NEWSLETTER
JUNE-JULY 2024

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BULK DRUG MANUFACTURERS ASSOCIATION (INDIA)
C-25,INDUSTRIAL ESTATE,SANATHNAGAR,HYDERABAD-500018,
WEBSITE:WWW.BDMAI.ORG,EMAIL:INFO@BDMAI.ORG,PH:04023706718/3910

BULK DRUG MANUFACTURERS ASSOCIATION (INDIA) HAD AN MoU WITH THE PHARMA PATASHALA AS ITS PROJECT IMPLEMENTAITON PARTNER

Bulk Drug Manufacturers Association of India entered into an MoU with The Pharma Patashala as its Project Implementation Partner for the BDMA Technology and Training Centre situated at Dhullapalli Road, DP Colony, Jeedimetla Phase-III, Hyderabad, Telangana.

We are pleased to inform you that BDMA Technology and Training Centre located at Jeedimetla, Hyderabad is now fully functional with two batches with each 30 students running from morning to evening for QC Job roles. The next batches of the training will be for Production and manufacturing job roles. .

BDMA training facility is aimed at providing specific training to fresh graduates making them suitable for the bulk drug industry whereby the need for individual units to train their new recruits is met. Specialized training will be given to existing staff to upgrade their skills and also expose them to the new developments and regulations in the pharma sector.

This is first of its kind in the country where an association is coming forward to have a skill upgradation Centre to the employees of their members.

Key Beneficiaries

The key beneficiaries of the project will be the Pharma units and specifically units located in and around Hyderabad. This centre would render holistic support to the students through fresh skilling to the B.Sc, B-Pharma, B-Tech Chemical, Inter, Diploma in Pharmacy, B.Tech Chemical, 10th, Intermediate and Any Degree or Any Master's Degree. The facility is envisaged as a common user facility. Training center will be a state of the art facility for training on subjects relevant to industry. The courses will cover Quality management & improvement, Virtual Simulation, Machine Operator, Manufacturing Assistant, Quality Analysis, Production Chemist, R&D, Supply Chain Management, sales & Marketing, Safety Health & Environment and on government regulations. It is contemplated to provide training under the different schemes of the Government also.

Our Faculty:

Faculty is an asset for any Training Institution. BDMAI and our associate The Pharma Patashala have an excellent team of experienced faculty with credentials and high proficiency in teaching experience in the requisite subjects to impart much needed training to the students. The faculty brings their Extensive knowledge, Professional, Research, Industrial Experience and Advanced education to their task at BDMAI. The faculty members have outstanding academic backgrounds and sound conceptual knowledge who are drawn from Industries, Universities etc,. The commitment to teaching shapes their involvement with the students. Faculty members emphasize both theory and practical's in the classrooms and labs.

Project Components

Training Centre: Phase I

- Class rooms , Staff rooms, Office, Director cabin, Meeting /Conference / Visitors rooms, Computer center , Virtual reality simulation Centre, Library
- Chemistry and Physics laboratories, Unit operations lab, Workshop, Stores

Technology Centre: Phase II

- Development Laboratory,
- Wet chemistry / analysis Lab, Instrumentation Lab

Other support facilities

Canteen, Parking and Internal roads, Landscaping, Security room, Auditorium with projection (to be setting up) and sound system, RO plant for drinking water etc.

In this background, we hereby request you to avail the opportunity by utilizing the training centre by sending your newly recruited staff to get trained for Industrial training purpose and give an opportunity for the fresh trainees to be observed in your organization. We request for your cooperation.

We enclose herewith a detailed brochure for your ready reference.

सं. / No. 50014/03/2020-CDN
भारत सरकार / Government of India
रसायन एवं उर्वरक मंत्रालय / Ministry of Chemicals and Fertilizers
औषध विभाग / Department of Pharmaceuticals
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जी-25, शास्त्री भवन, नई दिल्ली
G-25, Shastri Bhawan, New Delhi
Dated: 18th July, 2024

OFFICE MEMORANDUM

Subject: Monthly Summary Report in respect of Department of Pharmaceuticals for the month of June, 2024-reg.

The undersigned is directed to circulate herewith a copy of the Monthly Summary pertaining to the Department of Pharmaceuticals for the month of June, 2024 for information.

(Sanjay Meena)
Under Secretary to the Govt. of India
Tel. 011-23385473

To,

1. All members of Council of Ministers.
2. Vice Chairman, NITI Aayog, Yojana Bhawan, New Delhi.
3. The Principal Information Officer, M/o Information and Broadcasting, Shastri Bhawan, New Delhi.

Copy to:

1. Secretaries to the Govt. of India, All Ministries/Department.
2. The Chairman, UPSC, Shahajahan Road, New Delhi-110069.
3. Secretary to President of India (Rashtrapati Ke Sachiv), Rashtrapati Bhawan, New Delhi-110004.
4. Secretary to Vice- President of India (Uprashtrapati Ke Sachiv), New Delhi-110004.
5. PS to Prime Minister of India, South Block, New Delhi-110004.
6. Director, Cabinet Secretariat, Rashtrapati Bhawan, New Delhi-110004.
7. PS to Secretary (Pharma).
8. Director (NIC), Department of Pharmaceuticals, Shastri Bhawan, New Delhi.

Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals

1. Important policy decisions taken and major achievements during the month of June 2024:

A. National Institutes of Pharmaceutical Education & Research (NIPERs):

Research Papers, Patents and MoUs:

- Out of 156 research papers published during the current financial year, 48 were published in the month of June 2024.
- Out of 5 Patents filed during the current financial year, 4 were filed in the month of June 2024.
- Out of the 6 MoUs signed during the current financial year, 1 MoU was signed in the month of June 2024.

Workshops/Seminars/Training and other events:

- All NIPERs celebrated 10th International Yoga Day on June 21, 2024.
- NIPER Ahmedabad and NIPER Guwahati celebrated World Environment Day on June 5, 2024.
- NIPER Guwahati conducted a webinar on World Environment Day titled "The Legal and Regulatory Framework for Environment Protection in India" on June 5, 2024.
- NIPER Guwahati conducted an online awareness session on Lab-To-Market Program on June 10, 2024.
- NIPER Kolkata organised a two days Hands-on-training in Basic Techniques in Solid Phase Peptide Synthesis and HPLC Analysis from June 6, 2024 to June 7, 2024.
- NIPER Kolkata conducted a seminar cum workshop on "Recent advances in gene editing and next-generation sequencing technologies" from June 6, 2024 to June 8, 2024.
- NIPER Mohali organised a one week hands on training on HPLC from June 3, 2024 to June 7,2024.
- NIPER Mohali conducted a three-week training on Pharmaceutical Industrial Training at TDC Pilot Plant - API from June 4, 2024 to June 21, 2024.
- NIPER Mohali organised an orientation session on "Introducing Free, 24x7 Online & Counselling Platform for NIPER Mohali" on June 5, 2024.
- NIPER-Raebareli in collaboration with IIT Lucknow conducted a Short Term Computational Training from June 5, 2024 to July 2, 2024.

B. National Pharmaceutical Pricing authority (NPPA):

(i) During the 124th Authority meeting held on 7th June, 2024, fifty-four (54) retail prices for new drugs and ceiling prices of three (3) drugs with special features were fixed under NLEM 2022. These prices were notified vide S.O No. 2284(E) & 2285(E) and 2286(E), 2289(E) and 2290(E) respectively.

S. No.	Prices fixed/ Notified under Revised Schedule I (NLEM 2022)	During the month of 1st June 2024 to 30th June 24	Cumulative from 1st April, 2024 to 30th June 2024

1.	Retail Price of 'New Drug'	54	95
2.	i. Fixation of ceiling Price under revised scheduled-I (NLEM 2022) of DPCO, 2013 ii. Fixation of ceiling price with special features under scheduled - I (NLEM 2022) of DPCO, 2013	0 3	06* 3
3.	iii. Exemption under para 32 of DPCO, 2013 (NLEM 2022)	0	0

*Ceiling Prices of 742 formulations are fixed/refixed under NLEM 2022

ii. As part of enforcement activities, NPPA has received an amount of Rs 72,73,183/- (Rs Seventy-Two Lakh Seventy-Three Thousand One Hundred and Eighty-Three only) towards overcharging amount.
iii. On the basis of Monitoring and Enforcement activities, Enforcement Division of NPPA has issued Thirty-Nine (39) Preliminary Notices (PN) for drug price violations.
iv. NPPA through Price Monitoring and Resource Units (PMRUs) in the States/ UTs has conducted four (4) market availability surveys during June, 2024 for selected drugs and six medical devices.
v. NPPA is encouraging use of e-office to reduce the use of paper and in line with this effort, 424 new e-files were opened during the month.

C. Schemes:

(i) Status of Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP):

Number of PMBJP Kendras functional		Sales under PMBJP at MRP Value in Rs. Crore and saving to common man during the month of June, 2024		Product basket (As on 30.06.2024)		Sale of Suvidha Sanitary Napkins @ Rs. 1/- per pad during the month June, 2024	Incentive provided in the month of June, 2024
June 2024	Cumulative	Sale	Saving	Medicines	Surgical		
	(As on 30.06.2024)	In Rs. (crore)	In Rs. (crore) (Approx.)				
502	12616	137.56	687.60	2047	300	2.08 crore	0.72 crore

(ii) Status of PLI Schemes

S. No.	Name of Scheme		Total No. of Applications Received	Total no. of applications approved as on date
1.	Production Linked Incentive Scheme for Bulk Drug	Round 1	215	38
		Round 2	24	07
		Round 3	09	02

	(Last EC Meeting held on 26.03.2024 on PLI Bulk Drugs)	Round 4	01	01
		Total	**249**	**48**
2.	Production Linked Incentive Scheme for Medical Device (Last EC Meeting held on 26.03.2024 on Medical Devices)	Round 1	28	11
		Round 2	14	08
		Round 3	18	05
		Round 4	04	02
		Total	**64**	**26**
3	Production Linked Incentive scheme for Pharmaceuticals		**278**	**55**

(iii) Actual progress made as on date under the PLI Schemes:

Details	PLI for Bulk Drugs	PLI for Medical Devices	PLI for Pharmaceuticals
Actual Investment (Rs. in crore)	3,737.33	958.72	29,268
Actual Production (Rs. in crore)	1,067.45	5,986.56	1,61,209
Actual Employment (No. of persons)	3,565	5,396	71,763
Project Commissioned	31	19	261 manufacturing locations

D. International Cooperation:

(i) DoP participated in the 1st JWG meeting on cooperation in the field of health and medicine with Eswatini on June 13th, 2024.

(ii) DoP participated in the iCET Annual Review Meeting at the level of National Security Advisers on 17th June, 2024 wherein matters related to biotechnology and biopharmaceuticals supply chains were discussed.

(iii) DoP participated in the 2nd India-Cambodia Joint Working Group on Trade and Investment (JWGTI) on 19th June 2024 under the chairmanship of Joint Secretary, DoC in New Delhi wherein collaboration in research with NIPERs and CSIR were discussed.

(iv) A meeting was chaired by Secretary, Pharmaceuticals with Mr. Abdulla Azizov, Director of Pharmaceutical Industry Development Agency of Uzbekistan and H.E. Mr. Sardor Rustambaev, Ambassador of the Republic of Uzbekistan on 24th June 2024 wherein investment opportunities in Uzbekistan pharmaceutical market, benefits of Pharmaceuticals Free Economic Zones (FEZ) in Uzbekistan, overview of the Pharmaceutical Industry Development Agency of Uzbekistan and activation of Joint Working Group was discussed.

2. Important policy matters held up on account of prolonged inter-ministerial consultations:

NIL

3. No. of cases of 'sanction for prosecution' pending for more than three months:

NIL

4. Particulars of cases in which there has been a departure from the Transaction of Business Rules or established policy of the Government:

NIL

5. Status of ongoing Swachhata Abhiyan (progress under Special Campaign):

Department is updating data relating to Secretariat Reforms and Swachhata Campaign in the SCDPM Portal of DARPG on monthly basis.

6. Status of Rationalization of Autonomous Bodies:

Completed

7. Information on the specific steps taken by the Ministry/Department for utilization of the Space Technology based tools and applications in Governance and Development:

NIL

8. Vacancy position of senior level appointments in the Ministry/Department, including Autonomous Bodies/PSUs:

(i) Department of Pharmaceuticals:

S. No.	Name of the posts	Sanctioned Strength	In-position	Vacancy	Group
1	Principal Private Secretary	02	00	02	A
2	Section Officer	16	14	02	B
	Total	**18**	**14**	**4**	

(ii) Public Sector Undertakings:

(a) Karnataka Antibiotics & Pharmaceuticals Limited (KAPL):

S. No.	Designation	Vacant Positions
1	Senior Manager	06
2	General Manager	07
	Total	**13**

(b) Hindustan Antibiotics Limited (HAL) (under strategic sale):

S.No.	Designation	Vacant Positions
1	CGM	03
2	GM	03
3	DGM	12
4	Manager	20
	Total	**38**

(c) Bengal Chemicals & Pharmaceuticals Limited (BCPL) (under strategic sale):

S.No.	Designation	Vacant Positions
1	Manager (Legal)	01
2	Sr. Manager (Purchase)	01
3	DGM (Finance)	01
4	Factory Head (DGM/AGM)	02
5	AGM (QA/QC)	01
	Total	**06**

(d) Indian Drugs & Pharmaceuticals Limited (IDPL) : NIL

(e) Rajasthan Drugs & Pharmaceuticals Limited (RDPL) : NIL

(iii) National Institute of Pharmaceutical Education and Research (NIPER): The application for filling the vacant posts of Directors at NIPER Hyderabad and Hajipur was invited. After a thorough evaluation by the Search and Selection Committee, the applicants were shortlisted. Interview for the shortlisted candidates have been conducted on 9th April 2024.

9. List of cases in which ACC directions have not been complied with:

NIL

10. Details of FDI proposals cleared during the month and status of FDI proposals awaiting approval in the Ministry/Department:

(i)	Pending at beginning of the month	5
(ii)	Received during the month	0
(iii)	Disposed of during the month	0
(iv)	Pending at end of the month	5
(v)	FDI inflow approved during this month	NIL

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SRADHANJALI

(1949-2024)

We regret to inform you the sad demise of Sri B Sarat Gopal on 19th of July 2024. He was our Senior Member and also served as General Secretary of BDMA in the past.

He is an industrialist and also a philanthropist.

We pray for his soul to rest in peace.

Aum Shanti

PHARMA EXPORT REPORTS 9.7% GROWTH IN FINANCIAL YEAR 2023-24

Gireesh Babu, New Delhi

Exports of drugs and pharmaceuticals from the country has registered a 9.67 per cent growth during the financial year 2023-24, as compared to a meagre 3.25 per cent growth reported during the fiscal year 2022-23. The month of March, 2024 saw the exports growing 12.73 percent as compared to the same month of previous fiscal year. .

The exports of pharmaceuticals for FY 24 stood at $27.85 billion as compared to $25.39 billion registered for the corresponding 12 months of financial year 2022-23, according to provisional official data. The growth is significant, compared to the 3.25 per cent growth in exports reported in 2022-23, as compared to $24.59 billion in the fiscal year 2021-22.

For the month of March, the Indian pharma firms registered exports of $2.80 billion as compared to $2.49 billion reported in the same month of last year, registering a growth of 12.73 per cent. .

In Rupee terms, the pharma exports during the fiscal 2023-24 stood at Rs. 2.30 lakh crore, which is 13 per cent growth compared to Rs. 2.04 lakh crore of exports reported in the previous fiscal year. The exports in March stood at Rs. 23,262.4 crore, as compared to Rs. 20,458.97 crore, with a 13.7 percent growth. .

The imports of medicinal and pharmaceutical products, during the fiscal 2023-24 grew 2.02 per cent to $8.27 billion as compared to $8.10 billion in the previous fiscal year. The month of March, 2024 witnessed a decline of 2.85 per cent in imports, to $681.18 million as compared to $701.19 million in the same month of previous fiscal year. .

As reported earlier, the exports of drugs and pharmaceuticals during the month of February, 2024 posted a significant growth of 22.24 per cent to $2.51 billion as compared to $2.05 billion in the same month of previous fiscal year. .

It may be noted that the imports during the fiscal year of 2022-23 reported a decline of over 10 per cent, as compared to $9.07 billion reported during fiscal year 2021-22. .

In Rupee terms, the fiscal year saw imports growing at 5.16 per cent to Rs. 68,461.83 crore, as compared to Rs. 65,104.23 crore during the same period of previous fiscal year. The month of March, 2024 saw imports declining 2.02 per cent to Rs. 5,653.63 crore as compared to Rs. 5,769.97 crore in the same month of last fiscal year. .

The ministry of health and family welfare in June, last year, said that India's drug and pharmaceutical products exports grew by 125 per cent from Rs. 90,415 crore in 2013-14 to Rs. 2,04,110 crore in 2022-23. .

India's pharma exports contributed 5.6% of merchandise exports during 2022-23. Drug formulations & biologicals is the third largest principal commodity being exported by India, according to Pharmexcil. . .

The Council, in its Hand Book 2023, said that during FY-23 India has exported to over 210 destinations across the world and around 60% of exports are to highly regulated markets like North America and Europe. .

India has the maximum number of US FDA-approved manufacturing sites outside the USA. USA is the largest exporting partner of India by country and nine Indian companies featured among the top 25 global generic companies. Indian companies have bagged 41.74% of market authorizations granted by US FDA in the calendar year 2022. India shares 38.25% of Africa's generic market value of $ 8.5 billion. Almost 65-70% of WHO's vaccines (essential immunization schedule) requirements are sourced from India, it added.

Indian domestic formulations to cross Rs 5.5 lakh Cr by 2034: Avendus Capital report Investment bank Avendus Capital noted that India's pharmaceutical sector will receive a boost from fundamental shifts in the existing prescription model. .

ndia's domestic formulations (DomForm) market, including branded generic medicines, is expected to cross Rs 5.5 lakh crore in value by 2034, according to a report published by investment banking firm Avendus Capital. The country, which is home to 25% of the US Food and Drug Administration approved plants outside of the United States, consumes nearly half of the domestically produced drugs. Being among the lowest-priced markets has worked in favour of Indian pharmaceuticals, boosting the DomForm market currently valued at almost Rs 2 lakh crore, according to the report. Going forward, there may be a fundamental shift in the DomForm market such as a gradual transition from a primarily doctor-branded prescription model to an alternative marketing and channel mix, guided through government policies and regulatory measures with underlying business and economic factors also playing a part, the report noted.

"We are also encouraged by the Government of India's Pharma Vision 2047, which is aimed at making medicines more equitable, accessible and affordable while ensuring high quality and more sustainable manufacturing practices," said Anshul Gupta, Managing Director and Head, Healthcare Investment Banking at Avendus Capital, in a statement. However, India's position in the pharmaceuticals market is not without challenges, with "significant under penetration in the domestic market, especially in Tier II/III+ towns and rural areas", he added. The report cited lower doctor density in markets beyond metros and Tier I cities, resulting in lower productivity as a leading cause for the disproportionate focus on urban centres and big cities. To combat these challenges, some pharma companies are leveraging the Trade Generics (TGx) channels which rely on retailer or distributor "push" instead of the doctor "pull", incentivised by channel margins.

New companies that focus largely on TGx have grown faster than the overall market in the last five years, accounting for about 10% of the market, it added. Additionally, the DomForm market has attracted large strategic and private equity investments in deals worth over $14 billion over the last six years. “Pharma players are likely to expand their portfolios by either shifting focus to new chronic/lifestyle therapies or expanding into adjacencies like over-the-counter, point-of-care diagnostics, medtech, and nutraceuticals”, Gupta noted. With stabilisation of the US healthcare macro and the upcoming patent cliff, referring to a period where a large number of patents are set to expire, Indian pharma companies are presented with an opportunity to expand and rebalance the existing US vs India focus, turning to emerging markets like Latin America, Africa, Russia CIS, and South East Asia, which are growing at a faster pace.

Small Molecule API Market Trends

A Q&A with Sterling Pharma Solutions’ chief commercial officer about the current state of the small molecule market.

Tim Wright, Editor, Contract Pharma02.01.24

Sterling Pharma Solutions provides pharmaceutical manufacturing of small molecule active pharmaceutical ingredients (APIs), developing drug substances that go into therapeutics across the world. It currently employs over 1,350 people at its sites across North America and Europe.

The company has a strong heritage of more than 50 years in developing and manufacturing small molecule APIs from its headquarters in Cramlington, UK, and in recent years has undertaken a strategic growth program, adding two sites in the U.S. to its global network, and a further, dedicated facility for antibody-drug conjugate (ADC) development, in the UK. In 2023, Sterling also acquired a site from Novartis, in Ringaskiddy, Ireland, in addition to NewChem Technologies in the UK, bolstering its global capabilities and capacity for early-phase API development.

Its team of experts now offers a wide range of API synthesis and development services, which includes enzymatic biotransformations, high potency API handling and manufacturing, continuous flow technologies, and ADC conjugation, as well as solid state science and material characterization.

Contract Pharma had the chance to talk with Sterling’s chief commercial officer, Chad Telgenhof, about the company’s growth, the current state of the small molecule market, and how Sterling has adapted to meet the evolving needs of its customers.

Contract Pharma: Why were your most recent acquisitions important for the business and its customers?

Chad Telgenhof: The Ringaskiddy site was previously a dedicated manufacturing site for Novartis, and with the acquisition came a long-term agreement to continue to supply these products, but we also can utilize the site as a flexible manufacturing facility, providing additional capacity for contract development and manufacturing organization (CDMO) services. Being located within the European Union (EU), the site’s location also has several advantages in terms of supply chain, recruitment and exporting to customers.

The acquisition of NewChem Technologies provided us with a new facility in the UK in which to expand our capabilities for very early-stage, non-GMP projects. The site will operate in tandem with the plant in Cary, NC, which carries out similar projects, and allows us to access customers' early-stage programs that we will look to develop and grow across our global network, along the drug development program.

Our philosophy is very much to work with clients for as long as possible throughout development, following the molecule as it progresses, and ensuring that we have the capabilities and capacity to do so is vital. These two new sites are strategically important to our organization, increasing our presence and extending the supply chain with current partners, while providing access into a new customer base and complementing the existing capabilities we have at our other sites.

CP: What is the current state of the small molecule market?

Telgenhof: It remains very strong. The number of FDA approvals still sees a greater number of small molecules than biologics, and the clinical pipeline of drugs remains very healthy. The value of the global small molecule innovator CDMO market was estimated at $41.1 billion in 2020 and is predicted to rise to around $74.9 billion by 2030,[1] although we know that the market is, and is likely to remain, fragmented (*see sidebar at the end of this article*). A large share of that market is held by a disproportionately small number of CDMO players, and this is a trend that, we would suggest, will continue through consolidation and merger and acquisition (M&A) activity between larger companies.

There are numerous macro factors that are helping this growth, including: the ongoing trend of reshoring projects from the East back to western providers; the continued importance of supply chain security; and the need for companies to deliver effective and economical dual sourcing strategies considering lessons learned from the pandemic and the effects that it had on global supply chains.

There is also a change in the type of molecules that are being outsourced, with a growing number of "adjacent areas" to traditional small molecules that necessitate specialized equipment or expertise. These include peptides and oligonucleotides, ADCs, and the growing number of "ultra-high" potent molecules being developed.

Such molecules, combined with an increased demand for outsourced manufacturing, is escalating the pressure on CDMO capacity, and specifically, having the right capacity available, at the appropriate times, to meet customer need.

CP: How have CDMOs such as Sterling had to adapt to meet the needs of customers?

Telgenhof: There is intense competition between manufacturing organizations, and so it is incredibly important for a company to differentiate itself. At Sterling, we believe that while we have technology, capacity, and a broad range of services to offer customers, what sets us apart is our culture and our people.

At the heart of any success is a partnership between customer and service provider. As a company, Sterling originated, and trademarked the acronym PDMO, which stands for Partnership Development and Manufacturing Organization. It is our belief that partnership transcends the contract, and every company should aspire to work in this way—offering the best customer service possible.

There is no singular formula as to how to work with customers, indeed there is no “one-size-fits-all” strategy for API development. Every customer, project and relationship is different and unique, and while some work that is carried out is more transactional and akin to traditional “contract manufacturing,” it is vastly different to working with customers in early-phase development that require close collaboration and a sharing of ideas.

Companies need to be flexible and adaptable to changing needs—be they customers’ demands, evolving timelines, or unexpected circumstances. Agile project management is crucial so that decisions can be made quickly and efficiently, and communication between all stakeholders must be clear and understood. We come back to the point made previously, that it is critical to have the right capacity available at the appropriate time, so ensuring accurate scheduling within manufacturing facilities is vital. Through clear communication, partnerships and understanding, most challenges, and there will always be challenges, can be overcome.

Sterling now has six global facilities, and we see them working very much as one network, where, as they progress, the needs of projects can be matched to sites’ expertise to offer the best service to customers. One example of this is in ADC development: our U.S. site in Cary, NC looks to develop the linker chemistry; our high-potency production facilities in Germantown, WI can synthesize the warhead; and our facility in Deeside, Wales, UK, can undertake the final GMP conjugation steps to complete the manufacturing.

CP: What challenges does the industry face, and how is Sterling looking to address these?

Telgenhof: Time is always our greatest pressure, and through our handling of customer relationships, we ensure that expectations are realistic, and where there may be deviations from a schedule, we can work with customers to ensure the best outcome. Again, working in close partnerships means that programs’ progress is followed by both parties so that most events that can cause delay can be foreseen and mitigated against to a greater extent.

Supply chain security is a key focus throughout the industry, and as CDMOs, we make up a large section of our customers’ supply chain. However, we constantly review our procurement practices to identify any potential risks that could affect our business and customers’ delivery schedules. We also have the flexibility and ability to undertake raw material manufacturing within our own assets to alleviate any potential sourcing problems if necessary.

I have mentioned the importance of the people and culture within Sterling, and recruitment of the best employees with the correct mindset and skills is a constant process. Our talent acquisition team works hard through outreach programs with educational institutions to highlight the benefits of a career within the pharmaceutical industry, and for those who choose to work for us, we invest to ensure they can have access to training and grow within the business. Investment in our workforce is a cornerstone to our business, as we need specialized skills in our employees, which overall, are learned within the work environment through experience.

CP: What is next for Sterling?

Telgenhof: In the short term, our focus is very much on fully integrating the two new sites into our global network and get them aligned on all aspects of procedures and operations. This will then allow us to increase activity across the network and unlock the efficiencies that the additional capacity and technologies at the sites bring to help to grow Sterling’s business.

Looking further ahead, our ambition is to continue what has already been an exemplary growth journey which will be achieved through a combination of organic and inorganic growth, as and when appropriate. Sterling is a small molecule manufacturer—this will remain at the core of the business—and our focus is to continue to do what we do well, while we evaluate and capitalize on opportunities to invest in relevant adjacencies and technologies that add value to and complement our core expertise.

We get to work with projects across the development spectrum, and early-phase projects have a long and uncertain path to reach commercial launch. It is impossible to know which programs will make it, so trying to choose which projects to work on is a gamble. Our goal is to work with as many partner organizations as possible and deliver the best service we can to afford our customers the greatest chance of success based on what we can control. The industry often speculates regarding what “the next big thing” will be. At Sterling, we remain focused on continuing to do what we excel at and doing more of it.

Ministry of Finance

INDUSTRIAL SECTOR GROSS VALUE ADDED (GVA) ROSE BY 3.7 PER CENT IN FIRST HALF OF FY23

PRIVATE FINAL CONSUMPTION EXPENDITURE (PFCE) AS A SHARE OF GDP IN H1 OF FY23 WAS HIGHEST AMONG ALL HALF YEARS SINCE FY15

FDI INFLOW AT US$ 21.3 BILLION IN FY22 MARKING 76 PER CENT RISE FROM FY21

INDIAN PHARMACEUTICAL EXPORTS ACHIEVED 24 PER CENT GROWTH IN FY21

CUMULATIVE FDI IN PHARMA SECTOR CROSSED US$ 20 BILLION MARK BY SEPTEMBER 2022

COAL PRODUCTION FOR FY23 ESTIMATED TO INCREASE TO 911 MILLION TONNES

INDIA IS NOW THE 3RD LARGEST AUTOMOBILE MARKET

INDIA IS 2ND LARGEST MOBILE PHONE MANUFACTURER GLOBALLY

CREDIT TO INDUSTRY GROWING, PARTICULARLY FOR MSMEs

PLI SCHEME EXPECTED TO ATTRACT CAPEX OF APPROX ₹4 LAKH

CRORE OVER THE NEXT FIVE YEARS

INDUSTRY 4.0 IS INDIA'S WAY FORWARD IN ACHIEVING THE GOALS OF AATMANIRBHARTA AND AMBITIONS OF BECOMING A KEY PLAYER IN GLOBAL VALUE CHAINS

The **Overall Gross Value Added (GVA) by the Industrial Sector rose 3.7 per cent**, based on data available for the first half of the FY23, which is **higher than the average growth of 2.8 per cent achieved in H1 of the last decade**, stated the Economic Survey 2022-23 presented by the Union Minister for Finance & Corporate Affairs Smt. Nirmala Sitharaman in Parliament today.

OVERVIEW OF INDUSTRIAL SECTOR

Economic Survey tabled in the Parliament stated that Industry sector witnessed modest growth of 4.1 per cent in FY23 compared to the strong growth of 10.3 per cent in FY22. It explained that this is likely on account of input cost-push pressures, supply chain disruptions and the China lockdown impacting the availability of essential inputs and slowing the global economy.

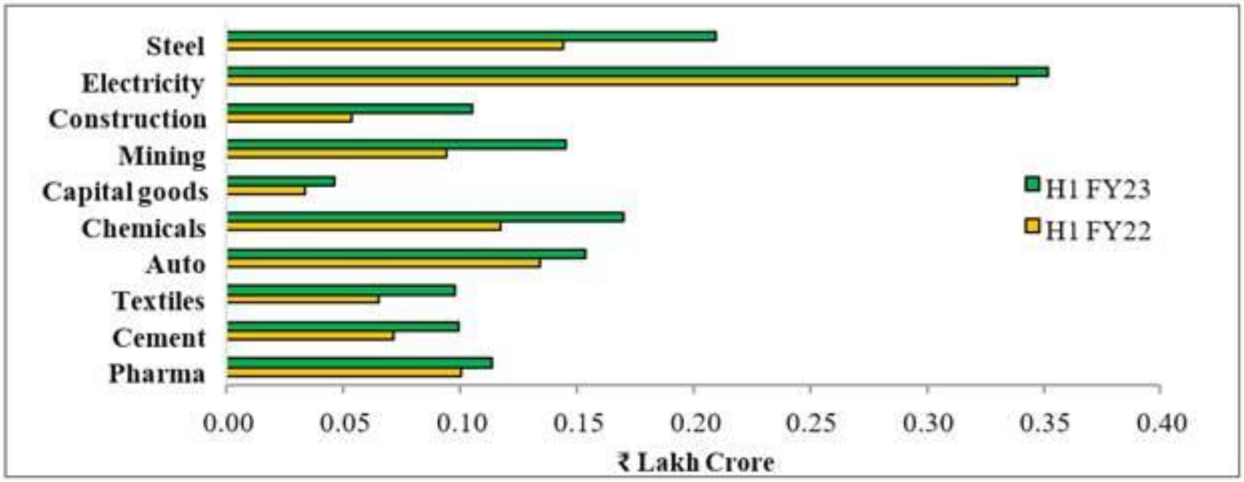
The Survey highlighted that the **PLI schemes** are set to unlock manufacturing capacity, boost exports, reduce import dependence and lead to job creation for both skilled and unskilled labour. The Survey was optimistic that **easing input prices and conducive demand conditions will support overall Industrial growth.**

DEMAND STIMULUS TO INDUSTRIAL GROWTH

Private Final Consumption Expenditure (PFCE) as a share of GDP in H1 of FY23 was the highest among all half years, H1 or H2, since FY15, the Survey stated. The Survey optimistically expressed that with world commodity prices on a downward trajectory and showing up in declining rates of India's wholesale inflation, core retail inflation is expected to relent, making domestic consumption demand much stronger to further induce industrial growth in the country.

Economic Survey stated that the strong export performance of FY22 continued somewhat in the first half of FY23 while exports of goods and services as a share of GDP have been the highest since FY16 during H1 of FY23.

The Survey warned that export growth may slow further in the second half of the current financial year and remain weak beyond that, too, if the global economy falls into recession. It added that however, the strong domestic consumption growth and investment revival is expected to keep industrial production humming.



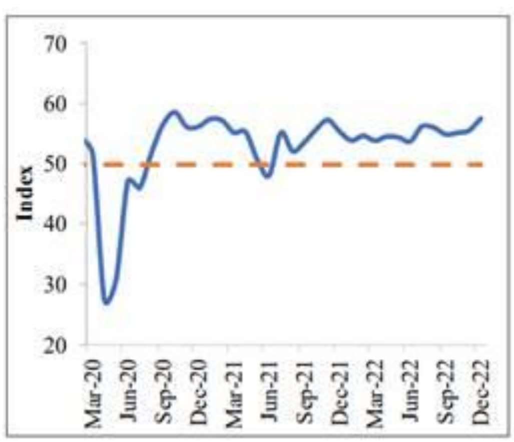
Private Investment gathers momentum

The Survey emphasized that New Investment announced in the manufacturing sector during April-December of FY23 was five times the corresponding level in FY20. The Survey analyzed this increase in investment demand was triggered by the **augmented capex of the central government in the current and the previous year** as compared to the pre-pandemic years. The leap also has crowded in private investment, already upbeat on the pent-up demand, export stimulus, and strengthening of the corporate balance sheets. It added that **Capacity utilization in the manufacturing sector has been rising** which bodes well for new investment activity in creating additional capacity.

SUPPLY RESPONSE OF INDUSTRY

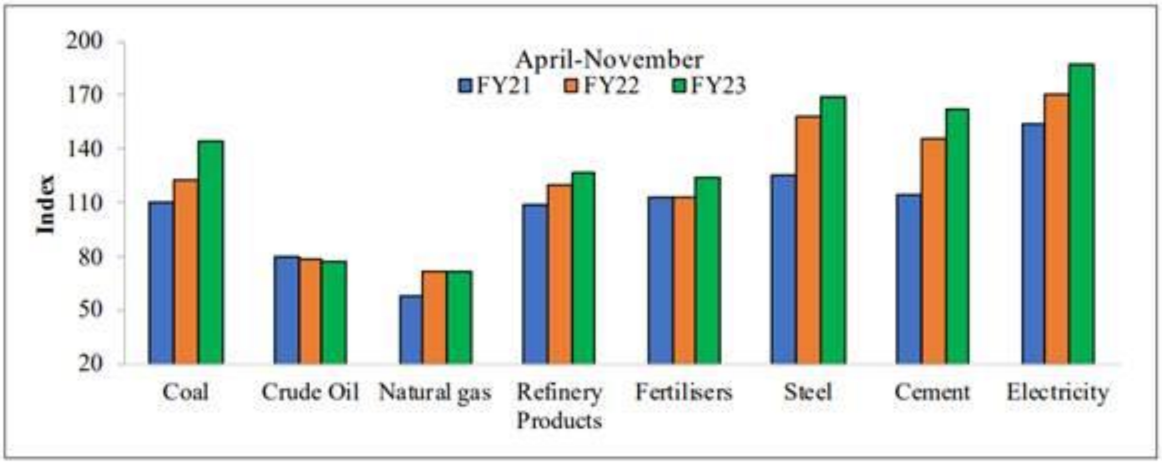
Purchaser's Manufacturing Index (PMI) manufacturing has remained in the expansion zone for 18 months since July 2021, and its sub-indices indicate an easing of input cost pressures, improving supplier delivery times, robust export orders, and future output, highlighted the Survey.

PMI Manufacturing remains in expansionary zone



The Survey noted the growth of the eight core industries of coal, fertilizers, cement, electricity, steel, and refinery products has held steady, reflecting a broad momentum in industrial activity.

Steady Growth in Components of Index of Core Industries

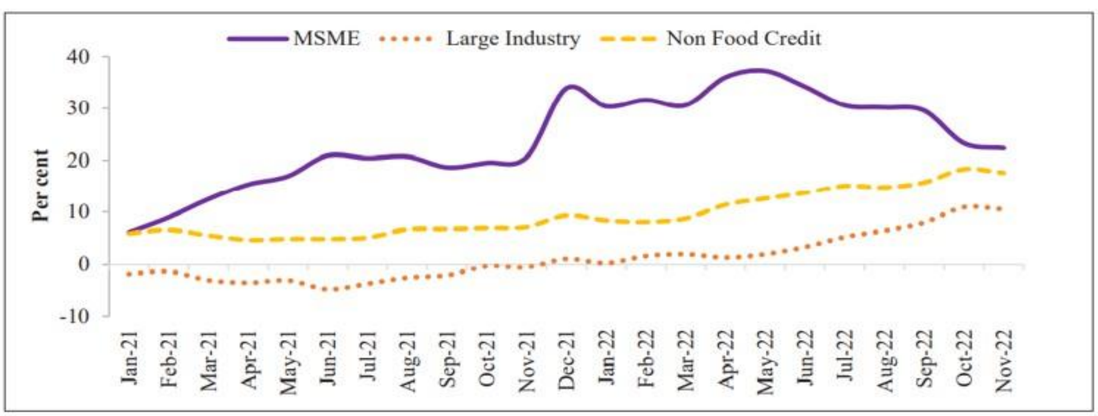


The Survey added that while growth in the consumer durables component of the Index of Industrial Production (IIP) is on account of the release of 'pent-up' demand, the increase in capital goods and infrastructure/ construction goods is indicative of the beginnings of a virtuous investment cycle that is expected to be led by the private sector.

ROBUST GROWTH IN BANK CREDIT TO INDUSTRY

The Survey highlighted that the **credit to industry** started recovering from January 2022 and has been **growing in double digits since July 2022**. It added that **Credit to MSMEs has also seen a significant increase** in part, assisted by the introduction of the **Emergency Credit Linked Guarantee Scheme (ECLGS).**

Double-digit credit growth in Industry driven by MSMEs



The Survey stated that the impact of ECLGS on increasing the growth of credit to MSME was felt most during the pandemic impacted years of 2020 and 2021. It continued in 2022 as the scheme was extended to March 2023.

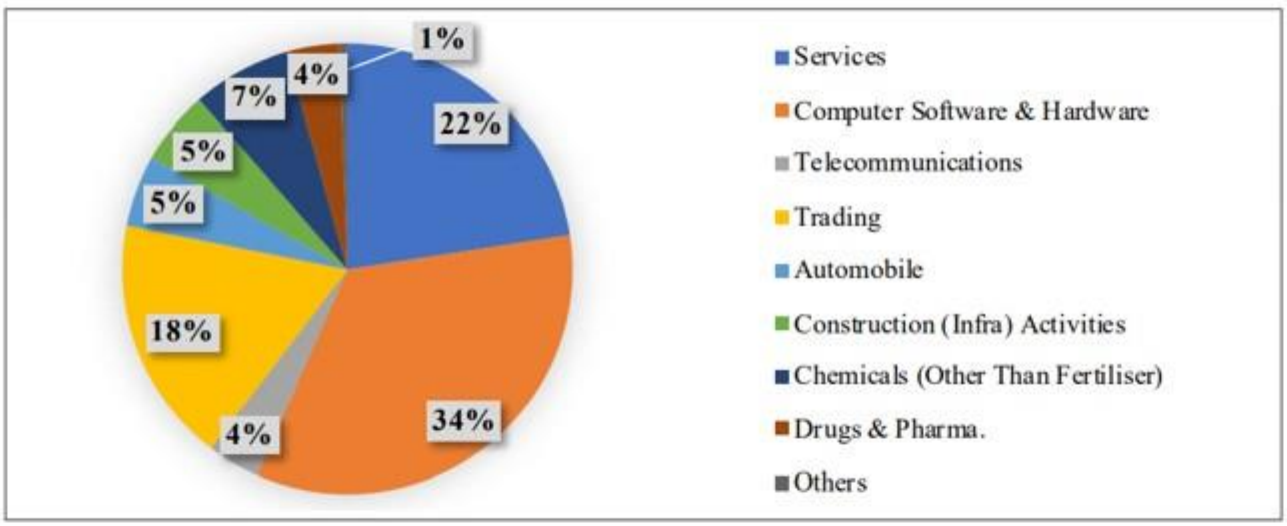
Further it added, growth in credit to MSME was buttressed by rebounding consumption levels, particularly in the services sector. Consequently, the share of MSMEs in gross credit offtake to the industry rose from 17.7 per cent in January 2020 to 23.7 per cent in November 2022.

The Survey expressed that robust growth in credit demand combined with rising capacity utilization and investment in manufacturing underscores businesses' optimism regarding future demand.

RESILIENT FDI INFLOW IN MANUFACTURING SECTOR

The Survey highlighted that the **FDI inflow jumped to US$ 21.3 billion in FY22 from US$ 12.1 billion in FY21** as the pandemic-driven expansionary policies of advanced economies led to a surge in global liquidity.

Sector-wise FDI Equity Inflows in 2022-23 during April-September 2022



The Survey mentioned that FDI equity inflow in manufacturing in the first half of FY23 fell below its corresponding level in the first half of FY22, with the rise in global uncertainty in the wake of the Russia-Ukraine conflict.

A rebound in FDI inflows is, however, expected as the Indian economy sustains its high growth while monetary tightening the world over eventually eases with the weakening of inflationary pressures, the Survey expressed optimism.

HIGHLIGHTS OF INDUSTRY GROUPS

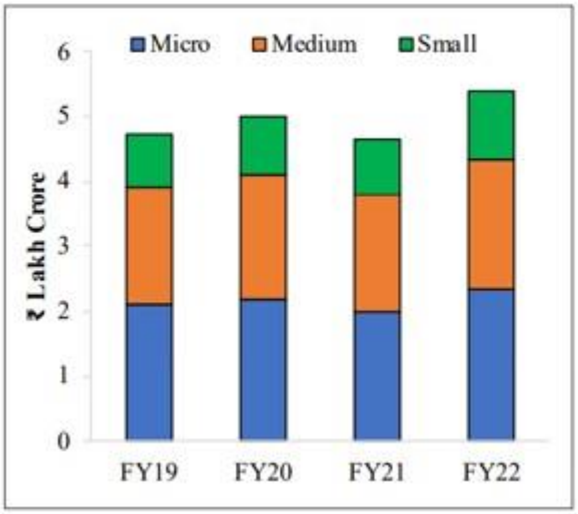
1. **MICRO, SMALL AND MEDIUM ENTERPRISES (MSMEs)**

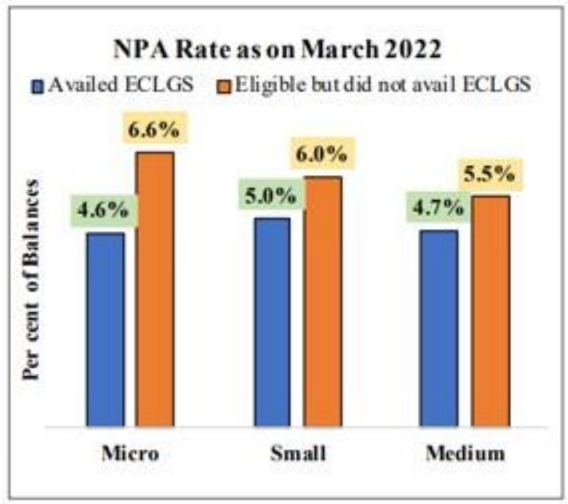
The Survey noted that the MSME contribution to the manufacturing sector's GVA also marginally fell to 36.0 per cent in FY21. The Survey further emphasized that the AatmaNirbhar Bharat Package by the Government provided cushion to the economic impact of the pandemic on MSMEs, which has helped post smart recovery from pandemic.

The Survey expressed that the recovery of the MSME sector from the pandemic-induced shock is evident in the trend in GST paid by the units of MSME sector in FY22 has crossed the pre-pandemic level in FY20.

Government's initiative of the Samadhaan Portal, CHAMPIONS:the single-window grievance redressal portal for MSMEs, Trade Receivables Discounting System (TReDS) platform for facilitating the discounting of trade receivables of MSMEs with a turnover of ₹200 crore or more, ‘Raising and Accelerating MSME Performance’ scheme (RAMP) etc. has helped in strengthening the MSMEs stated the Economic Survey.

GST paid by MSMEs in FY22 ECLGS aided MSMEs in improving their asset quality



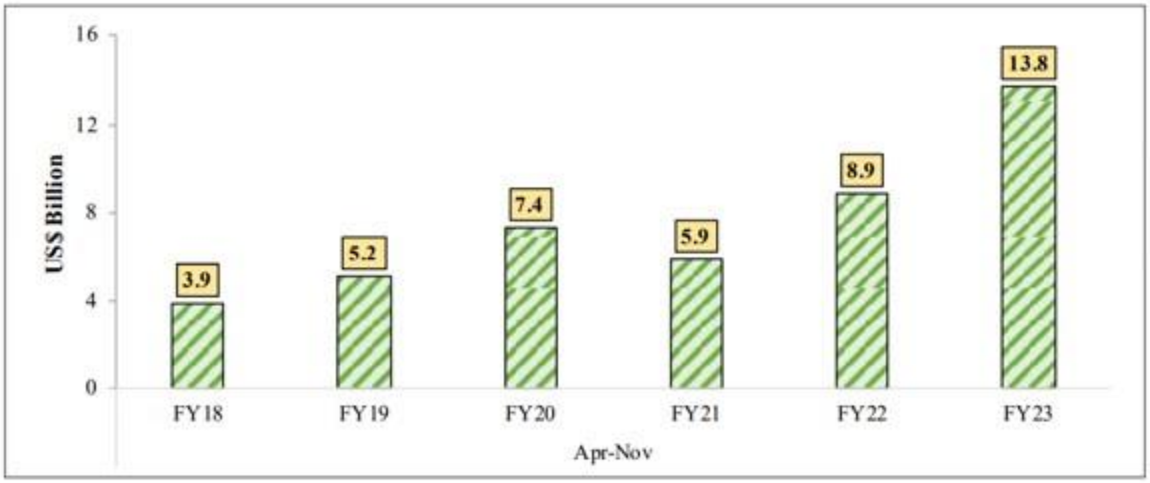


2. **ELECTRONICS INDUSTRY**

The Survey emphasized that Electronic goods were among the top five commodity groups exhibiting positive export growth in November 2022, with the exports in this segment growing YoY by 55.1 per cent.

Elaborating on the Electronics industry, the Survey stated that major drivers were mobile phones, consumer electronics and industrial electronics. It highlighted that India has become the **second-largest mobile phone manufacturer globally**, with the production of handsets going up from six crore units in FY15 to 31 crore units in FY22.

Robust growth in Electronics Exports



The Survey also mentioned that various initiatives and incentives of Government like PLI scheme for Large Scale Electronics Manufacturing, the PLI scheme for IT hardware, the Scheme for Promotion of Manufacturing of Electronic Components and Semiconductors (SPECS) has nurtured and enhanced the electronics manufacturing base.

Additionally, under the Programme for Development of Semiconductors and Display Manufacturing Ecosystem in India, the Cabinet approved the comprehensive development of a sustainable semiconductor and display ecosystem in the country with an outlay of ₹76,000 crore.

3. **COAL INDUSTRY**

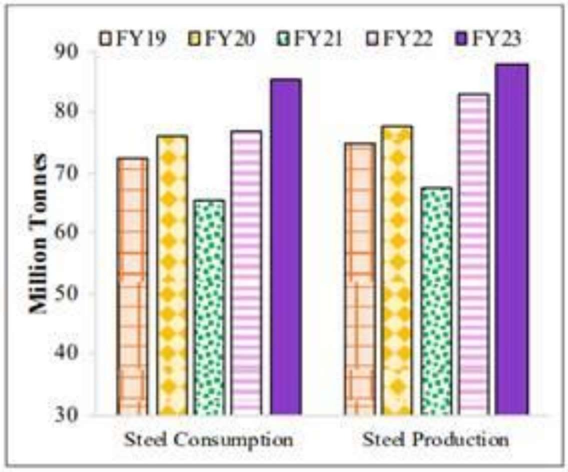
The coal production for FY23 is estimated to increase to 911 million tonnes, about 17 per cent higher compared to the previous year, highlighted the Survey. Consequent to the well-timed measures of the Government, India has been placed in a better position to cater to excess energy demand. It further added that the coal industry is expected to grow at 6-7 per cent annually to reach a production level of 1 billion tonnes by FY26 and about 1.5 billion tonnes by 2030.

4. **STEEL INDUSTRY**

Economic Survey highlighted the steel sector’s performance in the current fiscal year as robust, with cumulative production and consumption of finished steel at 88 MT and 86 MT, respectively, during April-December 2022, higher than the corresponding period during the previous four years.

The Survey stated that iron and steel exports are higher by 20 per cent over the corresponding pre-pandemic levels of FY20, despite moderation in the first eight months of the current fiscal owing to a slowdown in the global economy.

Increasing Steel production and Consumption (Apr-Dec)



5. **TEXTILE INDUSTRY**

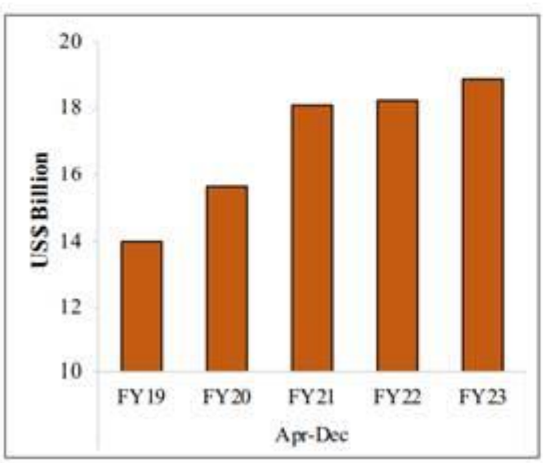
In the current financial year, the textile industry has been facing the challenge of moderating exports compared to FY22, mentioned the Survey. It added that export of readymade garments registered a growth of 3.2 per cent YoY basis during the same period.

The Government approved the setting up of **seven PM Mega Integrated Textile Region and Apparel (PM MITRA) Parks** and launched the **Textile PLI Scheme** with an approved outlay of ₹10,683 crore over five years starting from 1st January 2022 to promote investments. These would help to develop integrated large-scale and modern industrial infrastructure facilities for the entire value chain of the textile industry, the Survey stated.

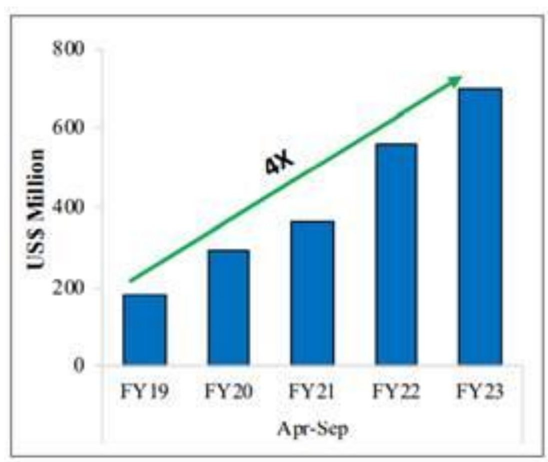
6. **PHARMACEUTICALS INDUSTRY**

The Survey highlighted that **Indian pharmaceutical exports achieved a healthy growth of 24 per cent in FY21**. It expressed hope that India's domestic pharmaceutical market is estimated to grow to US$ 65 billion by 2024 from estimated US$ 41 billion in 2021 and is further expected to reach US$ 130 billion by 2030.

Strong Growth in pharma exports



High Inflow of FDI in Pharma sector



Carrying forward this growth momentum, drug and pharmaceutical exports during April-October 2022 was 22 per cent higher than the corresponding pre-pandemic period of FY20, noted the Survey. It added that **Cumulative FDI in the pharma sector crossed the US$ 20 billion mark in September 2022 and FDI inflows have increased four-fold over five years until September 2022, to US$ 699 million**, supported by investor-friendly policies and a positive outlook for the industry.

7. **AUTOMOBILE INDUSTRY**

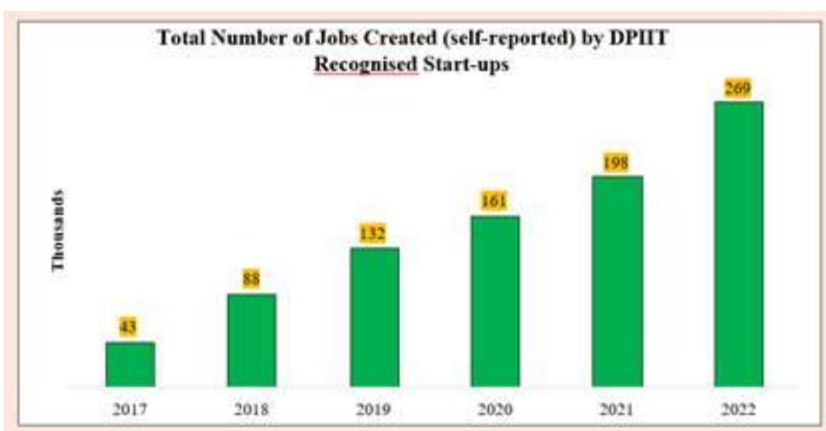
India became the 3rd largest automobile market, surpassing Japan and Germany in terms of sales, in December 2022, stated the Economic Survey. It added that in 2021, India was the largest manufacturer of two-wheeler and three-wheeler vehicles and the world's fourth-largest manufacturer of passenger cars.

Elaborating on the domestic electric vehicles (EV) market, the Survey stated that it is expected to grow at a compound annual growth rate (CAGR) of 49 per cent between 2022 and 2030 and is expected to hit one crore units annual sales by 2030. It added that the EV industry will create 5 crore direct and indirect jobs by 2030.

FOSTERING INNOVATION

Economic Survey stated that there was a 46 per cent growth in the domestic filing of patents over 2016-2021, signaling India's transition towards a knowledge-based economy.

Discussing the achievements of Start-ups, the Survey highlighted that an impressive 9 lakh+ direct jobs have been created by the DPIIT recognized startups (self-reported), with a notable 64 per cent increase in 2022 over the average number of new jobs created in the last three years. About 48 per cent of our startups are from Tier II & III cities, a testimony of our grassroots' tremendous potential.



INDUSTRY 4.0

The Survey highlighted that adoption of Industry 4.0 technologies such as cloud computing, IoT, machine learning, and artificial intelligence (AI) in the Indian manufacturing sector is underway, however, large-scale adoption is yet to happen and an enabling environment is rapidly developing.

The Survey mentioned that various Government Initiatives such as SAMARTH (Smart Advanced Manufacturing and Rapid Transformation Hubs) Udyog Bharat 4.0, establishment of the Centre for Fourth Industrial Revolution is the way forward in achieving the goals of Aatmanirbharta and its ambitions of becoming a key player in global value chains.

MAKE IN INDIA 2.0

The Survey mentioned that ‘Make in India 2.0’ is now focusing on 27 sectors, which include 15 manufacturing sectors and 12 service sectors. Amongst these, 24 sub-sectors have been chosen while keeping in mind the Indian industries’ strengths and competitive edge, the need for import substitution, the potential for export and increased employability.

PERFORMANCE LINKED INCENTIVE (PLI) SCHEME

PLI scheme is expected to **attract a capex of approximately ₹4 lakh crore over the next five years** having a **potential of generate employment for over 60 lakh in India** stated the Economic Survey. It added that Sectors under which the PLI scheme has been announced currently constitute around 40 per cent of the total imports. The scheme, spread across 14 sectors, can enhance India’s annual manufacturing capex by 15 to 20 per cent from FY23.

The Survey mentioned that **around ₹47,500 crore (US$ 6 billion) of actual investment has been made (As per recent reporting from implementing Ministries/ Departments); production/ sales of ₹3.85 lakh crore (US$ 47 billion) of eligible products and employment generation of around 3 lakh has been reported and 106 per cent achievement of actual investment reported** versus the corresponding projections of FY22.

The Survey stated that **more than 100 MSMEs are among the PLI beneficiaries** in sectors such as Bulk Drugs, Medical Devices, Telecom, White Goods and Food Processing. Key sectors such as Large-Scale Electronics Manufacturing, Pharmaceuticals, Telecom & Networking Products, Food Processing and White Goods have contributed considerably to investment, production, sales and employment.

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G20
ECONOMIC
SURVEY
2022-23
INDUSTRY: STEADY RECOVERY
GVA of the Industrial Sector rose by 3.7 per cent for the first half of FY 22-23
1/2
Exports of goods and services as a share of GDP have been the highest since FY16 in H1 of FY 22-23
PMI manufacturing has remained in the expansion zone
Healthy IIP indicates the beginning of a virtuous investment cycle
Credit to MSMEs has grown by around 30% since Jan 2022
Electronics exports rise nearly threefold in FY22
FDI flows into the Pharma Industry has risen four times in FY22


G20
ECONOMIC
SURVEY
2022-23
INDUSTRY: STEADY RECOVERY
Enhancing Manufacturing Capacity
2/2
PLI schemes
Employment generation of 3 lakh
More than 100 beneficiaries are MSMEs
Investment of ₹47,500 crores in the FY22
Make in India 2.0 covers a total of 24 sub-sectors
Enhancing Ease of Doing Business
7496 reforms implemented
39,000 compliances reduced
3500 provisions decriminalized

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