commissioned in the FY 2023 -24. As per Clause 15.2 of Scheme Guidelines, the applicant may submit the claim for disbursement of incentives on half-yearly or annual basis. Standard Operating Procedure (SoP) for claiming the incentive by selected applicants has been shared with applicants after consultations. Initially BE for FY 22-23 was projected, based on the annual requirement, which has to be claimed after the end of FY. Hence, appropriately re-appropriated in RE 22-23 to cater to the half yearly or three-quarters claims received up to December, 2022 subject to satisfaction of other eligible conditions such as minimum threshold sales / investments. As most of the incentive claims are expected in FY 2023-24, accordingly funds were sought in 2023-24 for disbursement of claims.

33. During evidence while referring to over dependence on China for bulk drugs/API the Committee asked about the present status. The Secretary replied as under :

> *"Sir, we are producing over 500 APIs and about 60,000 generic drug formulations. You mentioned about API dependence. There are 41 APIs in which we are dependent to the extent of 85 per cent or more on China. Overall, we have a healthy API industry. But there are other things on which we are dependent to the extent of 50 per cent or 60 per cent."*

34. Further, the Committee enquired whether the Department has thought of reviewing the 41 products approved under the scheme in consultation with industry as the demand and sale of API is subject to market dynamism and asked them to furnish their views on this suggestion of the Committee. The Department has stated that present scheme is formulated based on the recommendations of the Technical Committee, wherein the dependency of these products are more than 85% from a single country. Accordingly, Department of Pharmaceuticals has notified the 41 products under the Scheme. There is no plan, as of now, to revise the products.

(ii) Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices (PLI MD)-(Major Head2852)

35. The domestic medical devices industry faces several challenges including lack of adequate infra-structure, constraints in domestic supply chain and logistics, high cost of finance, inadequate availability of quality power, limited design capabilities and low investment on R&D and skill development. With a view to address some of these challenges in manufacturing of medical devices in India vis-à-vis other major manufacturing economies, the 'PLI Scheme for Promoting Domestic Manufacturing of Medical Devices' was approved by the Government of India on 20th March, 2020. The guidelines for implementation of the scheme were issued on 29.10.2020.

36. The Scheme is applicable only to the Greenfield projects and intends to boost domestic manufacturing and attract large investments in the Medical Devices Sector. The tenure of the scheme is from FY 2020-21 to FY 2027-28 with total financial outlay of Rs. 3,420.00 crore. Under the Scheme, financial incentive will be given to selected companies at the rate of 5% of incremental sales of medical devices manufactured in India and covered under the Target segments of the scheme, for a period of five (5) years. The details of Incentive under the scheme are as follows:

Category of applicant	Rate of Incentive on Incremental Sales of Manufactured Goods for respective FY	Incentive rate
Category A	FY 2022-23 to FY 2026-27	5% limited to Rs. 121 crore per applicant
Category B	FY 2022-23 to FY 2026-27	5% limited to Rs.40 crore per applicant

37. The products under the scheme has been categorized under the following four Target Segments-

i. Cancer care/Radio therapy medical devices.

ii. Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging devices.

iii. Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care medical devices.

iv. All Implants including implantable electronic devices.

38. In total 42 applications were received under the scheme. Out of these 21 applications have been approved with a total committed investment of Rs1,058.97 crore and expected employment generation of around 6,411 persons.

39. The Budget Estimate (BE), Revised Estimate (RE), actual expenditure and annual percentage increase in expenditure during the last 3 years and the proposed and approved BE allocations for the year 2023-24 is as under:

(Rs. in crore)

Financial Year	Budget Estimate	Revised Estimate	Actual Expenditure	Percentage increase/decrease
2020-2021	00	2.005	2.005	200%
2021-2022	2.36	3.31	3.31	65.08
2022-2023	216.00	21.56	1.71	551%
2023-2024	100.00	N/A	N/A	364%

40. Under this scheme the Committee observed that in 2022-23 Rs. 216.00 crore has been allocated at BE stage which was revised downward to Rs 21.56 crore at RE stage and only Rs. 1.71 crore has been utilised. The Committee therefore asked about the reasons for variation in BE, RE and actual expenditure figures during 2022-23, to which the Department replied that the current FY 2022-23 is the first year of production for the PLI scheme for Medical Devices. Under the PLI scheme for Medical Devices, 14 projects have been commissioned for 34 products based on December 2022 Quarterly Review Report (QRR). The more products are likely to commissioned in the FY 2023 -24. As per Clause 15.2 of Scheme Guidelines, the applicant may submit the claim for disbursement of incentives on half-yearly or annual basis. Standard Operating Procedure (SoP) for claiming the incentive by selected applicants has been shared with applicants after consultations. Initially BE for FY 22-23 was projected, based on the annual requirement, which has to be claimed after the end of FY. Hence, appropriately re-appropriated in RE 22-23 to cater to the half yearly or three-quarters claims received upto Dec.2022 subject to satisfaction of other eligible conditions such as minimum threshold sales / investments.

41. Further, the Committee also wanted to know about the plans to utilise Rs. 100.00 crore on the scheme during 2023-24, the Department stated that as most of the incentive claims are expected in FY 2023-24, accordingly funds were sought in 2023-24 for disbursement of claims. The proposal of Rs.100.00 crore has been sought based on consultation with selected applicants and sales projections submitted by them to PMA.

(iii) Production Linked Incentive Scheme for Pharmaceuticals (PLI 2.0) - (Major Head2852)

42. The Union Cabinet on 24.02.2021 approved this scheme with the objective to enhance India’s manufacturing capabilities by increasing investment and production in the

sector and contributing to product diversification to high-value goods in the pharmaceutical sector. The scheme covers pharmaceutical goods under the following three categories-

Category 1: Biopharmaceuticals; Complex generic drugs; Patented drugs or drugs nearing patent expiry; Cell-based or gene therapy drugs; Orphan drugs; Special empty capsules like HPMC, Pullulan, enteric etc.; Complex excipients; Phyto-pharmaceuticals; Other drugs as approved.

Category 2: Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates (except for the 41 eligible products already covered under the "PLI Scheme for promotion of domestic manufacturing of critical KSMs/DIs/APIs").

Category 3 (Drugs not covered under Category 1 and Category 2): Repurposed drugs; Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs; In vitro diagnostic devices; Other drugs as approved; Other drugs not manufactured in India.

43. The tenure of the Scheme is from Financial Year 2020-21 to Financial Year 2028-29. The scheme provides for incentives on incremental sales to selected participants for a period of 6 years at the rate of 10% for FY 2022-23 to FY 2025-26, 8% for FY 2026-27 and 6% for FY 2027-28.

44. The Department has stated that as per scheme guidelines, the applicants shall apply within the following three groups based on the following criteria:

- **Group A:** Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices more than or equal to Rs. 5,000 crore.
- **Group B**: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices between Rs. 500 (inclusive) crore and Rs. 5,000 crore.
- **Group C:** Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices less than Rs. 500 crore. This group shall include a sub-group for MSME applicants, i.e., applicants registered as Micro, Small & Medium Enterprises (MSME) with the Ministry of MSME, Government of India.

45. The details with regard to Budget Estimate (BE), Revised Estimate (RE), actual expenditure and annual percentage increase in expenditure during the last 3 years and the proposed and approved BE allocations for the year 2023-24 is given as under:

(Rs. in crore)

Financial Year	Budget Estimate	Revised Estimate	Actual Expenditure	Percentage increase/decrease
2020-2021	00	00	00	00
2021-2022	3.00	3.00	1.239	300%
2022-2023	3.00	694.20	165.74	23040%
2023-2024	1000.00*	-	-	-

*** Proposed BE is Rs. 3584.50 crore**

46. On being asked about the reasons for underutilization under the scheme during 2022-23 when Rs. 694.20 crore is allocated at RE stage for the scheme, the Department has elucidated that the current FY 2022-23 is the first year of production for the PLI scheme for Pharmaceuticals. Under the PLI scheme for Pharmaceuticals, 261 projects have been commissioned for 309 Project locations based on December, 2022 Quarterly Review Report (QRR). Further plants are likely to commissioned in the FY 2023 -24. An applicant may submit a claim for disbursement of incentive on Quarterly/ Half Yearly/ Annual basis. Claims for any period shall be made only once, unless withdrawn, and no subsequent part claims shall be allowed for the said period. Standard Operating Procedure (SoP) for claiming the incentive has been shared with selected applicant. FY 2022-23, Rs. 694.20 has allocated in R.E. stage and Rs. 165.74 has been released till date and remaining incentives are expected to be released by end of FY. The remaining claims received by the PMA are under examination.

47. In this regard, the Secretary, DoP during evidence assured the Committee as under

> "*Against the amount of Rs. 694.20 crore, claims worth Rs. 538.00 crore have already come in. We have already released Rs. 165.74 crore, and we will be releasing the next tranche. So, this is work in progress, and this is the quarter in which it has to be done."*

(C) UMBRELLA SCHEME: DEVELOPMENT OF PHARMACEUTICAL INDUSTRY- (Major Head 2852)

48. Under the umbrella scheme for Development of Pharmaceutical Industry (DPI), the Department implements the Central Sector Schemes namely 'Strengthening of Pharmaceuticals Industry' with three sub-schemes viz. (i) Assistance to Pharmaceutical Industry for Common Facilities (API-CF) (ii) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) and (iii) Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS), with total financial outlay of Rs.500.00 crore from FY 2021-22 to FY 2025-26 and Two Park Schemes viz. (i) Scheme for Promotion of for Bulk

Drugs Parks with total financial outlay of Rs.3000.00 crore from FY 2020-21 to FY 2024-25 and (ii) Scheme for Promotion of Medical Devices Parks with total financial outlay of Rs.400.00 crore from FY 2021-22 to FY 2024-25. The objective of this umbrella scheme is to increase efficiency and competitiveness of domestic pharmaceutical and MedTech industry so as to enable them to play a lead role in the global market and to ensure accessibility, availability and affordability of quality pharmaceuticals and medical devices for mass consumption.

(D) Strengthening of Pharmaceutical Industry (SPI)-(Major Head 2852)

49. The scheme "Strengthening of Pharmaceutical Industry" (SPI) is launched on 21.7.2022 with an objective to strengthen the existing infrastructure facilities and in order to make India a global leader in the Pharma Sector, with a total financial outlay of Rs.500.00 crore for the period from FY 2021-22 to FY 2025-26 and scheme guidelines were released on 11.3.2022. This Scheme is a Central Sector Scheme and comprises the following sub-schemes:

a. **Assistance to Pharmaceutical Industry for Common Facilities (API-CF)** to strengthen the existing pharmaceutical clusters' capacity by creating common facilities.
b. **Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)** to facilitate Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards (WHO-GMP or Schedule-M), interest subvention or capital subsidy on their capital loans will be provided, which will further facilitate the growth in volumes as well as in quality
c. **Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)** to facilitate growth and development of Pharmaceutical and Medical Devices Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry.

The above three sub-schemes are already approved by the DoP as part of scheme for 'Development of Pharmaceutical Industries' (DPI). Now, the Department has combined the above schemes into a single scheme namely 'Strengthening of Pharmaceutical Industry (SPI)' with modification in the scheme guidelines, after stakeholder consultations for effective intervention. SIDBI has been appointed as the Project Management Consultant(PMC) for the SPI scheme.

a. Assistance to Pharmaceutical Industry for Common Facilities (API-CF)-(Major Head2852)

50. The details with regard to Budget Estimate (BE), Revised Estimate (RE), actual expenditure and annual percentage increase in expenditure during the last 3 years and the proposed and approved BE allocations under the scheme for the year 2023-24 is given as under:

(Rs. in crore)

Name of Sub-Scheme	B.E (2020-21	RE (2020-21)	Actual (2020-21)	B.E (2021-22)	RE (2021-22)	Actual (2021-22	B.E (2022-23)	RE (2022-23)	Actual (2022-23) As on 31.12.22	Proposed BE (2023-24)	Approved BE (2023-24)
API-CF	12.00	7.23	7.22	18.00	15.61	9.89	36.00	32.00	7.67	61.90	51.00

51. During 2022-23, it is noted that under scheme 'Assistance to Pharmaceutical Industry for Common Facilities (API-CF)', Rs.36.00 crore was allocated at BE stage which revised downwards to Rs.32.00 crore at RE stage and the actual utilization is only Rs. 7.67 crore. Therefore, the Committee asked about the reasons for variation in BE, RE and actual expenditure figures during 2022-23, in reply, it is stated by the Department that the Scheme "Strengthening of Pharmaceuticals Industry" is launched on 21.07.2022 and applications are invited under the sub-scheme "Assistance to Pharmaceutical Industry for Common Facilities (API-CF)" through Project Management Agency (PMA), SIDBI from August, 2022 onwards. In total, 20 applications were received by PMA. Three Scheme Steering Committee (SSC) meetings have been held and accorded its final approval to 5 applicants, out of 20 applications. As only 30% Grant-in-Aid were to be released as 1st instalment, the amount was reduced to Rs.32.00 crore from Rs. 36.00 crore.

52. Regarding the reason for keeping BE 2023-24 on a higher side for API-CF scheme that is Rs. 51.00 crore for 2023-24 which is much higher than BE for 2022-23 i.e. Rs. 36.00 crore and the physical and financial targets that will be achieved with this higher allocation during 2023-24, the Department has replied that so far, out of 3 projects approved before 2022, one is completed and remaining two are expected to be completed shortly. For the budget available during the scheme tenure, already 5 projects selected and in-principle approval letter is being issued and 1st instalment is likely to be released shortly. Funds in BE 2023-24 was proposed based on approval given for 7 projects and new projects expected to be approved in 23-24 towards release of 1st/2nd installments.

53. A statement showing the physical targets and achievements fixed for the last three years from 2020-21 to 2022-23 is as under:

Financial Year	Physical Target	Achievement	Financial Target	Achievement
2020-21	2 Common Facility Centre will be approved	2 projects i.e. KIDC, H.P. and IPRF, Pune has been approved	1st installment to be released	1st installment was released to both approved projects
2021-22	3 Common Facility Centre will be approved	No new project was selected	1st installment to be released to newly select CFCs.	No amount was disbursed
	1 Old project of CPIIUC shall be commissioned	The project of CPIIUC commissioned	2nd Installment to the CFCs approved in 2020-2021	2nd installment to old projects was released.
2022-23	Completion of 2 projects	2 projects are likely to be commissioned by end of March, 2023	Release of 3rd and final installment to 2 projects	3rd installment was released. Final installment will be released after commissioning.
	5 New projects to be approved	DPR for new projects are received, which is under examination	Release of 1st installment to 5 new projects	After selection, the payment will be released

54. The Department has furnished the progress made under the projects that are commissioned or about to be commissioned in 2022-23 under the scheme API-CF as under :

S. No.	Name	Project	Place	Approved Project Cost	Approved Grant-in-aid	Status
1.	Chennai Pharma Industrial Infrastructure Upgradation Company (CPIIUC)	Common Effluent Treatment Plant (CETP)	Alanthur, Tamil Nadu	Rs. 11.02 crore	Rs. 11.02 crore	Completed
2.	Inducare Pharmaceuticals and Research Foundation (IPRF)	Common Testing Facility, R&D with pilot plant and common logistic center	Pune, Maharashtra	Rs. 31.44 crore	Rs. 20.00 crore	Final Approval: 31.03.2021 3 Installments released.
3.	Kala Amb Infrastructure Development Company (KIDC)	Common Effluent Treatment Plant (CETP)	Sirmaur, Himachal Pradesh	Rs. 7.20 crore	Rs. 5.04 crore	Final Approval: 31.03.2021 3 Installments released.

b. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) -(Major Head2852)

55. The details with regard to the Budget Estimate (BE), Revised Estimate (RE), actual expenditure and annual percentage increase in expenditure during the last 3 years and the proposed and approved BE allocations under the scheme for the year 2023-24 is given as under:

(Rs. in crore)

Name of Sub-Scheme	B.E (2020-21)	RE (2020-21)	Actual (2020-21)	B.E (2021-22)	RE (2021-22)	Actual (2021-22)	B.E (2022-23)	RE (2022-23)	Actual (2022-23) As on 31.12.22	Proposed BE (2023-24)	Approved BE (2023-24)
PTUAS	0.02	0.02	00	0.01	0.01	0.00	62.00	1.00	0.00	104.30	95.00

56. Under the scheme 'Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)', Rs.62.00 crore was allocated at BE stage which was revised downward to Rs.1.00 crore at RE stage and there is no expenditure made during 2022-23. In this regard, the Committee asked about the reasons for variation in BE and RE allocations and nil utilization as on 31.12.2022. In reply, the Department has stated that though extensive outreach was conducted on the benefits of the scheme, there were lukewarm response in FY 22-23 and accordingly the revised funds of Rs.1 crore was sought in RE 2022-23. However, now four applications have been received in 2023 which are under scrutiny of SIDBI (PMA).

57. When asked as to how the Department plan to spend Rs. 95.00 crore allocated for the year 2023-24 which is on a much higher side as compared to last year as nothing was spent on the scheme during 2022-23, it has been replied that it is expected that most of the applicants will be selected in FY 23-24. Hence, a budget of 95.00 crore is proposed. If most of the applicants opt for capital subvention mode, then the amount will be paid at the end of the completion of the projects only. In that case, this projected amount will be appropriately re-appropriated to other schemes. As the Scheme is on roll over basis, Department expects a positive and maximum response in 2023-24.

58. A statement showing the physical targets and achievements fixed for the last three years including the target set for the ensuing year 2023-24 is as under:

Financial Year	Physical Target	Achievement	Financial Target	Achievement	Reason for variations
2020-21	To upgrade 500 SME Units	**	Release payment to selected SME Units	**	**
2021-22	**	**	**	**	**
2022-23	To upgrade 150 MSME Units	Application has been invited	To release payment to selected applicants	**	**

59. Regarding the present status with respect to the physical targets fixed during 2021-22 and 2022-23 of upgrading 500 and 150 Small and Medium Enterprises (SMEs) units, respectively under PTUAS scheme, the Department reiterated the reason as lukewarm response for the scheme.

c. Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS) - (Major Head 2852)

60. The details with regard to the Budget Estimate (BE), Revised Estimate (RE), actual expenditure and annual percentage increase in expenditure during the last 3 years and the proposed and approved BE allocations under the scheme for the year 2023-24 are given as under :

(Rs. in crore)

Name of Sub-Scheme	B.E (2020-21)	RE (2020-21)	Actual (2020-21)	B.E (2021-22)	RE (2021-22)	Actual (2021-22)	B.E (2022-23)	RE (2022-23)	Actual (2022-23) As on 31.12.22	Proposed BE (2023-24)	Approved BE (2023-24)
PMPDS	1.00	0.50	0.49	2.00	2.00	1.20	2.00	3.00	0.24	5.00	4.00

61. Asked about the reasons for underutilization of funds of Rs.3.00 crore allocated during 2022-23 under the scheme Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS) and only Rs.0.24 crore could be utilized, it has been stated that Rs.3.00 crore was sought in RE 2022-23 under PMPDS keeping in view utilization towards conducting proposed National level Medtech expo in January, 2023 (Rs. 1 crore) and annual India Pharma and Medtech event in March 2023 (Rs.1 crore) and both

of these events could not be held as per the original plan. However, the Department has approved 5 new Studies in January, 2023 and the release of 30% of the cost of study as advance payment will be made during February and March, 2023.

62. A statement showing the physical targets and achievements fixed for the last three years is given as under:

Name of Scheme/ Project	2020-21		2021-22		2022-23	
	Physical target	Achievement	Physical target	Achievement	Physical target	Achievement
PMPDS	15 Seminar to be conducted	10 events organized	24 events to be conducted	1 event organized	25 seminars to be conducted	3 events organized
	1 study to be conducted	*	5 studies to be conducted	5 studies was awarded	10 studies to be conducted	Applications have been received, which is under examination

It is evident that during 2022-23, only 3 events out of target of 25 seminars have been conducted and in respect of 10 studies which were to be conducted, application received are still under examination. When asked to give details, the Department in its reply has not furnished any concrete reason for this under performance.

(E) Scheme for Promotion of Medical Device Parks-(Major Head2852)

63. The scheme "Assistance to Medical Device Industry for Common Facility Centre" has been revised and renamed as "Promotion of Medical Device Parks" and approved by the Government of India on 20 March, 2020. The total financial outlay of the scheme is Rs. 400.00 crore with Rs. 100.00 crore each for four Medical Device Parks to set up common facilities. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025. A total 16 States/UTs submitted their proposals under the scheme. The Department has given final approval to the States of Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh under the scheme. The expected date of completion of the Parks is June, 2024. First installment of Rs. 30.00 crore each have been released to the 4 States in FY 2021-22.

64. The objective of the scheme is stated to be to provide easy access to standard testing and laboratory facilities through the creation of world-class Common Infrastructure Facilities (CIF) at medical device parks. This would help reduce the cost of production and increase competitiveness and improve availability and affordability of medical devices thereby creating a robust ecosystem for domestic manufacturing of medical devices. The guidelines of the scheme were issued on 27th July 2020. The scheme provides grant-in-aid

to medical device parks with a maximum limit of Rs.100.00 crore per park or 70% of the project cost of common infrastructure facilities, whichever is less.

65. The details with regard to the Budget Estimate (BE), Revised Estimate (RE), actual expenditure during the last 3 years and the proposed and approved BE allocations for the year 2023-24 is given as under:

(Rs. in crore)

Scheme	Financial Year	Budget Estimates	Revised Estimates	Actual Expenditure
Assistance to Medical Device Industry for Common Facilitation Centre	**2020-21**	7.50	21.05	7.49
	2021-22	60.00	137.02	137.02
Promotion of Medical Devices Parks	**2022-23**	120.00	32.93	0.8968
	2023-24	200.00	-	-

 # Proposed BE is Rs.207.563 crore

66. During 2022-23, the initial allocation of Rs.120.00 crore made for the scheme at BE stage was reduced to Rs.32.93 crore at RE stage and the actual utilization was only Rs.89.00 lakh. When asked about the reasons for this gross under-utilization of funds, the Department in its reply has stated that a provision of Rs.120.00 crore was kept as BE 22-23 for release of 2nd Installment to the 4 States in FY 2022-23. The grant provided is for development of Common Infrastructure Facilities (CIFs) of the park and CIF development will follow after the physical infrastructure and land development work are attended by State Implementation Agencies (SIAs) with their funds. As informed by PMA, the tenders for the physical infrastructure works in the States are being finalized. Further, as per the scheme guidelines, SIAs have to spend 60% amount of 1st installment and equivalent amount of the State funds in order to become eligible for receiving 2nd installment. Despite the periodic review and regular follow-up, the States could not complete the required expenditure and submit the Utilization Certificates (UC) due to the requirement of huge technical consultations for arriving at the technical specifications for development of scientific common infrastructure facilities in the proposed Medical Devices Parks and slower pace of execution of physical infrastructure works. Further, only the State of Tamil Nadu has conveyed that they will be able to submit UC by 15th February 2023. Hence, a provision of Rs.32.93 crore was kept in RE. Recently, the State of Tamil Nadu conveyed that it will be able to submit the required UCs by first quarter of FY 2023-24 only. Hence, there is a lesser expenditure and the amount is being proposed for re-appropriation to other schemes of the Department.

67. The Secretary, DoP during evidence further added on the under-performance in budget utilization as under :

"I hope the Committee would also appreciate that this is the first time that these States are setting up Medical Device Parks. Secondly, the benchmark or the barriers are pretty high. We are not providing support for civic infrastructure like roads, drainage, water supply, etc. Those are to be borne and implemented by the States. What we are asking the States to do is to actually set up the scientific central infrastructure which includes things like gamma irradiation, specialized packaging for medical devices, testing laboratories for medical devices. That can be used as a common infrastructure by the medical device companies which will come in. This required some specialized designing to be done. There are limited resources in the country. However, the four States have now identified the resources. They have got the design made and they have also issued the tender. This certainly took longer than we anticipated. Possibly, it is because it is the first time that such an initiative has been taken."

68. Asked about the reasons for a higher allocation of Rs.200.00 crore at BE 2023-24 as compared to BE 2022-23 of Rs.120.00 crore, it has been stated that the second installment of Rs.30.00 crore each was not released in FY 2022-23 to the selected 4 States, hence it is proposed to release second and third installments in FY 2023-24 of Rs.120.00 crore each for this purpose making an expected expenditure of Rs.240.00 crore to the select 4 States for the year 2023-24. Out of the requirement of Rs.240.00 crore, provisions of Rs.200.00 crore in BE 2023-24 was kept for releasing subsequent both installments to the 4 States and payment of annual fee of Project Management Agency.

F. Scheme for Promotion of Bulk Drug Parks (erstwhile Assistance to Bulk Drug Industry for Common Facility Centre) - (Major Head2852)

69. The total financial outlay of this scheme is Rs.3000.00 crore and the tenure is from 2020-21 to 2024-25. The financial assistance by the centre is subject to a maximum limit of Rs.1000 crore per park or 70% of the project cost of Common Infrastructure Facilities (CIF) and 90% in case of North Eastern States and Hilly States, whichever is less. The scheme "Assistance to Bulk Drug Industry for Common Facility Centre" was revised in 2020 with a larger corpus and named "Promotion of Bulk Drug Parks" which was approved by Cabinet in February, 2020.

70. The Department has to have received proposals from 13 States and after evaluation of the proposals, Andhra Pradesh, Gujarat and Himachal Pradesh were conveyed final approval only in October-November 2022, for creation of common infrastructure facilities (CIF) in the proposed Bulk Drug Parks in these 3 States, under the scheme. The

Department has submitted that first installment of Rs. 299.25 crore has been released to the State Implementing Agency (SIA) of Gujarat. Rs. 299.25 crore each to Andhra Pradesh and Himachal Pradesh will be released in the current financial year i.e. 2022-23.

71. The details with regard to the Budget Estimate (BE), Revised Estimate (RE), actual expenditure during the last 3 years and the proposed and approved BE allocations under the scheme for the year 2023-24 is given as under:

(Rs. in crore)

Scheme	Financial Year	Budget Estimates	Revised Estimates	Actual Expenditure
Assistance to Bulk Drug Industry for Common Facilitation Centre	2020-21	21.52	1.68	1.68
	2021-22	36.24	2.25	2.25
Promotion of Bulk Drug Parks	2022-23	900.00	900.00	301.50
	2023-24	900.00#	-	-

 # Proposed BE is Rs. 900.00 crore

72. Expressing their concern over the inability of the Department to utilize funds during 2022-23 as out of the allocation Rs.900.00 crore for the scheme, only Rs.301.50 crore has been spent. the Committee, asked about the reasons for under-utilization of funds. IN reply, the Department has stated that out of the Rs. 900 crore earmarked for 2022-23, three state are to be given Rs. 299.25 crore each as second installment, after submission of UCs as per the guidelines and Rs. 2.25 is to be given to the PMA. The selection of 3 States under the Scheme has only been done in October/November, 2022. First installment has been released to one of the States and for the remaining two States, it will be done in the next fiscal year.

73. When the Department asked about advance measures that are being taken/proposed to be taken to fully utilize the allocated amount of Rs. 900.00 crore allocated during the year 2023-24, the Department has stated that a High Level Committee is constituted under the Hon'ble Union Minister to oversee the implementation of the scheme. Regular review meetings are being held at the level of Secretary. PMA is also pursuing with the States for implementation of the scheme as per the scheme guidelines. All these will ensure that the scheme is implemented as per the timelines and projected expenditure of Rs.900 crore happens in FY 23-24.

74. With regard to the present status with regard to the creation of Common Infrastructure Facilities (CIF) under the scheme for 3 Bulk Drug Parks, the Department has stated that the 3 selected States have issued tenders or are in the stage of issuing the

tenders for physical infrastructure works, including the common infrastructure projects approved under the scheme. The State Implementing agencies (SIA) of the three respective States have indicated completion of these projects within next 24-28 months. The Department is regularly monitoring the progress through the Project Management Agency hired for the scheme.

(G) Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) - (Major Head2852 and 2552)

75. A total financial outlay of Rs. 490.00 crore has been approved for Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) Scheme for the period 2020-2021 to 2024-2025. An amount of Rs.115.00 crore has been proposed as Budget Estimate 2023-24 and the same has been allocated. The details with regard to the Budget Estimate (BE), Revised Estimate (RE), actual expenditure and annual percentage increase in expenditure during the last 3 years and the proposed and approved BE allocations for the year 2023-24 is given as under:

(Rs. in crore)

Financial Year	Budget Estimate	Revised Estimate	Actual Expenditure	Percentage increase/decrease
2020-21	50.00	65.00	65.00	83.05%
2021-22	65.00	68.50	68.50	5.38%
2022-23	72.50	100.00	72.50 (As on 04.01.2023)	45.99%
2023-24	115.00#	-	-	-

 # Proposed BE is Rs.115.00 crore

76. The Department has stated that the RE allocation of Rs. 100.00 crore during 2022-23 will be fully spent on PMBJP.Then the Committee noticed that the BE for the year 2023-24, is Rs.115.00 crore which is on a higher side as compared to BE of Rs. 72.50 crore during 2022-23, therefore, the Committee wanted to know about the utilization strategy during 2023-24. In reply, it is sated thatin the light of the recommendations of Standing Committee, an amount of Rs.115.00 have been proposed for PMBJP scheme. The same has been allotted in BE-2023-24 that would be utilized to achieve the target for the year i.e. to open 1,000 new Kendras and enhance the product basket up to 2000 medicines and 300 surgical.

77. The details of the physical targets fixed vis-a-vis achievements under the PMBJP scheme are given as under:

Financial Year	Target (Number of Kendras)	Achievement (Number of Kendras)	Target (Product basket) (Medicine, Surgicals)	Achievement (Product Basket) (Medicine, Surgicals)	Target (No. of Warehouses)	Achievement (No. of Warehouses)
2020-21	7300	7557	1400 220	1449 204	4	3
2021-22	8300	8610	1600 240	1616 250	5	4
2022-23	9300	8998 (As on 04.01.2022	1800 280	1759 280 (As on 04.01.2022	6	4 (As on 04.01.2022)

78. Replying on the under achievement of the physical targets set under the scheme with respect to functional warehouses during 2020-21 and 2021-22 as 03 & 04 warehouses were established against the targets of 04 & 05 warehouses respectively and the expected achievement figures in respect of the warehouses during 2022-23 (as on 31.03.2023), the Department has stated that at present, four modern warehouses are set up at Gurugram, Guwahati, Chennai and Surat for storage and distribution of drugs are functional with storage area of approx. 2,15,000 squarefeet's. PMBI is doing direct supply to stores from warehouses to ensure sufficient availability of medicines at all the stores. Above under-achievement for establishing the warehouses was partly due to Covid pandemic. The expected achievement with respect to setting up of warehouses during the F.Y. 2022-23 is 05 warehouses by 31.03.2023.

79. In this context, the Department has also stated that it is targeted to establish 6 warehouses in the country by 2025. Accordingly, two more warehouses are planned to be opened in the country in couple of years, based on the requirement. PMBI, the implementing agency of the Scheme is focusing on improving its supply chain and implemented end to end supply chain management system.

80. On being asked about details of regular local survey that may be conducted by PMBI in all States/UTs to gauge the general demand of drugs in that local area in addition to the demand projected by the Janaushadhi Kendra owner to assess the local needs. the Department has submitted that each Jan Aushadhi Kendra is connected with PoS with distributors & warehouses. They can place orders at any place subject to availability and also if the medicine is part of product basket of PMBJP. PMBI has identified 125 drugs as

fast moving & proposed to increase it to 175 based on sale pattern & demand fore casting. While no such survey of kendras has been done in past 3 years but regular state-wise meetings with kendras are taken by PMBI and feedback from state distributors & marketing officers are taken to take corrective steps.

81. Further during evidence, the representative from Pharmaceuticals & Medical Devices Bureau of India (PMBI) added that:

> *"Sir, we not only take these inputs from the Kendra owners or shopkeepers but we also take feedback from the distributors, from the general public on our mail as well as through the helpline number. There is also a committee which has some experts who guide us for inclusion of medicines. As I just mentioned, 105 medicines have been added just last week after discussion with the committee members, who are doctors, pharmacologists, and all other experts."*

V. NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA) - (Non Scheme Major Head-2852)

82. The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Department of Pharmaceuticals was constituted by the Government vide resolution published in the Gazette of India No. 159 dated 29.08.97. The functions of NPPA, *inter-alia*, include fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government on pharmaceutical policy and issues related to the affordability, availability, and accessibility of medicines. The Government notified DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995.

83. While introducing about the nature and function of NPPA during evidence, the Secretary,DoP stated as under**:**

> ***"****Sir, we also have NPPA. It is autonomous in function, although, administratively, it is under our Department. It is the pharmaceutical pricing authority. About 20 per cent of the total marketing is under ceiling price control. Those are the essential medicines and they are known as 'scheduled drugs'. The remaining 80 per cent is outside ceiling price control. But there is a cap in the percentage of increase annually of 10 per cent even on the non-scheduled drugs."*

84. The details of year-wise BE, RE, and expenditure incurred by the NPPA during the last three years are given as under :

(Rs. in crore)

MH 2852	2020-21				2021-22				2022-23				2023-24
Name of Object Head	BE	RE	Allocated	Actually spent	BE	RE	Allocated	Actually spent	BE	RE	Allocated	Actually spent (4.1.23)	BE allocated
National Pharmaceuticals Pricing Authority (NPPA)	11.9	12.9	11.9	12.74	14.8	14.01	14.8	13.92	17.79	17.83	17.79	12.02	18.90

(Ref: DFG material Pg 21)

85. On being asked about the reasons for under-utilization of allocated funds in 2021-22 and the expected actual expenditure made by NPPA during 2022-23, as on 31.03.2023, it has been stated that the budget allocated during 2021-22 was Rs.14.80 crore and the actual expenditure incurred was Rs.13.92 crore The short fall of Rs. 0.88 crore 2021-22 is due to non-filling up of some contractual posts, late receipt of some bills, no official foreign visits as well as less number of domestic tours due to Covid pandemic. It is expected that the fund of Rs.17.79 crore allocated under “NPPA (Establishment)” during the FY 2022-23 will be fully utilized as on 31.3.2023. Hence, there is no shortfall.

86. The Committee also wanted to know about the new steps/programmes, if any, proposed to be initiated during 2023-24 to achieve the goals of NPPA. In reply, it has been stated that NPPA has proposed various steps like (i) Ceiling Prices fixation of remaining scheduled formulation/medical devices under National List of Essential Medicines (NLEM), 2022 (not fixed during 2022-23) and monitoring the Ceiling Price implemented by companies. (ii) Fixation of Retail Prices of new drugs. (iii) Monitoring the price revision of Non-Scheduled formulations/medical devices (annual 10%) and of Scheduled formulations (WPI basis). (iv) To take necessary action to avoid shortages of essential medicines. Increase public awareness through webinars, etc. Full operationalization of IPDMS 2.0-office automation. (v) Exploring schemes for reducing the litigation burden and take old cases to logical conclusion. (vi) Exploring new pricing methodology for rationalizing the high trade margin in selected drugs. And (vii) Exploring the possibility of putting in place a system for tracking the availability of drugs in the supply chain for ensuring last mile availability in consultation with various stakeholders.

87. Regarding the steps that NPPA has taken as the drug price regulator of the country and to ensure strict compliance of Drugs Prices Control Order, 2013 (DPCO) in the country, it has been stated that PMRUs are established for monitoring of prices in their respective jurisdictions. Analysis of market based data and purchase of samples to check price compliance is done, Over-Charging (OC) proceedings are initiated wherever violation

was found besides carrying analysis of market based data to check the compliance of provisions of DPCO.

88. The Committee asked about the challenges being faced by the NPPA when it comes to implementation of the Drugs Price (Control Order) DPCO in the States and Union Territories. In reply, it has been informed that PMRUs are not being fully operational in some States/UTs due to non-recruitment of staff or timely renewal of their contracts; and yet to be established in others. Continuous follow up and meetings are being conducted with senior officials of the States/ UTs.

89. The Committee further desired to know the status of Pricing Policy based on Trade Margin Rationalization (TMR), which was earlier implemented to anti-cancer drugs as a proof of concept, on non-scheduled drugs and medical devices to extend the benefit of TMR. In reply, it has been stated that NPPA has capped trade margin of non-scheduled formulations of 42 select Anti-cancer medicines under “Trade Margin Rationalization” approach as a pilot for proof of concept in February, 2019. Further, TMR approach was used to regulate the price of Oxygen Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer under “Trade Margin Rationalization” Approach in June/July 2021. On similar lines, to regulate the prices of non-scheduled drugs, proposal has been forwarded to DoP for consideration.

PART-II

OBSERVATIONS AND RECOMMENDATIONS

Proposed and Approved budgetary allocation for the year 2023-24

1. The Committee note that the Department of Pharmaceuticals (DoP) projected a budget allocation of Rs. 5728.57 crore for its various schemes/programmes and other activities during the year 2023-24.However, the Ministry of Finance reduced the same and has allocated Rs. 3160.06 crore only. Similarly, during 2022-23, the proposed allocation of Rs. 10383.25 crore was reduced to Rs. 2244.15 crore. The DoP, however is largely satisfied with an overall increase of 40.84 % in gross budget allocations in 2023-24 as compared to 2022-23 except that in two of its schemes viz. National Institute of Pharmaceutical Education & Research (NIPER) and Production Linked Incentive Scheme for Pharmaceuticals (PLI-Pharmaceuticals) in which the proposed allocation has been drastically reduced. Under the NIPER scheme (Major Head 2852 and 2552), against the projected allocation of Rs. 1286.00 crore, Rs. 500.00 crore and Rs. 50.00 crore have been sanctioned for NIPERs (Major Head 2852 and Major Head 2552, respectively). Again, in case of PLI-Pharmaceuticals scheme, against the proposed budget outlay of Rs. 2203.00 crore which was required to provide the incentives to the applicants under the scheme, only Rs. 1000.00 crore has been sanctioned.

Keeping in view an enhanced budgetary allocations during 2023-24, the Committee impress upon the Department to strategically plan, evaluate, monitor and implement its five central sector schemes, namely (a)National Institute of Pharmaceutical Education & Research (NIPER), (b) Production Linked Incentive (PLI) Schemes, (c) Development of Pharmaceutical Industry, an Umbrella Scheme (d) Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and (e) Consumer Awareness, Publicity and Price Monitoring (CAPPM) thus ensuring optimal

utilisation of allocated funds and making sufficient ground for approval of the proposed requirement of funds at RE stage.

Budgetary allocation and utilization during 2020-21, 2021-22 and 2022-23

2. The Committee are constrained to observe the recurring under-utilization of allocated funds by DoP during the last three years. During FYs 2020-21, 2021-22 and 2022-23, out of the allocated funds at RE stage of Rs. 470.41 crore, Rs. 823.11 crore andRs. 2268.54 crore, respectively, the Department could utilise Rs. 456.16 crore (96.97%), Rs. 774.94 crore (94.14%) and Rs. 843.78 crore (37.19%) (as on 20.02.2023), respectively. Obviously, under-utilization of funds in past and especially during the current year 2022-23 where only 37.19 percent of allocated funds have been utilised up to 20.02.2023 would have adversely affected the implementation of the various central sector schemes of the Department which are of paramount importance in the interest of general public and speaks poorly on the functioning of the Department. The Committee are unhappy to note the tardy progress in implementation of three PLI schemes of the Department during 2022-23 as the Department has been able to utilise Rs. 470.93 crore(28.31%) of the allocation of Rs.1663.20(up to 20.02.2023). While expressing their concern over the gross under-utilisation of allocated funds during 2022-23 so far for PLI schemes, the Committee exhort the Department to implement the schemes with all seriousness and take timely corrective measures so as to ensure optimum utilization of the remaining allocated funds by 31st March, 2022. The Committee would like to be apprised of the overall utilization of funds by the Department during 2022-23 up to 31.03.2023 and in particular in respect of its PLI schemes.

New Schemes under National Institute of Pharmaceutical Education and Research (NIPER) MH-2852

3. The Committee acknowledge the budgetary challenges faced by the DoP with respect to NIPER scheme. The Department had sought Rs. 4300.00 crore for a period of 5 years from 2021-22 to 2025-26.However, the Economic Finance Committee (EFC) approved Rs. 1500 crore only. Again, for the FY 2023-24, the Department sought an amount of Rs.1286.00 crore with an objective to launch new initiatives viz. National Institute of Medical Device and Education (NIMERs) (Rs.200.00 crore), Centres of Excellence (CoEs) (Rs.233.00 crore), Indian Council of Research & Development and Innovation in Pharma-MedTech Sector (ICPMR) (Rs.50.00 crore) and Promotion of Research & Innovation in Pharmaceutical Sector (PRIP) (Rs.243.00 crore).However, no funds have been allocated for the same and Rs. 550.00 crore only has been allocated for the existing NIPER scheme. The Committee are of the view that reduced budget allocation will adversely affect the progress and growth of NIPER scheme of the Department. This is regrettable since the establishment of more NIPERs across the country would fill a vital need. The Committee also recommend the establishment of a NIPER in a Southern State where interest in pharmaceutical education is high.

The Department has, however stated that keeping in view the budget 2023-24 announcements with respect to Pharma innovations and multidisciplinary courses for medical Devices, additional funds will be sought from Ministry of Finance at later stage. The Committee are of the view that the proposed initiatives of the Department viz. NIMERs will provide specialized courses in the field of medical devices and CoEs under PRIP are crucial to strengthen the foundation of research and development in pharmaceutical and medical device sector in the country which is still lagging far behind other countries. Further, setting up an R &

D Council like ICPMR is also the need of the hour to enable the Department for uninterrupted promotion and coordination in Pharma-MedTech field. The Committee share the concern of the Department that our country needs support in high end therapeutics and medical devices and would strongly recommend that financial allocations be stepped up for the NIPER scheme of the Department and at least maintained at the previous level of Rs. 1286.00 crore.

National Institutes of Pharmaceutical Education and Research (NIPERs) (MH2852)

4. The National Institutes of Pharmaceutical Education and Research (NIPERs) are autonomous institutes of national importance, which have been established by an Act passed in Parliament in 1998, for imparting postgraduate and doctorate education and conducting research in various specializations of pharmaceutical science. At present, there are seven functional NIPERs at Mohali, Ahmedabad, Hyderabad, Hajipur, Guwahati, Raebareli and Kolkata.

The Committee note with satisfaction that regular faculty and administrative posts sanctioned in all NIPERs have been filled up as per current needs. The Committee, however, are constrained to note that except NIPER- Mohali and NIPER-Guwahati, all the other five NIPERs do not have their own campuses and are functioning with the assistance of their mentor institutes.

Campus construction of NIPER Guwahati is just completed, about 60% construction has been completed at NIPER Ahmedabad, and Administrative Approval & Expenditure Sanction for construction of campuses of NIPERs at Kolkata, Hajipur and Raebareli through CPWD and at Hyderabad through NPCC has been made and the tenders are under finalization. The Committee are not happy with figures of utilization of funds so far during 2022-23 as out of the RE of Rs. 422.00 crore, the actual expenditure as on 31.12.2022 remained Rs.231.00 crore. The Department has, however been assured that before the end of this

financial year, the maximum amount will be utilized as about Rs.190.00 crore will be disbursed for construction of campuses of three NIPERS viz. Kolkata, Hajipur and Raebareli by CPWD subject to award of tender. The Committee further note that Rs. 550 crore has been allocated for the year 2023-24 under NIPER scheme for various activities viz. the construction of campuses, up- gradation of laboratories, payment of salaries to faculty/staff and fellowship to students etc. The Committee hope that as assured Rs. 422.00 crore allocated at RE, 2022-23 would be fully utilized and would like to be apprised of the figures for utilization of funds by NIPERs during 2022-23. The Committee would further like to be assured that construction of Campuses of NIPER Ahmedabad, Kolkata, Hajipur, Raebareli and Hyderabad would be accorded top priority and whatever might be the constraints, serious efforts will be made to complete the construction without further delay.

<u>Production Linked Incentive (PLI) Schemes (MH2852)</u>

5. The Committee note that among the three Production Linked Incentive (PLI) schemes, the PLI schemes for promotion of domestic manufacturing of API and Medical Devices were approved by the Government on 20 March, 2020 and scheme guidelines were issued on 29.10.2020. The third PLI scheme for Pharmaceuticals was approved on 24.02.2021. The Committee note that an amount of Rs.1629.00 crore was allocated for PLI schemes during 2022-23, which was increased to Rs.1663.20 crore at RE stage. However, the actual utilization as on 20.02.2023 was Rs.470.93 crore only. The Committee do appreciate the Department's view that there is a gestation period for one to two years and then there is a period of production and a period of incentive being released. However, the Committee fail to understand why an allocation of Rs.1629.00 crore was made and then enhanced to Rs.1663.20 crore at RE, 2022-23 and at the end of the year the maximum amount remained unspent. The Committee consider it to be a bad

budgeting. The Secretary, DoP during evidence also admitted that they had made provisions for incentives to be released in 2022-23 whereas 2022-23 was the year of production and they could have actually made this provision next year. The Committee desire that henceforth, the Department should be more realistic in projecting its estimates for better utilisation of funds.

PLI for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) (MH2852)

6. The PLI scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs)was launched on 20 March, 2020 to boost domestic manufacturing of 41 identified KSMs/ DIs and APIs, by attracting large investments in the sector and thereby reducing India's import dependence in critical APIs. The scheme has been formulated based on the recommendations of the Technical Committee, wherein the dependency of these products are more than 85% from a single country. Accordingly, DoP has notified 41 products under the Scheme. The Committee trust that the PLI scheme, subject to its effective implementation, will enable the country to attain self-sufficiency in critical APIs. The Committee desire that the Department should strive hard and periodically review the scheme to further reduce the dependency of KSMs/ DIs and APIs on a single country.

Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing for Medical Device (MH2852)

7. The Committee note that the DoP proposed an allocation of Rs. 102 crore for FY 2023-24 under PLI Scheme for Promoting Domestic Manufacturing for Medical Device, however, Rs.100.00 crore has been allocated. The proposed amount was based on consultation with the selected applicants and sales projections submitted by them to Small Industries Development Bank of India (SIDBI)which is

Project Management Agency (PMA) for this scheme. The Committee desire that the momentum be continued unabated with added thrust and impetus for attracting investment for promoting domestic manufacturing of medical devices. The Committee expect optimal utilization of Rs. 100 crore allocated for the purpose during FY 2023-24.

<u>Production Linked Incentive Scheme for Pharmaceuticals (MH2852)</u>

8. The Committee note that PLI Scheme for Pharmaceuticals has been approved with an objective to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high-value goods in the pharmaceutical sector. During 2022-23, against the RE allocation of Rs.694.20 crore, the Department could utilize Rs.165.74 crore up to 31.12.2022. However, it has been assured that a substantial amount of Rs. 538.00 crore, out of the allocated amount would be utilized by the end of this financial year. During 2023-24, against the proposed allocation of Rs. 3584.50 crore, the Department has been allocated Rs. 1000.00 crore only. The Department has stated that as PLI applicants have projected a claim of about Rs. 2203.20 crore for FY 2022-23, the allocated amount is 55 percent less than the projected applicant claims. Appreciating the initiative taken by the Department towards enhancing domestic manufacturing capabilities that will contribute to product diversification to high-value goods in the pharmaceutical sector, the Committee would like to emphasize on the need of developing an effective monitoring mechanism to constantly review the progress of the ongoing projects in the pharmaceutical sector to ensure that there is no let-up in fulfillment of the core objectives of the scheme. The Committee are of the opinion that in no case the financial constraints under the PLI scheme for pharmaceuticals be allowed to

bring down the physical achievements. Hence, funds for this scheme should be adequately enhanced at RE stage.

<u>Strengthening of Pharmaceutical Industry (SPI) (MH-2852)</u>

9. The Committee note that three sub-schemes of the DoP viz. (i) Assistance to Pharmaceutical Industry for Common Facilities (API-CF), (ii) Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) and (iii) Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS) which earlier came under the umbrella scheme 'Development of Pharmaceutical Industries' (DPI) has been rearranged into a new Central Sector Scheme i.e. 'Strengthening of Pharmaceutical Industry (SPI)'. Thereupon the sub-scheme guidelines were modified under SPI and released on 11.3.2022 after stakeholder consultations. The SPI scheme aims to strengthen the existing infrastructure facilities and make India a global leader in the Pharma Sector. SIDBI has been appointed as the Project Management Consultant (PMC) for the SPI.

The Committee note that for SPI, a total financial outlay of Rs.500.00 crore has been fixed for the period from FY 2021-22 to FY 2025-26 and for FY 2023-24, the Department has been allocated an amount of Rs.149.00 crore against the proposed allocation of Rs.171.20 crore. The Committee are hopeful that with required modifications in sub-scheme guidelines under SPI scheme after consultations with the stakeholders, the performance under the sub-schemes of SPI will improve and Rs.149.00 crore allocated for SPI scheme will be optimally utilised.

<u>Assistance to Pharmaceutical Industry for Common Facilities (API-CF)</u>

10. The Committee note that sub-scheme 'Assistance to Pharmaceutical Industry for Common Facilities (API-CF)' of the Central Sector Scheme i.e.

'Strengthening of Pharmaceutical Industry (SPI)' aims to strengthen the existing pharmaceutical clusters' capacity by creating common facilities. The Committee, however, note that under the sub-scheme API-CF, during 2021-22 and 2022-23, against the allocation of Rs.15.61 crore and Rs. 32.00 crore, the actual utilization was Rs.9.89 crore and Rs.7.67 crore (as on 31.12.2022), respectively. Obviously there was shortfall in achievement of physical targets during these years. The target related to approval of 3 Common Facility Centres (CFC)during 2021-22 remained unachieved. Till date, only 1 project has been made functional i.e. Common Effluent Treatment Plant (CETP) at Alathur, TamilNadu. Other two projects that were approved on 31.12.2021 *viz*. (i) a Common Testing Facility, R&D with pilot plant and common logistic center at Pune, Maharashtra and (ii) Common Effluent Treatment Plant (CETP) at Sirmaur, Himachal Pradesh are still in process of commissioning. During the FY2022-23, 5 projects targeted to be approved are still awaiting final approval. The Committee are concerned about the tardy implementation of the projects under sub-scheme API-CF of SPI scheme and urge the Department that API-CF scheme should be implemented with all seriousness and every effort should be made to remove the bottlenecks in expeditious implementation of the projects so that the allocation of Rs.51.00 crore during the year 2023-24 is optimally utilised.

Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

11. The sub-scheme Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) under the Central Sector Scheme, 'Strengthening of Pharmaceutical Industry (SPI), aims at facilitating Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards (WHO-GMP or Schedule-M) by making provision for them of interest subvention or capital subsidy on their capital loans, which will

further facilitate the growth in volumes as well as in quality. However, the Committee note that during 2020-21 and 2021-22, against the token allocation of Rs. 2 Lakhs and Rs. 1 lakh, respectively, there was nil utilization of funds. Though a higher allocation of Rs. 62.00 crore was made at BE, 2022-23, it was reduced to Rs. 1.00 crore at RE, 2022-23 and again there is nil utilization of funds. As a result, the physical target of upgrading 500 and 150 MSME units during 2020-21 and 2022-23, respectively was also not achieved. The Committee find that there is no use of fixing the targets when there is no progress with regard to the implementation of the scheme and nothing is spent on the scheme during the year. Nil utilisation of funds during the last three years under PTUAS scheme is attributed to lukewarm response to the scheme despite extensive outreach conducted on the benefits of the scheme. The Committee desire that the factors responsible for the lukewarm response to the PTUAS scheme are required to be looked into and remedial measures should be taken accordingly. Matter may be discussed with the stakeholders, and if needed, possibility of revising the scheme guidelines may be looked into.

12. The Committee note with satisfaction that four applications have been received in the year 2023 which are under scrutiny of Project Management Agency (SIDBI) and the Department is expecting better MSME industry response in 2023-24. The Committee further desire that the Department should continue to pay focussed attention for adequate publicity of the PTUAS scheme among MSMEs. The Committee would like to be assured that the Department would take immediate corrective measures and allocation of Rs.95.00 crore for the PTUAS scheme during FY 2023-24 will be fully utilised.

Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)

13. The sub-scheme 'Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)' under the Central Sector Scheme, 'Strengthening of Pharmaceutical Industry (SPI)' is designed to facilitate growth and development of Pharmaceutical and Medical Device Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry. The Committee are distressed to note the under-utilization of allocated funds under the scheme. During 2020-21 and 2021-22, against the allocation Rs. 1.00 crore and Rs. 2.00 crore, the Department could utilise Rs. 0.49 crore and Rs. 1.20 crore, respectively. During 2022-23, against the allocated funds of Rs. 3.00 crore, the actual utilization is Rs. 0.24 crore (as on 31.12.2021). The Department has failed to achieve the physical targets in respect of studies and seminars during 2021-22 and 2022-23. The Committee feel that the Pharmaceutical & Medical Devices Promotion and Development scheme should be given the attention it deserves for the growth and development of Pharmaceutical and Medical Device Sectors. Hence, the Committee urge the Department to take necessary steps to achieve the physical targets fixed for the FY 2023-24 under the scheme so that allocated funds of Rs. 4 crore are fully utilised.

Scheme for Promotion of Medical Devices Parks (MH 2852)

14. The Committee observe that the umbrella scheme 'Development of Pharmaceuticals Industry' includes the sub-scheme 'Promotion of Medical Devices Parks' with anobjective to promote 4 Medical Device Parks by providing Grants-in-Aid for creation of Common Infrastructure facilities (CIF). Total financial outlay for the Scheme is Rs. 400.00 crore for the period 2020-21 to 2024-25 and Rs.100.00 crore per Park or 70% of the cost of the CIF, whichever is less. The assistance would be 90% for North Eastern Region and Hill States. The Committee, however,

are greatly concerned to note the severe shortfall in utilization of allocated funds during FY 2022-23, where out of the allocated amount of Rs.120.00 crore at RE stage, the Department could utilize Rs.89 lakhs only up to February, 2023. The reason for the shortfall is stated to be that funds were not utilized as the States could not spend the 60 percent of 1stinstalment of Rs.30.00 crore and equivalent amount of the state funds, in order to become eligible for receiving 2ndinstalment as per the scheme guidelines as Utilization Certificates (UCs) could not be submitted to receive second instalment of Rs.30.00 crore. The Committee are of the strong view that scheme for promotion of Medical Parks for creation of Common Infrastructural Facilities should not be allowed to suffer for procedural delays. Hence, the Department should take up the matter with the respective State Governments at the highest level without further loss of time for early issue of Utilisation Certificates from respective States. Though this project entail substantial investment initially, the benefits accruing out of it over a period of time would also be far greater. The Committee hope that the Department would take immediate steps in this direction and would be able to optimally utilize BE, 2023-24 of Rs.200.00 crore under the scheme.

<u>Scheme For Promotion of Bulk Drug Parks (MH 2852)</u>

15. Another sub-scheme under the umbrella scheme 'Development of Pharmaceuticals Industry' (MH-2852) is 'Promotion of Bulk Drug Parks' which aims at promoting 3 Bulk Drug Parks by providing Grants-in-Aid for creation of World class Common Infrastructure Facilities (CIF). A Financial assistance of Rs. 1000.00 crore per Park or 70% of the cost of the CIF, whichever is less, is provided and the assistance would be 90% for North East Region and Hill States. Total financial outlay for the Scheme is Rs.3000.00 crore and the duration of its implementation is

2020-21 to 2024-25. The Committee are, however, dismayed to note that the three beneficiary States have been selected under this scheme after a long period of 2 years and 9 months. The scheme was launched in February, 2020 and the States were selected in October/ November, 2022. Resultantly, during 2022-23, out of an allocation of Rs. 900 crore under the scheme, Rs.301.50 crore only could be utilized up to February, 2023. The Committee draw some satisfaction from the fact that the State Implementing agencies (SIA) have indicated completion of these projects within next 24-28 months which will be around the year 2024-2025 being the last year of the scheme period. It is pertinent to note that the country is in urgent need of meeting the requirement of bulk drugs indigenously rather than through imports. The Committee have been apprised that a High Level Committee has been constituted under the Hon'ble Union Minister to oversee the implementation of the scheme. Regular review meetings are being held at the level of Secretary. PMA is also pursuing with the States for implementation of the scheme as per the scheme guidelines. The Committee are appreciative of the measures taken by the Government for effective implementation of the 'Promotion of Bulk Drug Parks' scheme and hope that an amount of Rs.900.00 crore allocated under the scheme for FY 2023-24 would be fully utilized.

<u>Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) (MH 2852 and MH2552)</u>

16. A financial outlay of Rs. 490.00 crore has been approved by the Government for Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) for the period 2020-2021 to 2024-2025. The Committee are happy to note that the DoP has been able to optimally utilise the funds allocated for the PMBJP during the last three years. Besides, physical targets fixed during these years to open new aushadhi kendras and enhance the product basket of medicines & surgicals and establishing wares

have been largely achieved except in respect of warehouses where during 2020-21, 2021-22 and 2022-23 as against the target to open 04, 05 an 06 warehouses, 03, 04 & 05 warehouses(expected), respectively could be opened. The Department has, however, stated that it is targeted to establish 6 warehouses in the country by 2025 and accordingly, two more warehouses are planned to be opened in the country in couple of years, based on the requirement. The Committee appreciate the efforts of the Government in making quality generic medicines available to all at affordable prices. Further, a budget outlay of Rs. 115.00 crore has been made for FY 2023-24 for PMBJP, which is on a higher side as compared to BE, 2022-23 of Rs. 72.50 crore. Keeping in view the previous record in utilisation of funds, the Committee sincerely hope that the DoP would be able to optimally achieve the physical and financial targets kept for FY 2023-24.

<u>National Pharmaceutical Pricing Authority (NPPA) (Non Scheme-MH 2852)</u>

17. The NPPA is an autonomous body under the administrative control of the DoP and categorized under the non-scheme of the Department. This body administers fixation and revision of prices of scheduled formulations under the Drugs (Prices Control) Order (DPCO), monitoring and enforcement of prices and providing inputs to the Government on pharmaceutical policy & issues related to the affordability, availability and accessibility of medicines.The Committee find that since its establishment in 1997, NPPA has been able to regulate prices of only 20 percent drug formulations under scheduled drugs category whereas 80 percent of non-scheduled drugs are still under 10 percent annual ceiling price. NPPA has capped the trade margin of non-scheduled formulations of 42 select anti-cancer medicines under "Trade Margin Rationalization" approach as a successful pilot for proof of concept in February 2019 and later in June/July 2021 for Oxygen

Concentrators, Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer under the same approach during Covid.

The Committee desire that NPPA being the national drug price regulator should put in extra efforts for access by common man to affordable medicines and medical devices and therefore DoP/NPPA shall jointly resolve the challenges in the way of effective implementation of the provisions of Drugs Price Control Order 2013 to ensure that maximum formulations are covered under the scheduled drug price regulation in the minimum time possible. The Committee would like to be apprised of the progress in this regard from time to time.

The Committee would also desire to be apprised of the progress with regard to the proposal to regulate the prices of non-scheduled drugs which is under consideration of the DoP.

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New Delhi;	**DR. SHASHI THAROOR**
20 March, 2023	**Chairperson,**
29 Phalguna, 1944 (Saka)	**Standing Committee on**
	Chemicals & Fertilizers.

APPENDIX-I

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2022-23)

Minutes of the Eleventh Sitting of the Committee

The Committee sat on Wednesday, the 15th February, 2023 from 1100 hrs. to 12.30 hrs. in Committee Room 'D', Parliament House Annexe, New Delhi.

PRESENT
Dr. Shashi Tharoor – CHAIRPERSON
MEMBERS
LOK SABHA

2. Shri C.N. Annadurai
3. Shri Deepak Baij
4. Shri Kripanath Mallah
5. Shri Satyadev Pachauri
6. Shri Arun Kumar Sagar
7. Shri Pradeep Kumar Singh
8. Shri Uday Pratap Singh
9. Shri Parbhubhai Nagarbhai Vasava

RAJYA SABHA

10. Dr. Anil Jain

SECRETARIAT

1.	Shri N. K. Jha	-	Director
2.	Smt. Geeta Parmar	-	Additional Director
3.	Shri Kulvinder Singh	-	Deputy Secretary
4.	Shri Panna Lal	-	Under Secretary
5.	Ms. Sonia Sankhla	-	Committee Officer

LIST OF WITNESSES

I. MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

1.	Ms. S. Aparna	-	Secretary
2.	Shri Sanjay Rastogi	-	Additional Secretary &Financial Advisor
3.	Shri Awadhesh Kumar Choudhary	-	Senior Economic Advisor

4.	Shri Rajneesh Tingal	-	Joint Secretary
5.	Shri N. Yuvaraj	-	Joint Secretary

II. ***NATIONAL PHARMACEUTICALS PRICING AUTHORITY (NPPA)/ PHARMACEUTICALS AND MEDICAL DEVICE BUREAU OF INDIA (PMBI)***

6.	Shri Kamlesh Kumar Pant	-	Chairman, NPPA
7.	Shri Ravi Dadhich	-	CEO, PMBI

III ***REPRESENTATIVES OF NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION AND RESEARCH (NIPERs)***

8.	Dr. Shashi Bala Singh	-	Director (NIPER- Hyderabad)
9.	Shri V. Ravichandran	-	Director (NIPER- Kolkata)

IV. REPRESENTATIVES OF PSUs

10.	Ms. Nirja Saraf	-	Managing Director, Hindustan Antibiotics Limited (HAL) & Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Bengal Chemicals & Pharmaceuticals Limited (BCPL) (Add Charge)

2. At the outset, the Chairperson welcomed the representatives of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers to the sitting of the Committee convened to take oral evidence of the Department on 'Demands for Grants 2023-24'. Drawing the attention of the witnesses to Direction 58 of the 'Directions by the Speaker' regarding confidentiality of the proceedings, the Chairperson asked the Secretary, Department of Pharmaceuticals to apprise the Committee of the broad parameters on the basis of which budgetary provisions for the year 2023-24 have been made under different heads and plan of action to execute their various schemes/programmes with optimum utilization of the earmarked funds during the year and also give an overview of the actual expenditure made during the current year 2022-23.

3. The Secretary, Department of Pharmaceuticals then briefed the Committee on the Demands for Grants for the year 2023-24, achievements in financial year 2022-23, plans for financial year 2023-24; status of Indian pharmaceuticals and medical devices industry, mandate and strategies of the Department on Central Sector Schemes; National Pharmaceuticals Pricing Authority (NPPA) and monitoring of prices of Drugs

and Medical Devices; implementation of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) by Pharmaceuticals and Medical Devices Bureau of India (PMBI); status of construction of campus in six NIPERs except NIPER Mohali and promotion of research in all seven NIPERs; introduction and promotion of education courses and R & D in medical device field by setting up National Institute of Medical Device Education and Research (NIMERs); and status of five Public Sector Undertakings viz. closure of Indian Drugs & Pharmaceuticals Limited (IDPL), processing of transfer of shares of Rajasthan Drugs & Pharmaceuticals Limited (RDPL) to Rajasthan Government; strategic disinvestment of Hindustan Antibiotic Limited (HAL), Bengal Chemicals & Pharmaceuticals Limited (BCPL) and Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), etc.

4. Thereafter, the Members raised several queries related to the subject such as under-utilization of budget allocations in flagship schemes of the Department *viz.* the Production Linked Incentives (PLI) scheme for promotion of domestic manufacturing of bulk drugs, medical devices and pharmaceuticals, scheme for promotion of bulk drug parks and medical devices parks, scheme for strengthening of pharmaceutical industry during the year 2022-23; reducing dependence on imported Active Pharmaceutical Ingredients (APIs); setting up new NIPERs in other states; status of Jan Aushadhi Kendras and setting up of more central warehouses in the country for smooth supply of drugs and medical devices to kendra owners, etc.

5. The Chairperson thanked the witnesses for appearing before the Committee as well as for furnishing valuable information and asked them to furnish the replies to the points raised by the Members during the sitting which remained unanswered.

6. A copy of the verbatim record of the proceedings of the sitting has been kept.

(The witness then withdrew).

The Committee then adjourned.

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2022-23)
Minutes of the Twelfth Sitting of the Committee

The Committee sat on Monday, the 20th March, 2023 from 1600 hrs. to 1630 hrs. in Committee Room No. 3, Block 'A', Parliament House Annexe Extension Building, New Delhi.

PRESENT

DR. SHASHI THAROOR- Chairperson

MEMBERS

LOK SABHA

2 Shri C.N. Annadurai
3 Shri Deepak Baij
4 Shri Prataprao Patil Chikhalikar
5 Shri Rajeshbhai Naranbhai Chudasama
6 Dr. Sanjay Jaiswal
7 Shri Ramesh Chandappa Jigajinagi
8 Shri Satyadev Pachauri
9 Smt. Aparupa Poddar
10 Shri Uday Pratap Singh
11 Shri Parbhubhai Nagarbhai Vasava

RAJYA SABHA

12 Dr. Anil Jain
13 Shri Ram Nath Thakur
14 Shri Vijay Pal Singh Tomar

SECRETARIAT

1. Shri Vinay Kumar Mohan - Joint Secretary
2. Shri Nabin Kumar Jha - Director
3. Smt. Geeta Parmar - Additional Director
4. Shri Kulvinder Singh - Deputy Secretary
5. Shri Panna Lal - Under Secretary

2. The Chairperson took up for consideration the following Draft Reports and adopted the same without any modification:

(i) XXX XXX XXX XXX
(iii) XXX XXX XXX XXX
(iii) Demands for Grants 2023-24 of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

3. The Committee then authorized the Chairperson to finalize the Reports and present/lay the Reports in both the Houses of Parliament in light of factual verifications received from the concerned Ministry/Departments.

The Committee then adjourned.