GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO.1061
TO BE ANSWERED ON THE 5TH DECEMBER, 2025

Proposals for Implementation SPI Scheme

1061. Shri Tangella Uday Srinivas:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the number of project proposals received, approved, and rejected under each component of the Strengthening of Pharmaceuticals Industry (SPI) Scheme during the last four financial years, State-wise and district/cluster-wise in the country, including Andhra Pradesh;
(b) the reasons for rejection of proposals;
(c) the funds allocated and disbursed for approved projects during the same period, Statewise and cluster-wise, especially for Andhra Pradesh;
(d) the total volume and value of domestically manufactured pharmaceuticals exported during the last four years, year-wise;
(e) whether the Government is aware of the fact that pharmaceutical consignments from the country failed quality tests in foreign markets and if so, the details of such cases; and
(f) the corrective actions taken/proposed to strengthen quality control and regulatory compliance?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) to (c): Project proposals are received and considered for approval and rejection under two sub-schemes of SPI scheme, namely, Assistance to Pharmaceutical Industry for Common Facilities and the Revamped Pharmaceuticals Technology Upgradation Scheme. Details of project proposals received, approved and rejected under each of these sub-schemes during the last four financial years, State- and district-wise in the country, including in the State of Andhra Pradesh, along with the reasons for rejection and the funds allocated and disbursed for approved projects during the said period, State- and district-wise, including in the State of Andhra Pradesh, are at Annex.

(d): The volume and value of domestically manufactured pharmaceuticals (bulk drugs, drug intermediates, drug formulations, biologicals) exported during the last four years, year-wise are as under:

Financial year	Export volume (metric tonnes)	Export value (crore ₹)
2020-21	6,42,718	1,74,064
2021-22	10,72,475	1,74,955
2022-23	10,55,352	1,94,254
2023-24	12,24,616	2,19,441
2024-25	12,40,537	2,45,966

Source: Directorate General of Commercial Intelligence and Statistics

(e) and (f): The Ministry of Health and Family Welfare has informed that manufacturers are required to obtain license for manufacturing of drugs for export as per the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder, as well as to comply with the requirements of the importing country.

As and when inputs are received regarding cases involving issues related to quality, the same are investigated by the licensing authorities concerned for taking action under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs Rules, 1945, as the licensing authorities are empowered to take action in case of any violation to the provisions of the said Act and rules.

The Central Drugs Standard Control Organisation (CDSCO) and the Ministry of Health and Family Welfare have taken several measures to ensure quality, safety and efficacy of medicines throughout the country, as stated below:

(i) To assess regulatory compliance of drug manufacturing premises in the country, CDSCO, in collaboration with State regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. This initiative has provided valuable insights into the ground reality of manufacturing practices and has led to relevant corrective actions, resulting in noticeable improvements in the regulatory framework.

(ii) Schedule M to the Drugs Rules, 1945 has been revised *vide* Ministry of Health and Family Welfare's notification dated 28.12.2023, in line with international standards {of the World Health Organization (WHO)}, and the same has come into effect for drug manufacturers with turnover more than ₹250 crore from 29.6.2024. However, for manufacturers having turnover of up to ₹250 crore, the timeline for implementation has been extended till 31.12.2025, *vide* notification dated 11.2.2025.

(iii) To require manufacturers to print or affix on packaging labels of top 300 brands of drug formulation products bar code or Quick Response (QR) code that stores data or information legible with software application to facilitate authentication, the Drugs Rules, 1945 were amended through notification dated 17.11.2022, which came into force from 1.8.2023, to provide for such printing or affixation in respect of the drug formulation products specified in Schedule H2 to the said rules.

(iv) On 18.1.2022, the Drugs Rules, 1945 were amended to provide that every active pharmaceutical ingredient (bulk drug) manufactured or imported in India shall bear QR code on its label at each level of packaging, that stores data or information readable with software application to facilitate tracking and tracing. Such stored data

or information shall include the minimum particulars, including unique product identification code, batch number, manufacturing date, expiry date, etc.

(v) On 11.2.2020, the Drugs Rules, 1945 were amended to provide with effect from 1.3.2021 that, along with the manufacturer, any marketer who sells or distributes any drug shall be responsible for the quality of that drug as well as other regulatory compliances under these rules.

(vi) The Drugs and Cosmetics Act, 1940 was amended through an amending Act of 2008 to provide for stringent penalties for manufacture of spurious and adulterated drugs. Certain offences were also made cognizable and non-bailable.

(vii) For speedy disposal of cases relating to offences under the Drugs and Cosmetics Act, 1940, State and Union Territory Governments have set up special courts.

(viii) To ensure efficacy of drugs, the Drugs Rules, 1945 have been amended to provide that applicants for grant of manufacturing license shall submit along with their application the result of bioequivalence study of oral dosage form of some drugs.

(ix) The Drugs Rules, 1945 have been amended to make it mandatory that applicants submit to the State Licensing Authority evidence of stability, safety of excipients, etc. before manufacturing license is granted by such authority.

(x) The number of sanctioned posts in CDSCO has been increased significantly over the last 10 years.

(xi) For uniformity in the administration of the Drugs and Cosmetics Act, 1940, the Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee meetings held with the State Drugs Controllers.

Annexure

Annexure referred to in the reply to parts (a) to (c) of the LOK SABHA UNSTARRED Q. NO. 1061 for answer on 5.12.2025, raised by Shri Tangella Uday Srinivas, regarding Proposals for Implementation SPI Scheme

Details of project proposals received, approved and rejected under each sub-scheme of the Strengthening of Pharmaceuticals Industry (SPI) scheme during the last four financial years, along with the reasons for rejection and the funds allocated and disbursed for approved projects

I. *Assistance to Pharmaceutical Industry for Common Facilities sub-scheme*

S. no.	Name of applicant	State / Union territory	District	Amount sanctioned (crore ₹)	Amount disbursed (crore ₹)	Status
1.	Tirupati Research & Development Pvt. Ltd.	Andhra Pradesh	Chittoor	20.00	10.00	Approved
2.	Welzo Research & Development Pvt. Ltd.	Himachal Pradesh	Solan	19.53	17.58	Approved
3.	Himachal Pharma Testing Lab Ltd.		Solan	17.87	0.00	Approved
4.	Inducare Pharmaceuticals & Research Foundation	Maharashtra	Pune	7.18	6.46	Approved
5.	Tindivanam Pharma Park Association	Tamil Nadu	Tindivanam	15.88	6.00	Approved
6.	Jeedimetla Effluent Treatment Ltd.	Telangana	Medchal Malkajgiri	20.00	18.00	Approved
7.	Telangana Lifesciences Foundation (earlier Hyderabad Pharma city Limited)		Hyderabad	18.87	4.72	Approved
8.	Devbhumi Pharmaceutical Analytical Testing and Training Foundation	Uttarakhand	Haridwar	20.00	18.00	Approved
9.	Pundrug	Punjab	Mohali	—	—	Rejected as the

10.	Brahma Kamal Biomed Foundation and Research Institute	Uttarakhand	Udham Singh Nagar	—	—	applicant did not meet the eligibility criteria as per scheme guidelines

II. *Revamped Pharmaceuticals Technology Upgradation Scheme*

S. No.	State / Union territory	District	Number of applicant approved/rejected	Approved grant-in-aid (in lakh ₹)	Status
1	Andhra Pradesh	Anakapalli	2	283.17	Approved
		Jaggayyapeta	1	200.00	Approved
		NTR	1	33.24	Approved
		Prakasam	1	50.27	Approved
		Srikakulam	1	200.00	Approved
		Krishna	2	—	Rejected as the applicant did not meet the eligibility criteria as per scheme guidelines
2	Assam	Kamrup	1	46.87	Approved
3	Bihar	Muzaffarpur	1	3.94	Approved
4	Dadra and Nagar Haveli and Daman and Diu	Daman	1	120.94	Approved
5	Gujarat	Ahmedabad	14	1,024.66	Approved
		Vadodara	5	758.98	Approved
		Banaskantha	1	45.04	Approved
		Bharuch	4	244.64	Approved
			1	—	Rejected as the applicant did not meet the eligibility criteria as per scheme guidelines
		Gandhinagar	4	390.32	Approved
		Sabarkantha	6	377.39	Approved

		Kutch	1	200.00	Approved
		Mehsana	9	739.24	Approved
		Panchmahal	1	58.27	Approved
		Rajkot	3	251.24	Approved
		Surat	3	216.18	Approved
			1	—	Rejected as the applicant did not meet the eligibility criteria as per scheme guidelines
		Surendranagar	2	26.72	Approved
		Valsad	2	137.12	Approved
6	Haryana	Ambala	1	128.09	Approved
		Faridabad	1	200.00	Approved
		Faridabad	1	—	Rejected as the applicant did not have drug license
		Gurugram	1	85.97	Approved
7	Himachal Pradesh	Solan	27	2,772.14	Approved
		Sirmaur	15	1,598.54	14 approved; one rejected as it was a duplicate application
8	Jammu and Kashmir	Pulwama	2	100.53	Approved
9	Karnataka	Bengaluru	4	538.93	Approved
		Dharwad	2	194.28	Approved
		Uttara Kannada	1	79.97	Approved
10	Kerala	Malappuram	1	157.67	Approved
		Palakkad	1	49.47	Approved
		Thrissur	1	70.40	Approved
11	Madhya Pradesh	Bhopal	1	103.36	Approved
		Dhar	1	67.95	Approved
		Indore	4	610.90	Approved
12	Maharashtra	Akola	1	200.00	Approved
		Nagpur	2	206.31	Approved
		Nasik	1	39.33	Approved
		Palghar	6	937.24	Approved
			1	—	Rejected as the applicant did not meet the eligibility

					criteria as per scheme guidelines
		Pune	5	420.58	Approved
		Raigad	5	571.52	Approved
		Ratnagiri	1	13.18	Approved
		Thane	7	517.67	Approved
13	Odisha	Cuttack	1	66.34	Approved
14	Puducherry	Puducherry	2	69.18	Approved
15	Punjab	Amritsar	1	11.07	Approved
		Ludhiana	1	35.56	Approved
		Sahibzada Ajit Singh Nagar	3	332.86	Approved
		Sahibzada Ajit Singh Nagar	1	—	Rejected as it was a duplicate application
16	Rajasthan	Alwar	1	63.83	Approved
		Jaipur	1	—	Rejected as the applicant did not meet the eligibility criteria as per scheme guidelines
17	Tamil Nadu	Chennai	1	115.88	Approved
		Kancheepuram	1	73.89	Approved
		Krishnagiri	1	200.00	Approved
		Thanjavur	1	10.96	Approved
18	Telangana	Hyderabad	1	105.84	Approved
		Medchal-Malkajgiri	3	325.73	Approved
		Sangareddy	1	—	Rejected as the applicant did not meet the eligibility criteria as per the scheme guidelines
19	Uttar Pradesh	Meerut	1	29.90	Approved
		Gautam Buddha Nagar	1	35.70	Approved
20	Uttarakhand	Dehradun	2	160.40	Approved
		Haridwar	8	741.61	Approved

		Udham Singh Nagar	2	138.92	Approved
21	West Bengal	Howrah	1	27.32	Approved
		Kolkata	3	247.72	Approved
		South 24 Parganas	2	223.52	Approved
		Purba Bardhaman	1	70.40	Approved

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