



PLI SCHEME IN MEDICAL DEVICES MANUFACTURING

Varun Gupta¹, Payal Kewlani¹, Siddesh Shewalkar¹, Dr. B Lakshmi², Mr. Sai Kishore V³
¹MBA, Pharmaceutical Management, NIPER Hyderabad, India

²Assistant Professor, NIPER Hyderabad, India

³Assistant Professor, NIPER Hyderabad, India

ABSTRACT:

The announcement of the PLI Scheme and its extensions in quick succession since April 2020 shows the will and urgency felt by the government of India to improve India's competitiveness in the world market. The scheme envisages the government giving a subsidy to players in the domestic medical devices market of up to 5% on additional sales compared to the base year sales for a qualifying firm. The total disbursement is expected to be close to ₹121 crore over 5 years. A financial outlay of 3420 Cr was approved to reduce import dependency and facilitate domestic market growth. CDSCO and ICMR regulate the control and quality of medical devices in the country under the Medical Devices Act of 2020. The scheme applies to four categories of medical devices, as mentioned. Of all the received applications, 21 have been approved, resulting in an investment of Rs. 1,059.33 crores and around 6,411 jobs. The project cost of the common infrastructural facilities for a chosen Medical Device Park would be covered by financial assistance to 70%. A State Implementing Agency will carry out the project for the Medical Device Park. The article also consists of a List of Approved Categories, Effects of the PLI Scheme on Fostering Domestic Medical Device Manufacturing, which includes Investing encouragement, Reducing reliance on imports, Driving innovation, Intensifying competitiveness, and Fostering the expansion of the MSME sector. India's Manufacturing Sector Benefits from the PLI Scheme, including Building large-scale manufacturing capacities, Export growth and import replacement, Employment generation, and Industry professionals' opinions on India's PLI Scheme for promoting the production of medical devices domestically. Similar schemes in other countries like China, Malaysia and the USA are mentioned along with The Backlog and methodology. The discussions include Simplification of eligibility criteria: Greater focus on quality, Greater coordination between government agencies, Emphasis on particular medical devices, Encouragement of innovation, Set up financial rewards, Construct infrastructure, Collaboration and coordination.

Keywords: Production Linked Incentives, Medical Devices, Dependency, State Implementing Agency, CDSCO, ICMR, MSME,

INTRODUCTION:

The development and introduction of new technologies are necessary for the medical device sector, which has a long gestation period and requires significant financial investment. To adapt to emerging technologies, healthcare professionals must receive additional training. Most cutting-edge high-tech products come from an established ecosystem and innovation cycle that has yet to reach its full potential in India.

The Indian Government established a program entitled "Promotion of Medical Devices Parks" on March 20, 2020, due to the significant expenditure needed to provide testing and laboratory facilities. The parks will provide centralized labs and standardized testing facilities, which will cut manufacturing costs and help the country build a robust ecosystem for the production of medical devices.

With imports accounting for more than 85% of the market in India, the country's domestic medical device sector is significantly dependent on imports.

The country's unequal playing field hampers medical equipment manufacturers in India concerning rival economies. A high cost of manufacturing is one of the difficulties faced in the production of medical equipment because:

- a. inadequate domestic supply chain, logistics, and infrastructure
- b. expensive finance
- c. a lack of reliable power sources
- d. restricted design talents; for example, less emphasis on R&D and skill development.

The Indian Government approved a program called "Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices" on March 20, 2020, to solve India's manufacturing disadvantage compared to other significant manufacturing economies.

OBJECTIVES:

The development of top-notch common infrastructure facilities will make it simple to access facilities for standard testing and infrastructure, drastically cutting the cost of manufacturing medical devices and enhancing the accessibility and affordability of medical devices on the local markets.

Reaping the rewards brought about by efficiencies and resource management, the Program aims to increase domestic production and investments in the medical device industry.

LITERATURE REVIEW:

Rs. 3,420 Cr. would be spent to promote domestic medical device manufacturing under PLI Scheme (FY 2020-2021 to 2028-29).

The Department of Pharmaceuticals has implemented the following programmatic measures to promote domestic manufacturing and lessen medical device import dependence:

- ❖ **Uttar Pradesh, Tamil Nadu, Madhya Pradesh, and Himachal Pradesh** are the states that have received final clearance for financial support of **Rs. 100 crore each** under the scheme "Promotion of Medical Devices Parks" to develop shared facilities in their Medical Device Parks. The Parks will provide standardized testing and laboratory facilities/centers in one area, significantly reducing production costs and creating a robust manufacturing ecosystem for the nation's production of medical devices. Each of the nominated States has received its first amount, totalling Rs. 30 crores (*Why the PLI Plan for Medical Device Manufacturers Didn't work- The Hindu BusinessLine, n.d.*)
- ❖ Under the sub-scheme "Assistance to Medical Device Industry for Common Facility Centre," it was approved for Andhra Pradesh MedTech Zone Ltd. (AMTZ), in Andhra Pradesh, to develop a Common Facility for Superconducting magnetic coil testing and research." (*Pharmaceuticals / Make In India, n.d.*)

- ❖ Five industry applications have been chosen under the PLI plan for pharmaceuticals, effective from FY 2020–2021 to 2028–2029. (*PLI Scheme: Why India's Attempts to Expand the Medical Devices Sector Are Fail*, n.d.)
- ❖ The PLI Scheme for Promoting Domestic Manufacturing of Medical Devices, which has a budgetary outlay of Rs. 3,420 Cr. and spans from FY 2020–21 to FY 2028–29, provides financial incentives to selected enterprises. **For a period of five years**, the incentive is **given at a rate of 5%** of additional sales of medical devices made in India. (Simplified Legality: Programmatic Interventions to Promote Domestic Manufacturing to Reduce Dependence on Imports of Medical Devices, n.d.)

The following four programme segments, which cover upscale medical gear:

- Medical equipment's for radiotherapy and cancer care
- Nuclear imaging devices and radiology and imaging medical equipment (both ionising and non-ionizing radiation products)
- Medical devices for anaesthesia, cardio-respiratory care, including cardio-respiratory category catheters, and renal care
- All implants, including those containing implantable electronics. 21 candidates in total have received approval under the programme.

India is home to about 800 manufacturers of pharmaceutical and medical products and equipment, and is Asia's fourth-largest market. CDSCO and the ICMR are the regulating agencies in India for medical devices.

In India, the **Medical Device Regulation Act of 2020** defines the **regulatory framework** for medical devices while the **Drugs and Cosmetics Act, 1940** oversees the **quality and safety** of medical devices. Prior to distribution or sale, every piece of medical equipment marketed in India would be subject to quality control, according to the new MDR 2020 regulations. (*Medical Device Parks' Scheme Notified - The Hindu*, n.d.)

Facilities for Common Infrastructure:

The Medical Equipment Park's medical device businesses cooperate on facilities like the component-testing facility, facility for Electronics System Design & Manufacturing, Printed Circuit Boards or sensors; institute for electromagnetic compatibility; testing centre for biomaterial, accelerated ageing or ,biocompatibility; Clinical tooling, machining, metal injection, and molding facility; Asepsis centres, pharmaceutical grade 3D printing, and product development; a centre for testing toxicity on animals. (*Ministry of Chemicals and Fertilizers Issues*, n.d.)

Financial Assistance:

The project cost of the common infrastructural facilities for a chosen Medical Device Park would be covered by **financial assistance to the tune of 70%**. 90% of the capital investment project would be covered by monetary assistance for the North Eastern and Hilly States (Union Territory of Jammu & Kashmir, Union Territory of Ladakh, Himachal Pradesh, Uttarakhand). For one Medical Product Park, the utmost amount of assistance under the programme will be Rs. 100 crore.

A State Implementing Agency will carry out the project for the Medical Device Park that is chosen under the Scheme (SIA).

The responsible State government shall create SIA as a legal organisation with the mission of carrying out the Medical Device Park project.

The Scheme Steering Committee (SSC), which was established by the Department of Pharmaceuticals (DoP), will accept any ideas submitted under the scheme. (Financial Support for Establishing Bulk Drug Parks under PLI - S.S. Rana & Co., n.d.)

Incentive Quantum:

The Scheme provides financial incentives to selected enterprises at a rate of 5% of increased sales (over Foundation Year) of products produced in India and falling within the purview of the Target categories during a five-year period, beginning FY 2021–22 through FY 2025–26.

In order to encourage local medical device manufacturing, the **Indian government has licenced eight businesses under the PLI programme**. As a result, a total of **21 applicants** had their applications approved in both rounds, resulting in **investment of Rs. 1,059.33 crore and the creation of around 6,411 jobs**.

The PLI Scheme for Promoting Domestic Manufacturing of Medical Devices later approved a few more applicants. The construction of these resources will help the country achieve self-sufficient in the medical devices industry for the designated target markets.

Medical devices are categorised as follows per the Medical Devices Rules of 2017:

- Class A- low risk items: It includes absorbent cotton balls, alcohol swabs.
- Class B- low moderate risk items: It consists of thermometer, BP monitoring device.
- Class C- moderately high risk items: It contains implants.
- Class D- high risk items: It includes heart valves.

List of Applicants Approved under PLI Scheme for Promoting Domestic Manufacturing of Medical Devices as on 25.04.2023 (*The PLI Scheme's approved applicants list as of 2023 is intended to encourage domestic production of medical devices.*)

List of Approved Category –A Applicants

S.No.	Applicant details	Eligible Products
Target Segment 1 - Medical Devices for Radiotherapy and Cancer Care		
1	Panacea Medical Technologies Private Limited	Linear Accelerator (LINAC); Rotational Cobalt Machine
Target Segment 2 includes medical equipment for radiology and imaging, including nuclear imaging devices and goods utilising ionising and non-ionizing radiation.		
1	Siemens Healthcare Private Limited	CT Scan and MRI

2	Allengers Medical Systems Limited (AMSL)	Ultrasonography, X-rays, CT scans, MRIs, and cath lab, Mammography and C arm.
3	Allengers OEM Private Limited (AOPL)	Monitors, flat panel detectors, and collimators
4	Wipro GE Healthcare Private Limited (WGHPL)	Ultrasonography, Cath Lab, and CT Scanning
5	BPL Medical Technologies Pvt. Ltd.	Fixed LF and HF X-Ray Products, X-Ray Panels, and Ultrasound Products for Surgical Use
6	Trivitron Healthcare Private Limited	Equipment for mammography, the C-Arm, MRI, ultrasonography, X-rays, and catheterization labs
7	Philips Global Business Services LLP	Coils for MRI
Target Segment 3: Anaesthetics, Cardio-Respiratory Medical Devices, including Renal Care Medical Devices and Catheters in the Cardio Respiratory Category		
1	Nipro India Corporation Private Limited	Dialyzer
2	Wipro GE Healthcare Pvt. Ltd. (WGHPL)	Anesthesia Unit Ventilators, Patient monitoring system, Connectivity Hub
3	BPL Medical Technologies Pvt. Ltd.	ECG, patient monitoring, syringe pump, defibrillators, stress test system, oxygen concentrator, vaporizer, ventilator, automated external defibrillators (AEDs), and anaesthesia workstation
4	Poly Medicure Ltd.	Dialysis kits for peritoneal dialysis, a dialysis machine, a dialysis machine, a fistula, a blood line, a dialysis catheter, and a transducer protector
5	Allied Medical Limited	Anesthesia workstations, anaesthesia units, gas scavengers, anaesthesia kits, anaesthesia masks, anaesthesia unit ventilators, automated external defibrillators (AEDs), oxygen concentrators, and other items are available. Intensive care ventilators, emergency ventilators, high flow oxygen devices, biphasic defibrillators, syringe and volumetric infusion pumps, suction machines, and intensive care ventilators
6	Deck Mount Electronics Ltd.	Ventilators, dialysis machines, and oxygen concentrators for anaesthesia units
7	Microtek New Technologies Pvt. Ltd.	Oxygen Concentrators

Target Segment 4: Implantable electronic devices and AII implants

1	Sahajanand Medical Technologies Pvt. Ltd. (SMTPL)	Heart Occluders, PTCA Balloon, Dilatation Catheter, Stents, and Heart Valves
2	Innvolution Healthcare Pvt. Ltd.	Stents, PTCA Catheter
3	Meril Healthcare Pvt. Ltd.	Knee replacements, hip replacements, and other types of trauma implants
4	Meril Life Sciences Pvt. Ltd.	Stents, heart valves, and a PTCA balloon catheter
5	Envision Scientific Pvt. Ltd.	Stents, balloon catheters, and heart valves
6	Bio India Interventional Technologies Pvt. Ltd.	Drug Eluting Balloons and Drug Eluting Stents

List of Approved Category –B Applicants

S. No.	Applicant Details	Eligible Product
Target Segment 2- It includes medical equipment for radiology and imaging, including nuclear imaging devices and goods utilising ionising and non-ionizing radiation.		
1	Samvardhana Motherson Maadhyam	Housing Diamond Emerald Metric 90 DEG, Housing/Center section Sapphire, Housing B-130, 180 Degree, Housing anode and SAPPHIRE III, Housing anode and SAPPHIRE III, Casting Housing Assembly, B18X Center Section, FABR Housing Anode End Std., FABR Housing Cathode End Std., Housing B-130, 180 Degree, Housing Center B-240, Support Cathode, Anode Outer Sealing Ring, Ring Sealing Cathode Inner, Sealing Ring, Shield, Cathode, Shield Cathode Cover, Collar, Anode Shield, Kovar Bushing, Cathode Can BULGED, Machined, Cathode Can Machined- 743708, Anode Can Cathode Can BULGED Machined, Housing Aluminium 4131Z
2	Indovasive Pvt. Ltd.	Biopsy Kits-Renal, Dialyser Reprocessing System, PCN Catheter/Kit (Abscess Drainage Catheter/Kit), Ureteral Catheter Malecot Catheter/Kit, Re Entry Malecot Catheter/Kit, Suprapubic Catheter/Kit, Dual Lumen Ureteral Catheter, IUI Catheter/Kit, Braided Shaft Catheter (Ureteral Access Sheath), Cysto Catheter/Kit,

		Urethral Stent, Double J Stent /Kit (Long Term), Double J Stent/Kit (Short Term), Endopyelotomy Stent/Kit, Mono J Stent/
		Kit, Stone Basket- G Paw, Stone Basket Helical, Stone Basket- Segura, Stone Grasper, Stone Basket- X Circle, Stone Basket- Zero Tip, Stonestop- Retrieval Coil, Perk Basket, URS Forceps, Urethral Dilator/Set Amplatz Dilator/Kit & Mini Amplatz Dilator/Kit, Fascial Dilator/Set Meatal Dilator, Filiform Self Dilator, Nephrostomy Balloon Dilator, Ureteral Balloon Dilator, Screw Dilator, Ureteral Dilator / Set S Curve Urethral, Dilator / Set Nottingham One Step Dilator, IP Needle, Chiba Needle, Penile Clamp, Evacuator Striped Guidewire, Striped Guidewire with Hydrophilic Tip, SS Guidewire, Hydrophilic (Nano Glidewire) Guidewire, PTFE Guidewire, Incontinance Sling-AQUA, Suction and Irrigation System, Thulium Fiber Laser & Laser Probes, Turp Loop/Cutting Electrodes, Endoscopes With Flexible/Fixed Shaft.
3	Omron Healthcare Manufacturing India Pvt. Ltd.	Automatic Blood Pressure Monitor
4	Meril Endo Surgery Pvt. Ltd.	Hernia Surgical Mesh Implants, Endocutter, Linear Stapler, Linear Cutter, Trocar, Litigation Clip, Hemostates
5	Neurovasive Pvt. Ltd.	Cerebral Spinal Fluid Shunt System (CSF), Flow diverter implants, Embolic liquid, Peripheral Stent, Carotid Stent, Intracranial Stent, Intrasaccular Device

Effect of the PLI Scheme on Fostering Domestic Medical Device Manufacturing:

- **Investing encouragement:**

Companies that invest in local medical device production are given financial incentives under the PLI plan. Due to this, both domestic and international businesses have decided to invest in India, increasing its production capacity and generating new employment opportunities. (Life Sciences, Biotechnology, and Nanotechnology in India, Medical Devices: Compliances and Regulations, n.d.)

- **Reducing reliance on imports:**

With imports making up a sizable market share of the market right now, the PLI scheme seeks to lessen India's reliance on these items. The programme might greatly lessen India's reliance on imports by encouraging home manufacturing. (Eight companies approved by the government under the PLI scheme for producing medical devices - *The Economic Times*, n.d.)

- **Drive innovation:**

Companies must make research and development investments in order to be eligible for the PLI scheme. This has encouraged greater innovation and the creation of innovative medical gadgets in India, which can assist in meeting the country's population's particular healthcare needs.

- **Intensified competitiveness:**

Due to financial incentives and lower production costs provided by the PLI plan, domestic manufacturing is now more competitive. This has improved India's standing in the global medical device market and made Indian-produced medical equipment more appealing to both domestic and foreign consumers.

- **Fostering the expansion of the MSME sector:**

The PLI programme is specifically designed to support the expansion of the Micro, Small, and Medium-Sized Enterprises (MSME) industry. This has prompted additional MSMEs to enter the medical device manufacturing sector, increasing competition and stimulating innovation. (*PLI: Effects of PLI Programs on India's Manufacturing Industry*, n.d.)

India's Manufacturing Sector Benefits from the PLI Scheme:

- **Building large-scale manufacturing capacities**

If, as a producer, you believe that the government should not boost production of a particular class of items for which demand is not particularly strong. You think that if products were produced and offered at competitive prices, demand may go up. You'll use PLI schemes in such a situation. Incremental turnover and production capacity have a direct correlation with the incentives. (*PLI Scheme: Why India's Efforts to Boost Its Medical Devices Industry Are Falling Short*, n.d.)

- **Export growth and import replacement**

With its extremely uneven import-export balance typically being controlled by imports of completed goods and raw materials, India's PLI programmes aim to reduce the gap. The PLI programmes are created to encourage local manufacturing, lowering India's short-term reliance on imports while eventually increasing the volume of its exports.

- **Employment generation**

The PLI programmes are anticipated to utilise India's vast people resources and offer possibilities for upskilling and technical education because large-scale manufacturing requires a huge labour force.

Industry professionals' opinions on India's PLI Scheme for promoting the production of medical devices domestically

While some experts have praised the programme for its potential to increase domestic manufacturing and decrease reliance on imports, others have voiced concerns about how it was implemented and how it might affect small and medium-sized businesses (SMEs). Here are some opinions from professionals in the field:

- "The PLI scheme is a positive step towards promoting domestic manufacturing of medical devices in India. It has the potential to increase production, create jobs, and reduce import dependency." - Pavan Choudary, Director General of Medical Technology Association of India (MTAI) (Vora et al., 2021)
- "The PLI scheme is a welcome move, but the eligibility criteria are too strict and limit the participation of SMEs. More needs to be done to support SMEs and encourage their participation in the scheme." - Rajiv Nath, Forum Coordinator of Association of Indian Medical Device Industry (AiMeD)
- "The PLI scheme is a good initiative, but the government needs to ensure that the funds are disbursed transparently and effectively. There is also a need for a regulatory framework to ensure quality standards are met." - Malini Aisola, Co-Convener of All India Drug Action Network (AIDAN)
- "The PLI scheme is a game-changer for the medical device industry in India. It has the potential to attract foreign investment, boost innovation, and make Indian-made medical devices more competitive globally." - Mahesh Zagade, President of Indian Pharmaceutical Association (IPA)
- "The PLI scheme is a step in the right direction, but more needs to be done to address the challenges faced by the medical device industry, such as lack of infrastructure, skilled manpower, and research facilities." - Anil Jauhri, CEO of National Accreditation Board for Testing and Calibration Laboratories (NABL)

Similar schemes in other countries

The PLI scheme's execution and effects differ somewhat from those of comparable programmes in other nations.

China:

China has put into effect a "**Made in China 2025**" initiative that offers financial rewards to businesses that commit to local medical equipment production. The initiative intends to lessen reliance on imports, foster innovation, and raise the calibre of medical products made in the country. Even while the plan has improved the capacity of domestic manufacturing, it has come under fire for how it affects international businesses and intellectual property rights.

Malaysia:

A similar financial incentive programme is included in Malaysia's **National Blue Ocean Strategy 2009** to promote domestic medical equipment manufacture. The programme provides corporations making investments in Malaysia with tax breaks, subsidies, and financing for research and development. The programme has expanded investment in the medical device business, but it has also run into issues with quality control and regulatory requirements.

United States:

In order to promote advanced manufacturing in a variety of industries, including the production of medical devices, the United States has adopted the "**Manufacturing USA**" initiative in 2014, which includes financial incentives and collaborations between public and private organisations. The project has encouraged innovation, R&D, and job creation, but it has also drawn criticism for its effects on small and medium-sized businesses (SMEs). ((6) *Importance Of Medical Device Parks And Its Contribution To MeDTech Industry Growth | LinkedIn*, n.d.)

The Backlog:

The issue of **smaller businesses being excluded from the PLI programme** becomes even more important for a nation with between 750 and 800 medical device makers, most of whom are involved in medium- and small-sized businesses. Nearly **95%** of **Association of Indian Medical Device Industry's members are MSMEs**, which represents the interests of **1,200 manufacturers**.

The **entrance barriers for MSME** medical products have remained high, notwithstanding the government's replacement of the minimal threshold investment with committed investment in the updated rules. Due to the **high threshold for minimal additional sales** of 60 crore during the first year, 120 crore throughout the second FY, and 180 crore throughout the third FY, 60 crore must be effectively represented as new sales each year for the first three years. (*Companies Chosen Under Rs. 3420 Cr PLI Scheme For Domestic Manufacturing Of Medical Equipment Include Siemens, Wipro, GE, Sahajanand, and Nipro*, n.d.)

It is important to remember that, in contrast to these intimidating figures, a small firm is one that has a turnover of less than \$50 million (and an investment of less than \$10 million), whereas a **micro-enterprise** is one with a **turnover of less than \$5 million** (and an input of less than \$1 million).

Because MSME businesses would otherwise have to establish entirely new plant, machinery, and equipment in addition to new R&D to be eligible for the programme, the fact that the scheme is **only relevant to greenfield investments** is a barrier to their ability to participate in it. (*Updates on Medical Device and IVD Regulation in India*, n.d.)

They have also expressed concerns about how the programme may **affect the costs of medical equipment**, as the scheme's increased production could result in a **surplus of gadgets and a subsequent drop in costs**. (The Center "in-Principle" Approves the Establishment of Medical Device Parks in Four States, n.d.)

METHODOLOGY

The study's data was gathered methodically and from reliable sources. The search for journal articles began in February 2023. For this literature review, articles from The Hindu, The Economic times, India Brand Equity Foundation (IBEF), Mondaq, LinkedIn and PLI scheme issued by the Govt. were used.

Using the search terms "PLI Scheme for Medical device manufacturing, Medical devices, Medical equipment's, PLI Scheme etc." articles were found online. We used Mendeley and Google Scholar as search engines.

The investigation only included publications, articles and research blogs published between 2020 and 2022 in English and translated into English. Throughout the screening process, duplicate reports and grey literature were eliminated. It is based on the PRISMA chart and after removing duplicate studies, only publications suitable for inclusion were considered.

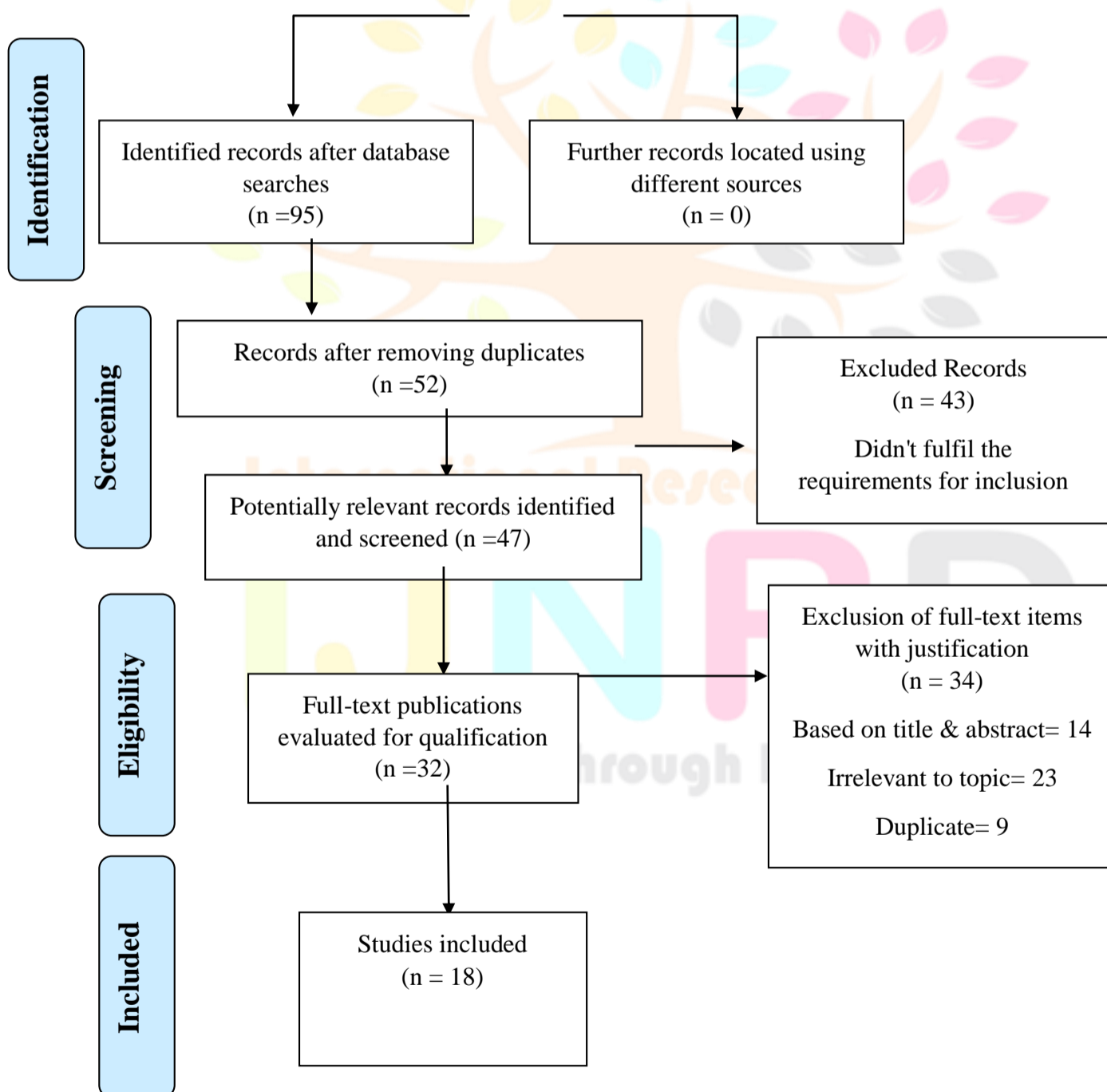
There were 95 articles found with these search criteria. These papers abstracts underwent additional scrutiny to ensure that they complied with the requirements for inclusion. 18 articles satisfied the inclusion criteria out of the 95 that were initially identified.

Inclusion & Exclusion criteria

Studies must fulfil certain requirements to be included in the current study. These criteria limited the number of studies. Such criterias were relevancy with the title, language published, repetition of the content, similarity in articles and number of citations of each article. Accordingly excluded the studies in which based on irrelevant information there is no proper Title, Abstract & Review.

The research database search produced all 95 research articles' keyword search results. There were 52 items left after the duplicates have been removed. All told, 47 articles were reviewed. 43 articles were disqualified for not fitting the criteria. 95 documents were accessed to determine eligibility. 23 were irrelevant to the topic, 9 were duplicates, and 14 were excluded based on the title and abstract. There are 18 articles in the final data set. The figure depicts the entire process.

PRISMA Flow chart



DISCUSSIONS/SUGGESTIONS/CONCLUSION:

It is possible to implement the PLI Scheme for Encouraging Indian Domestic Medical Device Manufacturing, by taking the following factors into account:

Simplification of eligibility criteria:

According to some experts, it may be necessary to simplify the program's qualifying standards in order to encourage the participation of small and medium-sized businesses (SMEs) in the medical device industry. They have argued that the criteria should be based **on turnover, employee count or income** rather than investments.

Greater focus on quality:

Numerous experts believe that the PLI plan should focus on improving the calibre of medical equipment produced in India. They have suggested that the government create a regulatory framework to ensure that medical devices developed in India adhere to the highest international standards.

This would help to increase the users' self-assurance and enhance the standing of the Indian medical device industry.

Greater coordination between government agencies:

Some experts believe that in order to provide a more comprehensive strategy for promoting domestic medical device manufacture, the PLI programme should be integrated with other government entities. To encourage the growth of the Indian medical device business, they advocate cooperation between the Department of Pharmaceuticals (DoP), the Ministry of Health and Family Welfare (MoHFW), and other organisations.

Emphasis on particular medical devices:

Some experts advise that the PLI programme should concentrate on specific medical devices that are heavily reliant on imports into India. They suggested that the strategy should focus on importing substantial amounts of medical devices such as pacemakers, stents, and orthopaedic implants.

Encouragement of innovation:

Many experts have advised that the PLI scheme should focus in order to promote the creation of new goods and technologies, they suggested that the government offer incentives for R&D and knowledge transfer.

Set up financial rewards:

The PLI programme should offer financial incentives to promote the production of expensive medical equipment in India. These inducements may take the shape of **tax reductions, grants, or subsidies**.

Construct infrastructure:

The government should develop the necessary infrastructure to support the growth of the medical device industry in India. This includes developing manufacturing facilities, improving logistics and supply chain management, and providing a skilled workforce.

Collaboration and coordination:

To properly create and implement the PLI scheme, the government should work and coordinate with industry players such as medical device makers, trade organisations, and research institutions. By doing so, the industry's problems will be addressed, and a favourable atmosphere will be created for the growth of India's medical equipment industry.

BIBLIOGRAPHY / REFERENCES:

Importance Of Medical Device Parks And Its Contribution To MedTech Industry Growth | LinkedIn. (n.d.). Retrieved April 27, 2023, from https://www.linkedin.com/pulse/importance-medical-device-parks-its-contribution-medtech-d-l-pandya/?trk=articles_directory

Centre “in-principle” approves four states to set up medical device parks. (n.d.). Retrieved April 27, 2023, from <https://www.thestatesman.com/india/centre-in-principle-approves-four-states-to-set-up-medical-device-parks-1503011259.html>

Financial Assistance for setting up Bulk Drug Parks under PLI - S.S. Rana & Co. (n.d.). Retrieved April 27, 2023, from <https://ssrana.in/articles/financial-assistance-for-setting-up-bulk-drug-parks-under-pli/>

Govt approves eight companies under PLI scheme for manufacturing medical devices - The Economic Times. (n.d.). Retrieved April 27, 2023, from <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/govt-approves-eight-companies-under-pli-scheme-for-manufacturing-medical-devices/articleshow/88187671.cms>

List of Applicants Approved under Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices as on. (2023).

Medical device parks’ scheme notified - The Hindu. (n.d.). Retrieved April 27, 2023, from <https://www.thehindu.com/news/national/medical-device-parks-scheme-notified/article36651325.ece>

Medical Devices: Compliances And Regulations In India - Life Sciences, Biotechnology & Nanotechnology - India. (n.d.). Retrieved April 27, 2023, from <https://www.mondaq.com/india/life-sciences-biotechnology--nanotechnology/1143212/medical-devices-compliances-and-regulations-in-india?login=true&debug-domain=.mondaq.com>

Ministry of Chemicals and Fertilizers issues. (n.d.). Retrieved April 27, 2023, from <https://www.teamleaseregtech.com/legalupdates/article/10086/ministry-of-chemicals-and-fertilizers-issues-scheme-for-promotion-of-medical-device-parks/>

Pharmaceuticals / Make In India. (n.d.). Retrieved April 27, 2023, from <https://www.makeinindia.com/sector/pharmaceuticals>

PLI scheme: Why India's efforts to boost its medical devices industry are falling short. (n.d.). Retrieved April 27, 2023, from <https://scroll.in/article/1028353/why-indias-efforts-to-boost-its-medical-devices-industry-are-falling-short>

Production Linked Incentive: Impact of PLI Schemes On India's Manufacturing Sector. (n.d.). Retrieved April 27, 2023, from <https://khatabook.com/blog/production-linked-incentives-schemes-india/>

Programmatic interventions to encourage domestic manufacturing to reduce import dependency of medical devices - Legality Simplified. (n.d.). Retrieved April 27, 2023, from <https://legalitysimplified.com/2022/12/10/programmatic-interventions-to-encourage-domestic-manufacturing-to-reduce-import-dependency-of-medical-devices/>

Siemens, Wipro GE, Sahajanand, Nipro Among Firms Selected Under Rs. 3420 cr PLI Scheme For Domestic Manufacturing Of Medical Devices. (n.d.). Retrieved April 27, 2023, from <https://swarajyamag.com/insta/siemenswipro-gesahajanandnipro-among-firms-selected-under-rs-3420-cr-pli-scheme-for-domestic-manufacturing-of-medical-devices>

Updates on Medical Device and IVD Regulation in India. (n.d.).

Vora, A., Gupta, A., Ojha, A., Pandey, P., Sagar Marwaha, M., Kadam, S., & Singh, S. (2021). *INDIA'S PHARMA AND MEDICAL DEVICES STRATEGIES: AN ASSESSMENT OF THE PRODUCTION LINKED INCENTIVE (PLI) SCHEME.*

Why PLI scheme for medical device makers won't deliver - The Hindu BusinessLine. (n.d.). Retrieved April 27, 2023, from <https://www.thehindubusinessline.com/opinion/why-pli-scheme-for-medical-device-makers-wont-deliver/article37151696.ece>

