

India
Tamil Nadu Medical Service Corporation

India
Preparatory Survey on Next Generation
Medical Logistics Centre Project
in India (PPP Infrastructure Project)
Final Report

June, 2022

Japan International Cooperation Agency (JICA)

Konoike Transport Co., Ltd.
Konoike Medical Co., Ltd. / Sojitz Corporation

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Abbreviation List

Abbreviation	Long Form
AIIMS	All India Institute of Medical Sciences
BIS	Bureau of Indian Standards
BMW	Bio-Medical Waste
BRAP	Business Reform Action Plan
CDC	Centers for Disease Control and Prevention
CDSO	Central Drugs Standard Control Organisation
CCEA	Cabinet Committee on Economic Affairs
CHC	Community Health Center
CFA	Clearing and Forwarding Agent
CLA	Commissionerate of Land Administration
CMCHIS	Chief Minister's Comprehensive Health Insurance Scheme
CPCB	Central Pollution Control Board
CSSD	Central Sterilization and Supply/Service Department
CTE	Consent to Establish
CTO	Consent to Operate
DALYs	Disability-adjusted Life Years
DDMS	Drug Distribution Management System
DME	Directorate of Medical Education
DMS	Directorate of Medical and Rural Health Services
DPH	Directorate of Public Health and Preventive Medicine
DPIIT	Department for Promotion of Industry and Internal Trade
DPR	Detailed Project Report
EAC	Expert Appraisal Committee
EC	(Prior) Environmental Clearance
EDI	Electronic Data Interchange
EIA	Environmental Impact Assessment
EIRR	Economic Internal Rate of Return
EOG	Ethylene Oxide Gas
ESC	Environmental and Social Considerations
FDI	Foreign Direct Investment
GC	General Condition
GDP	Gross Domestic Product
GNI	Gross National Income
HAIs	Healthcare-Associated Infections
HFWD	Health and Family Welfare Department
HMIS	Hospital Management Information System
HSC	Health Sub Center
HWC	Health and Wellness Center
IAS	Indian Administrative Service
ICMR	Indian Council of Medical Research
IEE	Initial Environmental Examination
IIPDF	India Infrastructure Project Development Fund
IPC	Infection Prevention and Control
IPCAF	Infection Prevention and Control Assessment Framework
IRR	Internal Rate of Return
JICA	Japan International Cooperation Agency
KPI	Key Performance Indicators
LCM	Lower of Cost or Market
LOA	Letter of Award
MCI	Medical Council of India
MD	Managing Director

MoEFCC	Ministry of Environment, Forest and Climate Change
MoHFW	Ministry of Health and Family Welfare
MoRD	Ministry of Rural Development
NBWL	National Board for Wildlife
NCDs	Non-Communicable Diseases
NHM	(National Health Mission
NHP	National Health Policy
NOC	No Objection Certificate
NSO	National Statistical Office
NPV	Net Present Value
OT	Operation Theatre
PHC	Primary Health Center
PPE	Personal Protective Equipment
PPP	Public Private Partnership
QBS	Quality-based Selection
QCBS	Quality and Cost-based Selection
RGGGH	Rajiv Gandhi Government General Hospital
SDGs	Sustainable Development Goals
SEAC	State Expert Appraisal Committee
SEIAA	State Environment Impact Assessment Authority
SIA	Social Impact Assessment
SPC	Special Purpose Company
SPD	Supply Processing and Distribution
SSI	Surgical Site Infection
TN	Tamil Nadu
TNDoE	Tamil Nadu State Department of Environment
TNIDA	Tamil Nadu Infrastructure Development Act
TNIDB	Tamil Nadu Infrastructure Development Board
TNIDF	Tamil Nadu Infrastructure Development Fund
TNMSC	Tamil Nadu Medical Services Corporation
TNPCB	Tamil Nadu State Pollution Control Board
TPS	Toyota Production System
TSEC	Tender Scrutiny and Evaluation Committee
UHC	Universal Health Coverage
VGF	Viability Gap Funding
WHO	World Health Organization

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Chapter 1 Background and Objectives of the Study

1.1 Background

In the Republic of India (hereinafter referred to as "India"), the need for the development of medical infrastructure to cope with the increasing population of people, especially the elderly, is becoming an issue. Specifically, there are issues such as the shortage of medical personnel - doctors and nurses, and poor access to medical care for the poor. In response, the Indian government has been implementing a variety of initiatives, including the establishment of AIIMS (All India Institute of Medical Sciences) and the establishment of a national health-protection program targeting the poor. However, it is undeniable that both quantitatively and qualitatively efforts are underway. In addition, the global pandemic of the new corona (COVID-19) that occurred in early 2020 has led to a serious trend in India, putting an extremely heavy burden on health-care infrastructures. It is also necessary to be prepared for a repeating outbreak, and the importance of India's medical care is increasing even further.

The main reason for the State of Tamil Nadu (hereinafter referred to as "TN") being investigated out of twenty-eight (28) States and nine (9) Union territories that constitute India is that it is a state of advanced medical technology, which has given us an understanding of new approaches in the medical field. The state-specific medical insurance system covers about 35 million persons, which is half of the state population, and the infant death rate, the mother and child health management index, and the indicator of infectious diseases are good in comparison with the other states. New initiatives such as free ambulance service and oral screening through the use of public-private partnerships have been actively introduced, and medical care is advancing even in India as many cases have been adopted in other states.¹

On the other hand, the TN has a population share of over 60 years old, which is more than 10%, and is also one of the aging states (ranked third in the country). According to a report by the Ministry of Foreign Affairs of Japan, TN is one of the most urbanized states in India, and the population growth in slum areas is expected in the future as a result of the population influx from rural areas to urban areas, as well as the increase in the number of people living in poverty. Enhanced access to medical institutions is an important issue, particularly because medical facilities that provide public medical services for the urban poor do not provide sufficient services. In addition, noncontaminants are increasing due to changes in life habits and other factors, and the need for countermeasures including early detection and early treatment of illnesses is increasing.

TN thus has a foundation to accept this project, which provides a new type of medical logistic service. On top of that, since Japan's ODA through JICA has been implemented or is currently being implemented in TN, the state government has experience of receiving financial assistance and technical cooperation from Japan in the health sector and have high expectations. Furthermore, there is also an accumulation of relationships with Japanese private companies, as many of these companies invest directly within TN.

The ultimate decision to locate this project in Chennai was the enthusiastic invitation from the state government, particularly Dr. Vijayabaskar, the Minister (then) of Health and Family Welfare of TN. When he visited Japan in 2018, he inspected the sterilization facility of Konoike Medical Co., Ltd., a Konoike Transport's group company, immediately recognized the validity of the sterilization facility, and strongly requested that this project be implemented in Chennai. (The current status of health services in India as a whole and in TN and the need for this project are

¹ JICA Report "Information Collection and Confirmation Survey Report on TN-State Non-Infective Diseases Prevention Measures (May 2017)" http://open_jica.go.jp/pdf/12302022_the_jicareport.
Ministry of Foreign Affairs report, The Project for Strengthening Urban Health in TN Province
https://www.mofa.go.jp/mofaj/gaiko/oda/press/shiryo/page25_000016.html

detailed in Chapter 2.)²

The reason of providing the services for not private hospitals but state hospitals first is the significance of social and developmental point of view. Patients of state hospitals are from middle- or lower-income families and the quality improvement of those hospitals benefits them directly. Further, proposed sharing of surgical instruments will fit into the group of hospitals that use the same specification and quality of instruments. Also, the scheme of in-hospital logistics seems to be common to all state hospitals. A single prescription of logistics improvement can be applicable to every state hospital.

Prior to this survey, the Konoike Transport Group has conducted two surveys³ (hereinafter referred to as "previous surveys") funded by the Cabinet Secretariat of Japan in TN in view of the contribution to the solution of medical environmental problems in India and how Japanese medical-related technologies and services can be utilized for medical development in India, with the aim of contributing to the development of medical-related industries in Japan. Through these investigations, the concept of "Next-generation Medical Logistics Centre Project" which is the object of this feasibility study has been developed.

At the government level, the Memorandum of Cooperation between the Cabinet Secretariat of Japan plus the Ministry of Health, Labor and Welfare of Japan and the Ministry of Health and Family Welfare of India was concluded in 2018, and "upgrading of healthcare distribution system in India" is specified as a concrete cooperation field among them.

In October 2019, the Japan-India Joint Committee on Healthcare in Tokyo further strengthened the stance of cooperation between the two countries in the field of healthcare. The committee informed the Central Government of India that this project (Next-generation Medical Logistics Centre Project) was an initiative by the TN Government and the Konoike Transport Group, and that it was the subject of support by the Japanese government, and it was to be recognized between the two governments.

At JICA level, it meets the "Support for Sustainable and Inclusive Growth-Development of Fundamental Social Services (Health, Hygiene, Water Supply and Sewerage, etc.)" described in Section 3.(3) of the Indian Country Aid Policy in March 2016.

1.2 Purpose

The formal title of this survey is "Next generation Medical Logistics Centre Project Feasibility Study (PPP infrastructure project) [Preparatory Survey]". As such, a preliminary investigation of JICA's cooperative preparatory survey (PPP infrastructural project) will be conducted as a transition type (hereinafter "Next-generation medical Logistics Centre Project" is referred to as "the Project").

This project aims to provide better medical services to the Chennai metropolitan area through the development of efficient centralized sterilization facilities, medical supply and distribution facilities, and distribution networks for state hospitals in Chennai, specifically the Rajiv Gandhi Government General Hospital ("RGGGH"), and four state hospitals in the city (Stanley Medical College Hospital, Kilpauk Medical College Hospital, Medical College at Omandurar Estate Hospital, Royapettah Hospital) (hereinafter referred to as "four hospitals") as well as other state hospitals.

In this preparatory survey, we will examine whether this project can be implemented as a PPP

² As a result of TN assembly election in April 2021 (vote count in May), the Dravida Munnetra Kazhagam Party (DMK) took back the administration. Vijayabaskar, who belonged to the All India Anna Dravida Munnetra Kazhagam Party (AIADMK), took the position with opposition lawmakers.

³ Survey in the Indian Republic on the Promotion of the International Medical Partnership in FY2018 (FY2018), FY2019 (FY2019) Survey for Comprehensive Improvement of Healthcare in the Indian Republic

project by refining the information obtained from the aforementioned Cabinet Secretariat survey and subsequent survey originally conducted by the Konoike Transport Group. The survey objectives are largely grouped into three.

- (1) Confirmation of feasibility of out-of-hospital sterilization services using the PPP model in TN
- (2) Confirmation of feasibility of the site of the centre
- (3) Preparation of in-hospital logistics plan for RGGGH

1.3 Subject Area and TN State Implementation Organization

1.3.1 Territory

The area covered by the Project is Chennai in TN, southern India, where RGGGH and Four Hospitals (hereinafter referred to as "five hospitals") are located. The biggest point of the out-of-hospital sterilization and sharing service of surgical instruments, which makes it possible to provide safer and more secure surgical instruments in the countermeasure against transmission, is that the improvement of physical distribution and sterilization quality of those hospitals and economical efficiency can be pursued by targeting multiple hospitals rather than single hospitals. Therefore, in addition to RGGGH, which is TN's largest hospital, Four Hospitals in the neighborhood of RGGGH, of which three are attached to the state medical colleges, were also taken into the scope of the Project.

In-hospital logistics can be optimized for the whole hospital by enabling distribution and inventory control using the system in the hospital in RGGGH, which can be said to be the core hospital in TN. However, it is not assumed to replace the function of TN Medical Services Corporation (TNMSC). It complements RGGGH function of TNMSC and covers warehouses in Chennai City in TNMSC and various departments using warehouses, pharmaceuticals, and medical materials in RGGGH. (TNMSC is described in detail in Section 2.)

Candidate site for the centre is planned to be provided by the TN government. Check the status of the land in Chennai City provided by the state and conduct surveys on the infrastructure required for the operation of external sterilization facilities and access to hospitals.

The positional relationship of five hospitals to be investigated in Chennai City is shown in Figure 1-1.

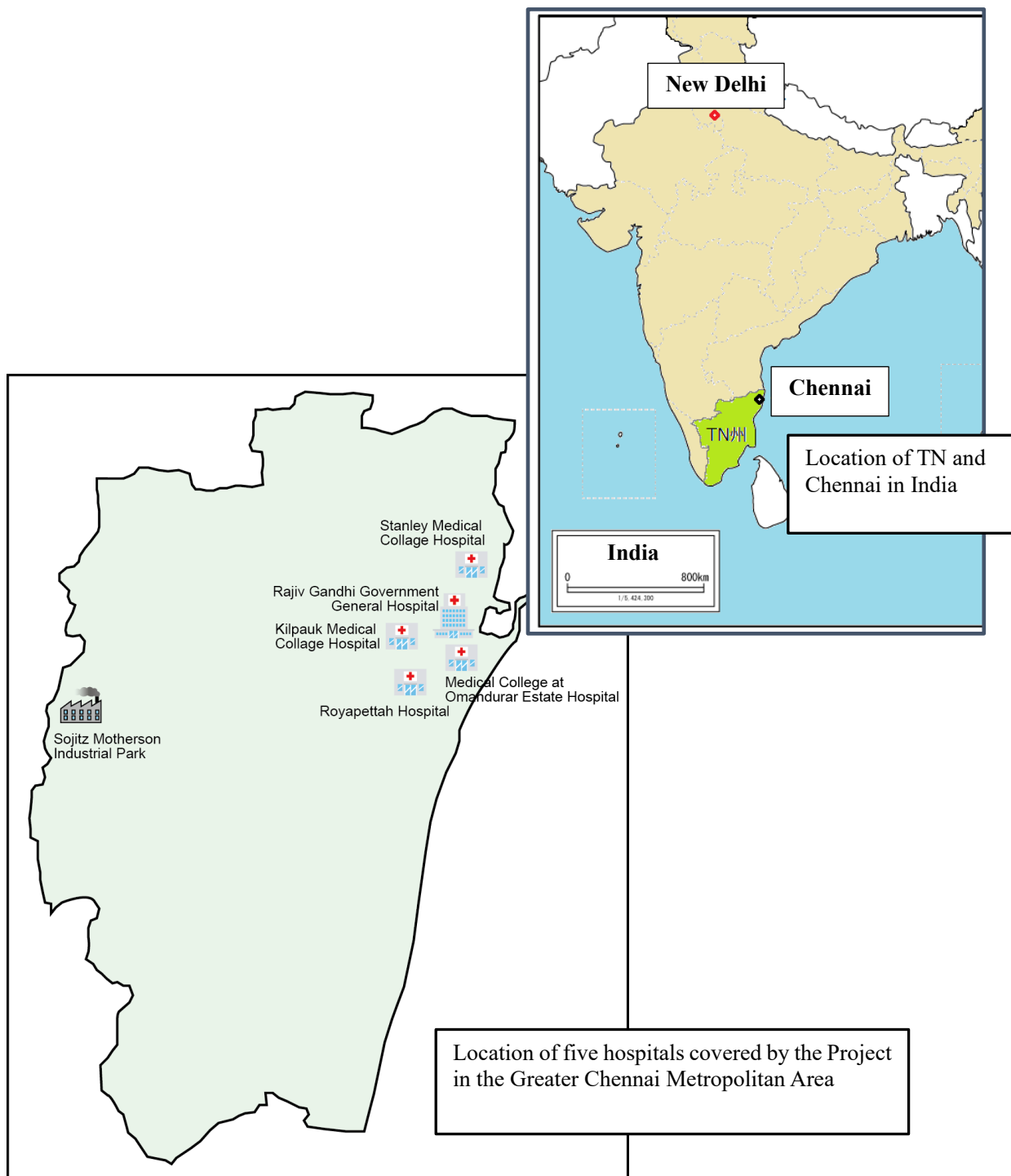


Figure 1-1 Location of five hospitals to be investigated

Sources: Survey Team

1.3.2 TN State Implementation Organization

This project aims to improve in-hospital logistics by providing out-of-hospital sterilization services for state hospitals. Since the State Hospital is under the jurisdiction of the TN Health and Family Welfare Department (HFWD), it was once considered that HFWD would become the state-side implementation organization before the start of this survey. However, HFWD is an administrative organization and there are no divisions/sections organizationally dealing with the creation and implementation of new projects. In addition, important decision-making had to be raised to the Principal Secretary to Government, and there was a possibility that organizational decision would take a long time. On the other hand, TNMSC that is supposed to complement the functions in this project is an independent public corporation, although under state jurisdiction, and the decision can basically be made by the MD (Managing Director). Based on these, TNMSC finally positioned JICA as a TN Implementation Organization, and its MD became a signatory of Minutes of Meeting (M/M) exchanged prior to the implementation of this survey.

As of April 2022, Dr. Radhakrishnan, IAS, is in the position of Principal Secretary to Government. MD of TNMSC is Mr. Deepak Jacob, IAS. Dr. Umanath, IAS, was the MD of TNMSC when M/M of JICA was signed.

1.4 Survey schedule

This survey was carried out on the following schedule.

2021	4 November	Conclusion of a consignment contract between JICA and a joint venture
	14-29 November	First field survey
	2-16 December	Second field survey
2022	14-26 March	Third field survey

As mentioned above, the M/M of JICA was signed in February 2020, and at that time the first field survey was planned to be conducted in May or June of the same year. However, it was forced to delay about a year and a half by the pandemic of the new corona viruses (COVID-19) soon after. In addition, the third field survey was scheduled for January 2022, but it was further postponed for two months due to the spread of the new corona viruses-omicron strain. The counterpart of this survey is state hospitals, and it is necessary, of course, to give top priority to the new corona countermeasures, and it is unavoidable that a considerable amount of time was required before the hospital side became ready to accept the investigation team.

Chapter 2 Current Status of the Healthcare Sector and the Rationale for the Project

2.1 General Situation in India and TN State

2.1.1 Socio-economic conditions

India's population is estimated at 1,210.57 million (2011 Census), with an estimated population of approximately 1,380 million in 2020. It also has a high percentage of the working-age population (15-64 years) (67.2%)⁴. India is expected to surpass China as the world's most populous country around 2027⁵. Population expansion has been one of the factors supporting economic growth, and the Indian economy has maintained stable growth, but the economy contracted for the first time in 40 years in 2020 due to the impact of COVID-19. In particular, during the second wave of COVID-19 that began in March 2021, there was a series of lockdowns to restrict outings and factory closures throughout India, and economic activity temporarily stagnated. Although the economic impact of the second wave was severe, the economy is on the road to recovery, and in its latest Economic Survey, the Indian government has projected real economic growth of +9.2% in FY2021-22, +9.2% and +8.0-8.5% in FY2022-23⁶.

In the recent COVID-19 pandemic, many cities suffered a collapse of healthcare during the second wave, exposing the fragility of the healthcare system, including a lack of healthcare infrastructure and workforce. Going forward, there is a need to rapidly strengthen the healthcare system and provide efficient healthcare services through the development of healthcare infrastructure and expansion of healthcare personnel to match the growing population.

Table 2-1 Socio-economic Indicators

Indicators	India	Japan	Year
Geographical area	3,287,000 km ²	378,000 km ²	-
Population	1,380 million	125.83 million	2020
Population growth	0.99%	-0.34%	2020
Working age (15-64) population ratio	67.2%	59.4%	2020
GDP (current USD)	2,660,245 million USD	5,057,758 million USD	2020
GNI per capita, Atlas method (current USD)	1,920 USD	40,360 USD	2020

Sources: [World Bank, 2022]

TN, the project site, is located in southeastern India, with an area of 130,000 km² (equivalent to about 4% of the total land area) and a population of 72.14 million (equivalent to about 6% of the total population). TN is the most urbanized state in India (48.5% urban population), and 20.3% of the urban population, or 7.3 million people, are considered poor⁷.

TN is the second-largest state economy, accounting for 9.84% of India's gross domestic product (GDP) (FY2020-21). Amidst the disruption brought on by the COVID-19 pandemic, TN's economy grew by 5.28% in FY 2020-21, higher than other industrial states such as Andhra Pradesh and Uttar Pradesh. The secondary sector accounts for 29.5% of the State GDP, with manufacturing contributing 18.2%. TN has the largest number of factories in India (38,131), a number of people engaged in the industrial sector (about 2.55 million), and has a strong presence across various industry sectors, including the automotive, textile and garment industries⁸.

In March 2012, the TN formulated and published a medium-term economic plan called "Vision

⁴ World Bank Open Data. (online) March 15, 2022. <https://www.worldbank.org/en/home>.

⁵ World Population Prospects 2019: Highlights. 2019

⁶ Ministry of Finance. 2022. Key Highlights of the Economic Survey 2021-22. (online) January 30, 2022. (Cited: March 15, 2022.)

⁷ 2011 Census

⁸ Government of Tamil Nadu. 2021. Industries Department Major Industries Policy Note 2021-2022. 2021.

2023”. The plan aims to “become India’s most prosperous and progressive state with no poverty by 2023” and includes the following goals: (1) the per capita income of TN’s residents will reach 10,000 USD per annum (at 2010 prices) – the current median income of Upper Middle-Income countries - by 2023; (2) TN will attain a high standard of social development, with the Human Development Index of the state matching those of developed countries by 2023; and (3) TN would provide to its residents, high-quality infrastructure all over the state comparable with the best in the world.

2.1.2 Current status of healthcare

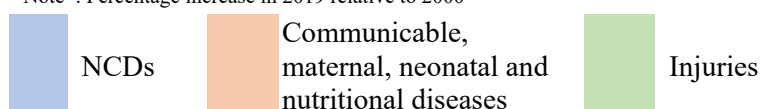
In India, health indicators have improved over the past several decades, including increased life expectancy and decreased maternal and under-five mortality rates. However, there are disparities in health status due to differences in regional and socio-economic conditions. Furthermore, the disease burden from infectious diseases such as tuberculosis and malaria remain significant, and the burden of noncommunicable diseases (NCDs) is increasing, making the double burden of disease a challenge⁹.

In India, NCDs are on the rise, surpassing infectious diseases, and the disease structure has been changing. According to the World Health Organization (WHO), NCDs account for 63% of all deaths in India (cardiovascular disease 27%, chronic respiratory disease 11%, cancer 9%, diabetes 3%, other NCDs 13%), infectious diseases, maternal and nutrition-related diseases 26%, and injuries 11%¹⁰. Comparing causes of death between 2000 and 2019, there have been significant increases in mortality from cardiovascular disease, chronic respiratory disease, cancer, and diabetes and kidney diseases (Table 1-2).

Table 1-2 Changes in Causes of Death in India from 2000 to 2019

Rank in 2000	Rank in 2019	Change*(%)
1 Cardiovascular diseases	1 Cardiovascular diseases	53.1
2 Respiratory infections & TB	2 Chronic respiratory infections	42.3
3 Enteric infections	3 Cancer	69.7
4 Maternal and neonatal disorders	4 Respiratory infections & TB	-33.9
5 Chronic respiratory infections	5 Enteric infections	-41.2
6 Cancer	6 Diabetes and kidney diseases	71.9
7 Other infectious diseases	7 Maternal and neonatal disorders	-49.7
8 Unintentional injuries	8 Unintentional injuries	3.8
9 Digestive diseases	9 Digestive diseases	9.7
10 Diabetes and kidney diseases	10 Self-harm and injuries	-12.4

Note*: Percentage increase in 2019 relative to 2000



Sources: [ICMR, PHFI, and IHME, 2020]

⁹ NITI Aayog, Health System for a New India: Building Blocks. 2019-2021, 2019

¹⁰ WHO, Noncommunicable Diseases (NCDs) Country Profiles, 2018.

The major health indicators for India and TN are shown in Table.

Table 2-3 Major Health Indicators for India and TN

Indicator	India	TN	Year
Average life expectancy (years) Total	69.4	72.1	2014-18
Male	68.2	70.2	
Female	70.7	74.2	
Maternal mortality rate (per 100,000 live births)	113	60	2016-18
Neonatal mortality rate (per 1,000 live births)	22	10	2019
Infant mortality rate (per 1,000 live births)	30	15	2019
Under-five mortality rate (per 1,000 live births)	35	16	2019
Mothers who had at least 4 antenatal care visits	58.1%	89.9%	2020-21
Institutional births	88.6%	99.6%	2020-21
Births attended by skilled health personnel*	89.4%	99.8%	2020-21
People with high blood sugar levels** Male	15.6%	22.1%	2020-21
Female	13.5%	20.7%	
People with high blood pressure*** Male	24.0%	30.2%	2020-21
Female	21.3%	24.8%	

Note: * Doctor/nurse/lady health visitor/auxiliary nurse midwife/other health personnel,

**15 years of age or above with a blood sugar level of 140 mg/dl or higher or taking medicine to lower blood sugar level,

*** 15 years of age or above with systolic blood pressure of 140 mmHg or higher or diastolic blood pressure of 90 mmHg or higher or taking medicine to control blood pressure.

Sources: [Office of the Registrar General & Census Commissioner, 2020], [Office of the Registrar General & Census Commissioner, 2022], [IIPS and ICF, 2020]

In TN, maternal and child health indicators such as maternal and infant mortality rates are well below the national average. In the National Health Index, an assessment of the health status and health system performance of states by the NITI Aayog, TN's ranking is second in the country, after Kerala¹¹. As shown in Figure 2-1, the burden of disease¹² due to infectious diseases and maternal and nutrition-related diseases is lower in TN than in other states. However, TN has the highest disease burden for cardiovascular disease and diabetes and the highest disease burden for all NCDs and injuries in the country¹³.

¹¹ NITI Aayog, Healthy States, Progressive India: HEALTH INDEX ROUND IV 2019-20, 2021

–, 2021. Healthy States, Progressive India: HEALTH INDEX ROUND IV 2019-20, 2021

¹² Disability-adjusted life years (DALYs), a measure of the loss of health (burden of disease) due to a specific disease or injury, is used.

¹³ ICMR, PHFI, and IHME, 2020, GBD India Compare Data Visualization, 2020

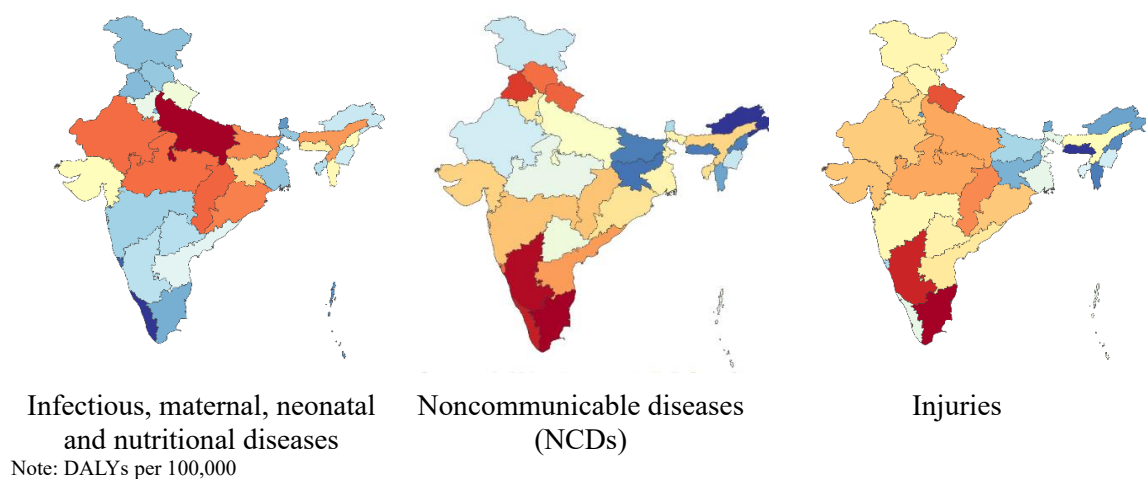


Figure 2-1 Disability-adjusted life years (DALYs) for infectious diseases, maternal and nutrition-related diseases, noncommunicable diseases (NCDs), and injuries (2019)

TN is one of the most aged states in India, with 10.4% of the population aged 60 years and above¹⁴ (3rd in the country, 2011 Census) and 13.6% (estimated in 2021)¹⁵, which makes the need to address NCDs even greater. In addition, advanced diagnosis and treatment are needed to lower the number of premature deaths.

With regard to the provision of health care services, the shortage of the health workforce is a chronic issue. In terms of the number of doctors, nurses and midwives per 10,000 population, only Kerala (65) meets the WHO recommendation of 44.5, while other states do not meet the standard; even TN is below the appropriate level with 32¹⁶. In order to address the shortage of health workforce, in addition to training of human resources, proper allocation of human resources and improvement of operational efficiency are required.

Regarding healthcare infrastructure such as healthcare facilities, private hospitals account for approximately 75% of all hospitals in India¹⁷. According to a survey by the National Statistical Office (NSO), 66% of the population uses private hospitals and healthcare facilities. For example, the cost per hospitalization in private hospitals is seven times higher than that in public hospitals, and even though private hospitals are more expensive, the use of private hospitals is higher in all income groups. However, lower-income groups tend to use public hospitals more. In TN, more people use public hospitals and medical facilities (54% public and 45% private) than in other states, but about half of the population uses private hospitals. Reasons for using private hospitals include poor quality of service in public hospitals, long waiting times, and lack of necessary specialists, forcing people to go to private hospitals¹⁸. Therefore, it is essential to improve healthcare services in public hospitals in order to reduce the out-of-pocket costs of healthcare for poor households and improve their access to healthcare.

2.2 Policies and Systems in the Healthcare Sector

2.2.1 Relevant healthcare policies

Since independence, the development of the healthcare sector has been a priority area in policymaking for the Indian government. It has issued three National Health Policies (NHPs),

¹⁴ The national average for the percentage of the population aged 60 and over was 8.6% in 2011 and 10.1% in 2021.

¹⁵ NSO, 2021

¹⁶ DEMO, 2021, Health Sector Report, 2021

¹⁷ METI. 2022. Healthcare International Expansion Country Report, Basic Information on the Healthcare Market Environment in Emerging and Other Countries, India Edition (in Japanese). 2022.

¹⁸ I. Anand and A. Thampi, Less than a third of Indians go to public hospitals for treatment, 2020

which are guiding documents for steering the country's health care system and policies. The first NHP was published in 1983, the second in 2002, and the latest, the third, in 2017. The third NHP stated the objective of achieving the highest level of health status through universal access to quality healthcare services for everyone without facing financial difficulties, as well as to increase public health-related expenditures to 2.5% of GDP by 2025 (1.87% in FY 2019-20¹⁹), free drugs, diagnostic and emergency services in all public hospitals, and increased collaboration and partnerships with the private sector.

Ayushman Bharat, announced in 2018, involves both the public and private sectors to improve the quality of healthcare through a comprehensive approach to health promotion, disease prevention, primary, secondary, and tertiary care, and to ensure that citizens receive quality healthcare. Ayushman Bharat consists of two components: (1) strengthening primary healthcare through the establishment of Health and Wellness Centers (HWCs) and (2) providing health protection cover to the poor and vulnerable families for secondary and tertiary care through the establishment of PM-JAY²⁰.

PM-JAY is an initiative to achieve Universal Health Coverage (UHC). It covers about 107.4 million poor households (about 500 million people) and provides up to Rs. 500,000 (about 810,000 Japanese yen²¹) per household per year for medical expenses, including three days of pre-hospitalization care and 15 days of post-hospitalization care and drugs, when a person is hospitalized to a registered public hospital or private hospital.

In addition, the Government of India formulated the Strategy for New India @75 in 2018 and set development goals for 2022-23. In the healthcare sector, the government has prioritized the steady implementation of Ayushman Bharat, strengthening of human resources for health, provision of comprehensive primary health care services, implementation of PM-JAY to achieve UHC, strengthening of public healthcare facilities, and involvement of the private sector and among others. Thus, the Indian government is strongly aware of private-sector collaboration and procurement efficiency to improve the efficiency of the healthcare system in public hospitals, the healthcare provider side, while also preparing measures for the poor, who are the primary recipients of healthcare services in public hospitals.

On the other hand, in its aforementioned "Vision 2023" (2012), TN has adopted the theme of "Health for all" and aims to ensure universal access to healthcare facilities by working to develop world-class infrastructure for the provision of quality healthcare services. Accordingly, the following three areas of investment in healthcare infrastructure have been identified.

- (1) Creation of new healthcare facilities
 - Establishment of new medical colleges (15)
 - Development of two Medi-cities with a mission to contribute to the medical tourism industry, including investments in hospital facilities, educational facilities, logistics, and hospitality services.
- (2) Upgrade of healthcare facilities
 - Upgrade of existing medical college hospitals to international standards
 - Strengthening primary and secondary healthcare facilities involves increasing the bed strength, addition of laboratory and radiology infrastructure, etc.
- (3) Other projects
 - Quality improvement of public health institutions
 - Introduction of Electronic medical records management and hospital management system

¹⁹ CBHI, National Health Profile 2021, 2021

²⁰ Ayushman Bharat –Pradhan Mantri Jan AarogyaYojana (AB-PMJAY) to be launched by Prime Minister Shri Narendra Modi in Ranchi, Jharkhand on September 23, 2018. (online) September 22, 2018. (cited: March 15, 2022.)

²¹ Rps. 1 = 1.61465 Japanese yen (JICA exchange rate in April 2022)

In addition, HFWD of TN has developed the “Tamil Nadu State Health Policy Vision 2030” based on the 3rd NHP, Sustainable Development Goals (SDGs), and TN’s “Vision 2023” and others. The policy was formulated against the backdrop of various issues such as the increasing burden of disease due to NCDs in TN, remaining challenges in maternal and child health, high out-of-pocket expenses due to increased healthcare costs in the private sector, and the need to strengthen public healthcare services at all levels.

Table 2-4 Vision and Objectives of TN Health Policy Vision 2030

Vision	Accelerating improvements in the health status of the people of TN with a special focus on the most vulnerable and marginalized in the society, towards building a healthy and equitable society, improving quality of life through a comprehensive, robust and sustainable health systems approach which is accessible, affordable and quality-driven.
Objectives	<ol style="list-style-type: none"> 1. To strengthen the health system to provide quality-driven and people-centric care and delivery of preventive, promotive, curative, rehabilitative and palliative health care services to all the people. 2. To ensure universality of access and inclusiveness in providing healthcare with concentrated policy directives to address social, economic and environmental determinants of health. 3. To strengthen the quality of care with a greater focus on the clinical processes, competent care, and patient experience through the continuous quality improvement of health facilities, services, programmes, schemes, medical logistics and supplies, medical education and continuing professional development. 4. To strengthen the system readiness to address the existing epidemiologic burden and emerging health issues and challenges and to create innovative and appropriate models of health care delivery. 5. To strengthen advocacy and health education of the public, create awareness of health issues and promote preventive health behaviours. 6. To promote citizen engagement to improve accountability and citizen empowerment through more community-centric initiatives in the health sector with multi-stakeholder collaboration.

Sources: [HFWD, n.d.]

The TN government established the Chief Minister’s health insurance scheme for the poor in 2009. Since 2012, the Chief Minister’s Comprehensive Health Insurance Scheme (CMCHIS) has been in place for families with an annual household income of less than Rs. 72,000 per family and provides up to Rs. 100,000 per family per year. PM-JAY has been operationalized by the TN government integrated along with CMCHIS since September 2018. Approximately 7.77 million households have been identified as eligible; as of 2021, 1,059 hospitals (267 public and 792 private) are registered under the scheme, covering a total of 1,450 medical and surgical treatment procedures, with an annual maximum of Rs. 500,000 per household²².

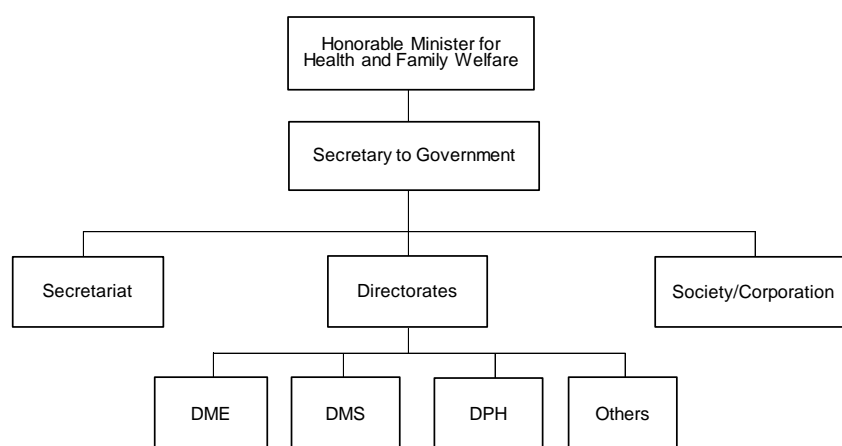
2.2.2 Healthcare administration and service-related organizations

In India, under the Constitution, the Ministry of Health and Family Welfare (MoHFW) of the central government is responsible for formulating health policies and regulations and is not directly involved in the provision of health care services. The state government’s Department of Health and Family Welfare (HFWD) is responsible for health service delivery²³.

²² HFWD, Policy Note 2021-2022. 出版地不明: Government of Tamil Nadu, 2021

²³ DMEQ, Health Sector Report, 2021

The organogram of the TN HFWD is shown in Figure 3. A number of directorates, societies, corporations and others are established in HFWD. The Directorate of Public Health and Preventive Medicine (DPH) is responsible for providing primary health care and public health, the Directorate of Medical and Rural Health Services (DMS) is responsible for providing secondary care, and the Directorate of Medical Education (DME) is responsible for providing tertiary care²⁴. The TN HFWD has a staff strength of over 123,000 health workforce catering for an average of 650,000 outpatients and 70,000 inpatients per day. The TN government’s health budget is on the rise: in FY 2019, it was Rs. 125.6 billion (about 208.2 billion Japanese yen), an increase of about 11% from the previous year²⁵.



Sources: [HFWD, 2021], [HFWD, n.d.]

Figure 2-2 Organogram of the Health and Family Welfare Department (HFWD), TN

Healthcare facilities in India are broadly classified into public and private healthcare facilities, and public healthcare facilities are classified into five tiers (medical college hospitals, district hospitals, community health centers, primary health centers, and sub centers). Medical college hospitals provide tertiary care, district hospitals provide secondary care, and community health centers and below provides primary care²⁶.

Table shows the types and numbers of public healthcare facilities by the level of care in TN. The target hospitals for this project are five of the 62 tertiary-level medical college hospitals that provide highly specialized medical care.

²⁴ HFWD, 2021

²⁵ HFWD, Tamil Nadu State Health Policy Vision 2030, n.d.

²⁶ METI, Healthcare International Expansion Country Report, Basic Information on the Healthcare Market Environment in Emerging and Other Countries, India Edition (in Japanese). 2022.

Table 2-5 Type and Number of Public Healthcare Facilities in TN

Level	Facility	Number of Facilities	HFWD Directorate in charge
Tertiary	Government Medical College	25	DME
	Hospitals attached with the Medical Colleges	62	
	Multi Super Specialty Hospital	1	
Secondary	District Headquarters Hospitals	18	DMS
	Taluk Hospital	205	
	Non-Taluk Hospital	67	
Primary	Community Health Center (CHC)	400 (urban 15, rural 385)	DPH
	Primary Health Center (PHC)	2,330 (urban 1,870, rural 460)	
	Health Sub Center (HSC)	8,713	

Note: Excluding specialty hospitals and dental hospitals. A medical school has multiple attached hospitals.

Sources: [HFWD, 2021], [CBHI, 2021]

(1) Tertiary healthcare facilities

At the tertiary level, there are 62 medical college hospitals and one multi-super specialty hospital. In its “Vision 2023”, the TN government has set the goal of establishing new medical colleges and increasing the number of medical college hospitals, as well as upgrading existing medical college hospitals to international standards.

(2) Secondary healthcare facilities

There are three types of secondary healthcare facilities in TN: 1) District Headquarters Hospitals, 2) Taluk hospitals, and 3) Non-Taluk hospitals. The number of hospitals in each category is 18 for the District Headquarters Hospital, 205 for the Taluk Hospital, and 67 for the Non-Taluk Hospital²⁷.

(3) Primary healthcare facilities

At the primary level, there are 8,713 Health Sub Centers (HSCs), 2,330 Primary Health Centers (PHCs), and 400 Community Health Centers (CHCs)

- HSCs are the most peripheral healthcare facilities that provide maternal and child health care services to the rural population. One facility is established for every 5,000 people (or one facility for every 3,000 people in hilly areas).
- One PHC is established for every 30,000 people in rural areas (and one for every 20,000 people in hilly areas). Doctors, nurses, and other health personnel are assigned to provide preventive and curative services.
- CHCs are established as a referral facility for four PHCs, one for every 80,000 to 120,000 people. CHC is staffed with four specialists (surgeon, internist, gynecologist, and pediatrician) and other medical personnel, provides outpatient care 24 hours a day, has 30 hospital beds, and offers services such as laboratory tests and X-rays.

Ayushman Bharat intends to transform current sub centers and PHCs into Health and Wellness Centers (HWCs) to provide comprehensive primary care at locations closer to residents. Specifically, services at HWCs cover both maternal and child health and NCDs, including free essential medicines and diagnostic services²⁸. In TN, the policy is to transform HSCs and PHCs

²⁷ HFWD, Policy Note 2021-2022, unknown place of publication: Government of Tamil Nadu, 2021

²⁸ MoHFW. 2019. Ayushman Bharat - Health and Wellness Centre. (online) 2019. (cited: March 15, 2022.) <https://ab-hwc.nhp.gov.in/home/aboutus>.

into HWCs and provide additional services as directed by the central government²⁹.

2.2.3 Healthcare services-related laws and regulations

There are many laws and regulations related to healthcare services in India. In this project, an independent sterilization facility (plant) will be constructed and operated outside the hospital, and all surgical instruments will be owned, managed, and rented out (sharing). Hospitals will outsource part of the reprocessing (cleaning, assembly, sterilization, etc.) of surgical instruments that have been conventionally performed in the hospital. Below is an overview of the laws and regulations related to the out-of-hospital sterilization business covered by this project. For laws and regulations related to environmental and social considerations, please refer to the chapter “9. Environmental and Social Consideration”.

(1) Construction and installation of sterilization facility (plant)

The five hospitals in this project are all medical college hospitals³⁰. The “Minimum Standard Requirements for the Medical College” of the Medical Council of India (MCI)³¹, which regulates medical education, stipulates that teaching hospitals, or medical college hospitals, should establish a central sterilization room.

In addition, guidelines and standards for the construction of sterilization departments have been established based on the size and use of hospitals and healthcare facilities. The “Bureau of Indian Standards (BIS), 2003” defines the facilities, number of rooms and area within the Central Sterilization and Supply Department (CSSD) in general hospitals³².

As noted above, regulations exist for sterilization departments and CSSD established within hospitals and healthcare facilities, but no laws or regulations were identified for stand-alone sterilization facilities established off the premises of a healthcare facility.

(2) Cleaning, disinfection, sterilization and sharing of surgical instruments

The medical instruments handled in this project are surgical instruments and fall under the category of critical instruments in Spaulding³³’s classification. Regarding the cleaning, disinfection, and sterilization of medical devices in healthcare facilities, the “National Guidelines for Infection Prevention and Control in Healthcare Facilities (2020)” states that “semi-critical and critical instruments (in Spaulding’s classification) should be disinfected or sterilized at a high level in CSSD, or dedicated areas as needed. In addition, the same guideline provides sterilization procedures for non-critical and semi-critical instruments³⁴.

Although guidelines exist that specify procedures for the cleaning, disinfection, and sterilization of medical instruments in healthcare facilities, no laws or regulations were identified that clearly stipulate that hospitals and healthcare facilities should not outsource the reprocessing of surgical instruments.

In addition, although the project involves the sharing of surgical instruments among the five target hospitals, no laws or regulations regulating the sharing of surgical instruments among hospitals and medical facilities were identified.

(3) Sterilization equipment and devices used in sterilization facilities (plants)

The regulatory authority for medical devices in India is the Central Drugs Standard Control Organisation (CDSCO) under the MoHFW. In addition to CDSCO, the Medical Equipment and Hospital Planning Division of the Bureau of Indian Standards (BIS) is responsible for the

²⁹ HFWD, 2021

³⁰ Royapettah Hospital is attached with Kilpauk Medical College.

³¹ National Medical Commission (NMC) after 2020.

³² CPWD, Compendium of Norms for Designing of Hospitals & Medical Institutions, 2019

³³ In Spaulding Classification, three categories, i.e., non-critical, semi-critical and critical, are specified depending upon the level of contact between surgical instruments and the patients. Necessary disinfection and sterilization intensity depends on the category.

³⁴ NSDC, 2020

standardization of medical equipment, including surgical instruments.

Medical devices in India are governed by the Medical Devices Rules, 2017. CDSCO issued a notification on February 11, 2020, amending the Drugs and Cosmetics Act, 1940 and the Medical Devices (Amendment) Rules, 2020, were promulgated. As a result of this amendment to the Drugs and Cosmetics Act of 1940, all medical devices, including sterilizers, have become regulated as “Drugs” as defined in the Act since April 1, 2020. Manufacturers and importers are required to register medical devices under the Act on the online portal opened by the CDSCO, except for those specified by the Medical Devices (Amendment) Regulations 2020 in its supplementary provisions. Registration is voluntary for 18 months from April 1, 2020, but will be mandatory thereafter. Previously, not many medical devices were regulated in India, but the Medical Devices Regulations, 2017, came into effect in January 2018, expanding the scope of regulation³⁵.

Although the Medical Device Regulations of 2017 govern the manufacture, importation, and sale of medical devices, no regulations or rules were identified that govern sterilizers and equipment used in sterilization plants (facilities).

2.3 Current Status and Challenges of Medical Distribution Services.

2.3.1 Current Status and Challenges of TN State Medical Distribution Services.

Previous surveys have shown that factors that commonly complicate India distribution include the presence of many healthcare distribution intermediates, such as agents (CFAs: Clearing and Forwarding Agent manufacturers' distributors), dealers and distributors. This is by no means limited to India, and Japan was in a similar situation until the 20th century.

In order to address this issue in TNs, Tami Nadu Medical Services Corporation (TNMSC) was established in 1994, and a central purchase system was adopted for all public hospitals in the state. Regarding the five hospitals surveyed, about 90% of pharmaceuticals and medical supplies procured via TNMSC on a monetary basis and the remaining 10% are directly procured by hospitals (Local Purchase). All procurements from TNMSC are electronized and are efficiently procured in large lots to meet statewide demands. In addition, a warehouse is set up at 32 locations in the province (including three locations in Chennai) to provide complete coverage within the province.

This is the medical logistics service in the state of TN with advanced efforts, but it is not without challenges. The first is the risk of long-term inventory. This has been attributed to the tightness of storage warehouse spaces, which makes it difficult to ensure adequate storage volumes in current warehouses, as the demand for pharmaceuticals and medical materials also expands according to the ever-increasing number of patients in state hospitals. Mountain cardboard boxes are collapsed in the lowest box, making it difficult to practice first-in and first-in to prevent expiration.

The following is a deterioration of the working environment due to insufficient 5S. It is related to the tightness of the warehouse space mentioned above, and in some cases, there is a risk of accident such as the drop of a weighty box on top of the worker.

In addition, the length of the delivery lead time is also indicated. In our country, pharmaceuticals and medical materials are delivered the day after ordering from the medical institution or two stock days after. In contrast, TNMSC may be up to 15 days. This makes it necessary for hospitals to retain large quantities of stock (which compresses the hospital's warehouse space and makes it difficult to manage inventory).

Finally, security risks are mentioned. Inadequate monitoring cameras and entrance/exit security systems in TNMSC warehouses and inadequate locking control do not eliminate the risk of theft of pharmaceuticals and medical materials. If a part of the poor stock of the management condition,

³⁵ JETRO, Promulgation of Medical Devices (Amendment) Rules, 2020 (India) (in Japanese). (online) February 21, 2020 (cited: April 1, 2022.) <https://www.jetro.go.jp/biznews/2020/02/a6c09d1a16947459.html>.

which is considered to be the product waiting for the manufacturer's return, is missed in the community, it may lead to an unexpected medical adverse event.

2.3.2 Current Status and Challenges of In-hospital Logistics

The in-hospital logistics was examined on the basis of the case of the Chennai's largest public medical institution, RGGGH. Of the four remaining hospitals, Stanley, Kilpauk, Royapettah has a separate size of more than thousands, and the challenges identified in RGGGH are likely to be present as well. Only Omandurar Hospital is relatively small, and RGGGH events may not apply.

First, the problem in the procurement of the medical product is mentioned. More specifically, there are many deficiencies due to delivery, small numbers of supplies from TNMSC and low quality due to prioritization, and an increase in the burden due to direct purchases, all of which are issues between hospitals and TNMSC.

Next, the problem of insufficient management in the hospital is mentioned. Problems such as accident risk due to delayed information systems, risk of missed opportunities to provide medical services due to missing products, and multiple out-of-speciality operations are pointed out.

Finally, the problem of the traceability management is mentioned. In the case of direct hospital procurement, the possibility of contamination of counterfeit or poor-quality products cannot be denied. In addition, the risk of theft cannot be eliminated due to inadequate monitoring cameras, entrance security systems, and insufficient locking management.

The challenges of in-hospital logistics are discussed in detail in Section 4 of Chapter 4.

2.3.3 Need for this project

The project consists of three components (plan at the start of this survey):

- (1) Improving RGGGH in-hospital logistic
- (2) Construction and operation of an out-of-hospital sterilization center including bundled ownership, management, and lending of surgical instruments.
- (3) Construction and operation of logistics centres (integrated with the above-mentioned out-of-hospital sterilization centers)

Of these, the need for (1) is discussed in detail in Section 5 of Chapter 4 and is not mentioned here. Regarding (1) and (3), as mentioned above, there is much room for improvement in the current situation, and the application of the services provided in our country by the proposed companies is considered to be able to be improved. When describing (1) specifically, an integrated management system of hospital stock is introduced to manage the stock constant. At the same time, technical cooperation, such as introduction and thoroughness of 5S, can improve the in-hospital logistics. Regarding (3), the five hospitals covered in (2), TNMSC handles only the pharmaceuticals and medical materials handled by the logistics centre, thereby reducing the burden on existing TNMSC warehouses and settle the issues between TNMSC and hospitals noted in 2.3.2 for the five hospitals.

All three components were proposed by the proposed companies to the state of TN based on the services being provided in our country. However, it is also possible to perform each independently. The proposal for integrating (2) and (3) is that if it is newly constructed, the construction and operation can be efficiently carried out in a single location, and the sterile surgical instruments and pharmaceuticals and medical materials can be delivered simultaneously (by the same transport means) to the hospital.

Chapter 3 Regulatory Framework for the PPP

3.1 PPP Regulatory Setup

3.1.1 Application of State Laws and Ordinances

The Public-Private Partnership (PPP) framework in India has two layers: central and state levels. Central Government's PPP regulations apply to all central sector PPP projects, i.e., PPP projects sponsored by Central Government Ministries or Central Public Sector Undertakings; and its procedure for project appraisal has been approved by decision of Cabinet Committee on Economic Affairs (CCEA) on 27 October 2005 and further modified on 22 March 2007³⁶.

On the other hand, PPP framework of TN is based on Tamil Nadu Infrastructure Development Act, 2012 (TNID Act) which applies to all PPP projects implemented by the Government of TN.

In accordance with TNID Act and the said Central Government's guidelines, since the proposed project is: (a) to be located within the State, (b) to be sponsored by Health and Family Welfare Department (HFWD) of the Government of TN or its public agency, and (c) not to be undertaken by the Central Government either fully or partially, therefore, the project is deemed to follow the PPP procedure set forth under the state laws and ordinances of TN. In the present section, salient particulars of the PPP framework of TN are discussed in relation with preparation and implementation of the project.

3.1.2 Legal Basis, Rules and Regulations

Laws, rules and regulations related to PPP project formulation, appraisal and implementation of TN are as follows:

- Tamil Nadu Infrastructure Development Act, 2012 (TNID Act)
- Tamil Nadu Infrastructure Development Rules, 2012 (TNID Rules)
- Tamil Nadu Infrastructure Development Board Regulations, 2013 (TNIDB Regulations)
- Tamil Nadu Transparency in Tenders Act, 1998 (TN Tender Act)
- Tamil Nadu Transparency in Tenders (Public Private Partnership Procurement) Rules, 2012 (PPP Procurement Rules)

“Tamil Nadu Infrastructure Development Act, 2012” (TNID Act) is the primary legal basis of implementing PPP projects in TN. TNID Act comprehensively governs social and economic infrastructure development in the State to be implemented through both government funding and PPPs. PPP is defined in Section 2 (m) of TNID Act as “an arrangement between a public agency and a private sector participant for the provision of infrastructure through investment made or through design, development, construction, maintenance or operation undertaken by the private sector participant, where risks are allocated between them such that the private sector participant takes on the risk beyond the stage of design and construction and the payment for the services are performance linked, in the form of user charges, annuity or unitary payment.”

“Tamil Nadu Transparency in Tenders Act, 1998” (TN Tender Act) is applied to the procurement procedure of PPP projects, i.e., the selection of a private sector partner and procedure for the concession agreement. “Tamil Nadu Transparency in Tenders (Public Private Partnership Procurement) Rules, 2012” (PPP Procurement Rules) sets forth specific rules applicable to PPP procurement.

3.1.3 Institutional Setup

- (1) Tamil Nadu Infrastructure Development Board (TNIDB)

³⁶ The information in the present paragraph is based on Ministry of Finance (2013) “Guidelines for Formulation, Appraisal and Approval of Central Sector Public Private Partnership Projects”.

In accordance with Chapter II (Section 3 to 13) of TNID Act, the State Government has established Tamil Nadu Infrastructure Development Board (TNIDB) as the nodal agency to coordinate, appraise and facilitate the PPP projects. TNIDB is chaired by Chief Minister of TN and consists of other board members from the State cabinet. Its Executive Committee chaired by Chief Secretary of the State is delegated to perform TNIDB's functions. Chief Executive Officer (in the rank of Secretary to the State Government) is appointed for day-to-day affairs and operation of TNIDB and supervision over all staff of TNIDB.

TNIDB's major functions stipulated in TNID Act are summarized as follows:

- Coordinate among the State Government agencies for infrastructure development in the State
- Identify, prioritize and determine the sequence of Projects
- Formulate infrastructure sector policies
- Prepare documents including feasibility study reports and detailed project study reports
- Scrutinize, evaluate and prioritize the projects proposed by a public agency
- Prescribe tender document forms
- Approve concession agreements in respect of the projects identified by TNIDB
- Evaluate and recommend financial support from the Government under the Tamil Nadu Infrastructure Development Fund or from the Central Government
- Manage and utilize the Project Preparation Fund

(2) Administrative Department

Section 2 (a) of TNID Act defines the Administrative Department as a State Government department that is administratively concerned with a project. HFWD is deemed as the Administrative Department for the proposed project.

(3) Sponsoring Agency

According to Section 2 (u) of TNID Act, a Sponsoring Agency is defined as a public agency designated by TNIDB to implement an infrastructure project through PPP. A public agency may be any department of the State Government or any public sector undertaking of the State Government, a State Government Company, etc. owned or controlled by the State Government (Section 2 (o), TNID Act).

(4) Procuring Entity

According to Section 18 of TNID Act, a public agency designated by TNIDB to implement a project shall be a Procuring Entity under the TN Tender Act.

3.1.4 Infrastructure Projects and PPP Modality

According to Section 1 of TNID Act, the State Government may have any PPP project implemented following TNID Act regardless of its investment value³⁷; and "health infrastructure" is one of the 21 sectors listed in Schedule I of TNID Act. If the proposed project is regarded as "health infrastructure", TNID Act will be deemed applicable to its development and implementation.

Section II of TNID Act has listed several types of PPP modality as nature of concession agreements applicable to the Act which are classified into "1. Investment and Financing related

³⁷ According to Section 1 (3) of TNID Act, the Act applies to all infrastructure projects of a value exceeding INR 5 billion implemented by a public agency, provided that the State Government may apply the Act to any PPP project, the project value of which is less than INR 5 billion.

Agreements” and “2. Operations and Maintenance related Agreement”. The former includes Build-Operate-Transfer (BOT), Build-Own-and-Operate (BOO), Build-Own-Operate-Transfer (BOOT), etc. out of which a suitable concession agreement structure should be considered for the proposed project in later stage of the study.

3.1.5 Procurement Process of PPP Projects

In accordance with Section 18 (a) of TNID Act, “Tamil Nadu Transparency in Tenders Act, 1998” (TN Tender Act) shall apply to the procurement of PPP projects. Specific procedure to follow for the implementation is set forth by “Tamil Nadu Transparency in Tenders (Public Private Partnership Procurement) Rules, 2012” (PPP Procurement Rules).

According to Rule 3 and Rule 4 of PPP Procurement Rules, a two-stage, open competitive tendering shall be the mode of procurement. Except in cases, where the project value is less than INR 100 million, wherein a single stage, two cover, open competitive tendering may be adopted. The Final Offer (or financial offer) shall be in the form of a single objective criterion.

The process will include invitation of tenders, tender documentation, tender process management, and final selection. Under the bid documentation (which can be Request for Expression of Interest, Request for Qualification, Request for Proposal, etc.), the procuring entity can publish the Minimum Technical Requirements (MTR), which are a description of outcomes that are sought to be achieved by the project; to the extent possible the MTR shall be technology and brand neutral. The MTR will include scope of the project, output specifications, design and safety codes and standards, operation requirements, maintenance requirements, and testing and monitoring requirements.

The final selection of the preferred bidder is based on the evaluation of the bids in the following forms:

- Quality-cum-Cost-Based Selection (QCBS): Evaluation based on the cost committed by the bidder and the technical qualification of the bidder
- Quality-Based Selection (QBS): Evaluation based on the technical qualification of the bidder
- Least Cost Method (LCM): Evaluation based on the cost of the completed asset or cost of service committed by the bidder.

As Section 18 of TNID Act stipulates that the procuring entity shall submit the tender documents for prior approval of TNIDB, the selection method of the preferred bidder will be determined by TNIDB in the project implementation process.

3.1.6 Applicability of Single Source Procurement

Apart from the competitive bidding described above, another procurement option is based on the single source procurement. This option is based on Section 16 of TN Tender Act and generally used when a particular entity has exclusive rights in respect of the goods or services provided and no reasonable alternative or substitute exists. In this model, the private entity is directly appointed by procuring entity, on a nomination basis.

However, in most cases, public entities undertaking the single source procurement to appoint a private partners need to be extra careful. Recently, the Central Vigilance Commission, a Central Government body to address governmental corruption, has reiterated in an order to all government departments that award of contracts through open competitive bidding should remain the most preferred mode of tendering, while highlighting that award of contracts on nomination basis without adequate justification amounts to restrictive practice eliminating competition, fairness, and equity.

3.1.7 Treatment to Unsolicited Proposal

TNID Act and other related laws, rules, and regulations of Tamil Nadu do not have stipulations that allow preferential treatment for an unsolicited project proponent, such as application of the Swiss challenge method in tender procedure, which is practiced among several states in India.

3.2 Public Procurement Regulatory Setup

The present section briefly addresses the legal basis on which a public agency conducts the procurement of service provision in case that the proposed project is implemented only through private investment, as an alternative mode rather than PPP, wherein the private entity develops its facilities on private land and enters into a service contract with the public agency.

In this case of service contracts, the public procurement is made based on the said TN Tender Act and “Tamil Nadu Transparency in Tender Rules, 2000” (TN Tender Rules).

According to Rule 4 of TN Tender Rules, the public procurement of construction and/or goods and services are made based on the following tender methods:

- (1) Piece-work contract
- (2) Lump-sum contract
- (3) Turn-key contract
- (4) Multi-stage contracting including pre-qualification and two cover system
- (5) Fixed Rate contract

The same rule also stipulates that the Tender Inviting Authority shall decide the method of tendering to be followed in each case having regard to the category, size, and complexity of the procurement.

3.3 Public Support Facility for PPP Projects

3.3.1 State Support

Section 30 of TNID Act provides that the State Government may provide financial support to PPP projects which may include the following based on Section 2 (v) of TNID Act:

- (1) Subsidy or capital grant not exceeding such proportion of the cost of the project, as may be prescribed in the rules
- (2) Equity
- (3) Loans
- (4) Guarantee by the State Government
- (5) Opening and operation of escrow account
- (6) Conferment of right to develop any land
- (7) Incentives in the form of exemption from the payment of, or deferred payment of, any tax or fees levied under any law or such other incentives, as may be prescribed in the rules.

Rule 11 of “Tamil Nadu Infrastructure Development Rules, 2012” (TNID Rules) stipulates that State Support for a project in the form of subsidy, capital grant, equity participation during the construction period shall not in the aggregate exceed 20% of the total project cost. The said State Support includes that of “Tamil Nadu Infrastructure Development Fund” explained below. Likewise, the total public financial support including both Central and State Government Support for a project in the form of subsidy, capital grant, equity participation, net present value of operational grants, loans and the net present value of quantifiable tax incentives shall not exceed 40% of the total project cost. These ceilings of financial support shall not include any annuity payable to the concessionaire under the concession agreement.

3.3.2 Tamil Nadu Infrastructure Development Fund (TNIDF)

Section 24 of TNID Act states that the State Government constitutes “Tamil Nadu Infrastructure Development Fund” (TNIDF). TNIDF may be utilized for providing financial support to facilitate design, development, working, administration, and management of projects. The use of TNIDF is listed in Rule 10 of TNID Rules as follows:

- (a) Subsidy or capital grant during the construction period of the project intended to improve the viability of the project
- (b) Operational grants during the operational period or part thereof of the project
- (c) Annuity payments for a specified period in life of the project
- (d) Equity investment in the entity implementing the project including a special purpose vehicle created for the purpose
- (e) Loans to the entity implementing the project including a special purpose vehicle created for the purpose
- (f) Any other form of project financing which the State Government may notify from time to time.

3.3.3 Project Preparation Fund

In accordance with Section 25 of TNID Act, the State Government constitutes the Project Preparation Fund to provide financial support for conducting studies, hiring expert and consultant services, preparing feasibility studies, detailed project studies, capacity building, etc., which are specified under Rule 15 of TNID Rules as follows:

- (a) Any technical study required to finalize the technical, legal or financial parameters of a project including legal reviews and commercial assessment studies
- (b) Preparation of Impact Assessment Studies including Environmental Impact Assessment Studies
- (c) Preparation of tender documents including standard tender documents
- (d) Preparation of other essential project documentation prior to signing concession agreement
- (e) Training
- (f) Conduct of outreach events including seminars and conferences.

3.3.4 Central Government Support

(1) Viability Gap Funding (VGF)

Cabinet Committee on Economic Affairs (CCEA) of the Government of India in its meeting of July 25, 2005, approved the Scheme for financial support to PPPs in Infrastructure called Viability Gap Funding (VGF) scheme, which is administered by the Ministry of Finance and provides financial support (up to 20% of project cost) in the form of grants, one time or deferred, to PPP infrastructure projects with a view to make them commercially viable. Eligibility of VGF support is as follows:

- (a) The PPP projects may be posed by the Central Ministries, State Government or Statutory Authorities (such as Municipal Authorities and Councils), which own the underlying assets
- (b) To be eligible for financing under the scheme, the PPP projects should be implemented, i.e., developed, financed, constructed, maintained and operated for the Projects term by a Private Sector Company to be selected by the Government or a statutory entity through a transparent and open competitive bidding process
- (c) The criterion for bidding should be the amount of VGF required by the Private Sector Company for implementing the project where all other parameters are comparable
- (d) The project should provide a service against payment of pre-determined tariff or user

charge

- (e) This Scheme will apply only if the contract/concession is awarded in favor of a private sector company which is not a “Government Company” as defined under section 2(45) of the Companies Act, 2013.
- (f) The approval to projects is given prior to invitation of bids and actual disbursement takes place once the private entity has expended his portion of the equity
- (g) The final VGF is determined through the bidding.

However, according to “Scheme and Guidelines for Financial Support to Public Private Partnerships in Infrastructure” (2013) by Department of Economic Affairs, Ministry of Finance, which lists the eligible sectors, the provision of VGF is only applicable to “education health and skill development, without annuity provision”. As the proposed project expects annuity or similar form of payments from the State Government, its eligibility for VGF is considered questionable and necessary for further study and consultation with authorities.

(2) India Infrastructure Project Development Fund (IIPDF)

The India Infrastructure Project Development Fund (IIPDF) provides financial support for quality project development activities. The Sponsoring Agency will be able to source funding to cover a portion of the PPP transaction costs, thereby reducing the impact of costs related to procurement on their budgets. The IIPDF will contribute up to 75% of the project development expenses to the Sponsoring Agency as an interest free loan.

3.4 PPP Project Development and Implementation Process

The present section summarizes the development and implementation process of PPP projects based on TNID Act and other related laws and rules, referring to “TNIDB Manual (Draft)” published by TNIDB in March 2014. Table 3-1 shows the overall process and indicative duration of each stage described in TNIDB Manual.

Table3-1 PPP Project Development and Implementation Process

Phase	Stage	Steps	Duration Indicated in TNIDB Manual(days)		Remarks
			Duration	Cumulative	
Project Development (PD)					
	Stage I: Project Conception and Planning – Project Concept Note	1. Project Scoping 2. Option Analysis 3. Pre-feasibility Study 4. Project Concept Note	10	10	-
	Stage II: Project Development – TNIDB Directive to conduct Feasibility Study	1. Approval of Project Concept Note 2. Support from TNIDB for financial assistance and facilitation support	10	20	Sequential from Stage I of PD
	Stage III: Project Development – Feasibility Study	1. Feasibility assessment 2. Structuring	90	110	-
	Stage IV: Application for TNIDF	Application for financial support	30	140	-
	Stage V: Recommendation of TNIDB on Feasibility Study, Project Concept Note and Mode of Implementation	1. Approval of Feasibility Study and Project Concept Note 2. Determination of mode of implementation by TNIDB	30	140	Sequential from Stage IV of PD
	Stage VI: Approval from Government on Mode of Implementation	1. Receipt of State Government direction 2. Publication of project details 3. Submission of observations and suggestions	60	200	Sequential from Stage V of PD
	Stage VII: Project Structuring and Final Approval for PPP Projects	1. Finalization of scope and structure 2. Finalization of financial support	30	230	Sequential from Stage IV of PD
Procurement – Planning and Process (PP)					
	Stage I: Preparatory Stage	1. Formation of tender inviting authority, tender scrutiny and evaluation committee, etc. 2. Engaging consultants or advisors (optional) 3. Procurement process modalities 4. Preparation of tender documents 5. Selection of basis for tender evaluation criteria 6. Approval of tender documents and concession agreement	30	260	Parallel with Stage III of PD and/or Sequential from Stage VII of PD

	Stage II: Approval of Tender Documents and Concession Agreement by TNIDB	Submission and approval of tender document	30	260	Sequential from Stage I of PP
	Stage III: Notice Inviting Tenders	Publication of tenders and supply of tender documents	10	-	Sequential from Stage II of PP
	Stage IV: Bid Process Stage	Request for Expression of Interest (ROEI)	30	-	Sequential from Stage III of PD or Stage III of PP
		Request for Qualification (RFQ)	60	320	Sequential from Stage III of PP
		Request for Technical Proposal (RFTP) (optional)	-	-	-
		Request for Proposal (RFP)	60	380	Sequential from RFQ or RFTP of Stage IV of PP
	Stage V: Bid Finalization Stage	1. Opening of tenders 2. Selection and evaluation of lowest tender 3. Finalization and award of project	45	425	Sequential from Stage IV of PP
Implementation and Monitoring					
	Project Management	1. Appointment of project managers 2. Preparation of Project Management Plan 3. Project monitoring 4. Exit strategy for continued service delivery after exit	-	-	Sequential from Stage V of PP

Sources: Survey Team based on "TNIDB Manual (Draft)" TNIDB, March 2014

3.4.1 Project Development

(1) Stage I: Project Conception and Planning – Project Concept Note

Project Scoping and Option Analysis

Typically, a project starts with an Administrative Department or a Sponsoring Agency initiating it by creating a framework for addressing the various aspects of the project. At the time of scoping the project, the project agency should the need or service to be achieved and the expected improvement.

An option analysis is a mode in which the Sponsoring Agency ensures that various asset-lean options such as using a non-asset solution and improving existing assets have been evaluated.

Pre-feasibility Study

Pre-feasibility Study is not elaborate but normally conducted at the department or Sponsoring Agency level. As the aspects that a pre-feasibility study should ideally cover, TNIDB Manual lists the following:

- ① Technical Pre-feasibility
 - (a) The engineering and technical aspects as envisaged
 - (b) New technology (if any)
 - (c) Places where it has been implemented
 - (d) Operational aspects and ease/ difficulty of managing the same
 - (e) Technical and operational risks summary
- ② Financial Feasibility
 - (a) Approximate costs of the project
 - (b) Financial risks in the project
 - (c) Private sector interest in the project
 - (d) Identification of socio-economic benefits

As for the nature of pre-feasibility study, TNIDB Manual states that “while the feasibility study is more to decide on a go/ no go decision, this cannot in anyway substitute a full-fledged assessment of the project.” The present First Phase of the Preparatory Survey is considered as a pre-feasibility-level study.

Project Concept Note

In accordance with Regulation 7 of “Tamil Nadu Infrastructure Development Board Regulations, 2013” (TNIDB Regulations), the Sponsoring Agency shall prepare “Project Concept Note” which covers the basic information of the project in terms of types of infrastructure and service to be provided and submit it to TNIDB along with the feasibility study report if available. From TNIDB point of view, Project Concept Note is a first step towards registration and acknowledgement of the project for the consideration of TNIDB. The detailed format of Project Concept Note is presented as per Appendix I of TNIDB Regulations and consists of the following parts:

- ① General: project title, Sponsoring Agency, Government Department, implementing mode (PPP or public investment), etc.
- ② Project Description
- ③ Brief Project Description: technical aspects, operational aspects, preliminary risk assessment, socio-economic assessment, environmental assessment scoping, etc.
- ④ Financials: Estimated total project cost, financing sources (equity, debt, necessary public financial support, financial and economic IRRs, etc.)
- ⑤ Next Steps

(2) Stage II: Project Development – TNIDB Directive to conduct Feasibility Study

After reviewing the Project Concept Note, TNIDB can send it with a recommendation to conduct a feasibility study. The Sponsoring Agency/Department can expect both facilitation support and financial assistance from TNIDB for engaging consultants to conduct a feasibility study.

- Facilitation Support: As per Regulation 6 of TNIDB Regulations, TNIDB maintains a list of empaneled consultants from which the Sponsoring Agency may select a consulting firm to conduct a feasibility study.
- Financial Assistance: The Project Preparation Fund created under TNID Act is managed by TNIDB and helps the Sponsoring Agency appoint consultants for the feasibility study.

(3) Stage III: Project Development – Feasibility Study

Regulation 8 of TNIDB Regulations has determined the format of Feasibility Study Report and detailed items required to cover therein as per Appendix II of the Regulations, which can be summarized as follows:

- ① Executive Summary
- Part A: Feasibility Assessment
- ② Project Background
- ③ Strategic Needs Assessment, Demand Assessment and Project Scoping
- ④ Service Standard – Output and Services
- ⑤ Market Assessment
- ⑥ Technical Feasibility
- ⑦ Financial Feasibility
- ⑧ Environmental Impact
- ⑨ Legal Framework
- ⑩ Stakeholder Consultation Findings and Public Interest Evaluation
- ⑪ The Public Sector Comparator (PSC), Value for Money and Recommendations
- ⑫ Conclusion and Recommendations on Feasibility Assessment
- Part B: Structuring
- ⑬ Risk Assessment
- ⑭ Key Commercial Principles Including Payment Mechanisms
- ⑮ Evaluation Criteria for Selection of the Private Entity
- ⑯ Implementation Plan
- ⑰ Project Resource Requirement
- ⑱ Conclusion and Recommendations on Structuring
- Appendices (other supporting documents)

(4) Stage IV: Application for TNIDF

According to the TNIDB Manual, the financial support from Tamil Nadu Infrastructure Development Fund (TNIDF) shall ordinarily be approved only after the opportunities to avail state support and other public financial support from the Sponsoring Agency's own resources or regular departmental budgetary resources or Central Government support have been exhausted. Before TNIDB recommends a project for implantation to the State Government under Section 14 (4) of TNID Act, TNIDB shall provide a preliminary indication of the extent and form of state support and specifically support from TNIDF (See also Section 3.3 of this Chapter on State Support).

(5) Stage V: Recommendation of the Board on Feasibility Study, Project Concept Note and Mode of Implementation

On considering the note prepared by CEO of TNIDB as per Regulation 7 (5) of TNIDB Regulations, on the Project Concept Note and the Feasibility Study, the Board of TNIDB shall make decision to implement the project. Upon deciding that the project is feasible and is of priority, the Board shall decide as to whether the PPP mode or the public sector mode would be appropriate for the project implementation (Section 14 (4), TNID Act).

In case that the Board of TNIDB recommends implementation through the PPP mode, it shall (i) be subject to the criteria set forth in Regulation 11 of TNIDB Regulations; (ii) indicate the appropriate form of Concession Agreement out of those in Schedule II of TNID Act (See Section 3.1 (4) of this Chapter); and (iii) indicate the possible extent and form of public support that the project may require in accordance with Rule 12 of TNID Rules.

(6) Stage VI: Approval from Government on Mode of Implementation

In accordance with Section 14 (6) of TNID Act, the State Government shall consider the recommendations of TNIDB and communicate its decision on the implementation of the project including the mode of implementation within 30 days. Further steps for PPP projects are as follows:

- ① Step 1: Receipt of State Government's direction
- ② Step 2: Publication of project details
- ③ Step 3: Submission of observations and suggestions.

(7) Stage VII: Project Structuring and Final Approval for PPP Projects

Based on the report mentioned above about the observations and suggestions received from the public, if TNIDB is of the view that the information is adequate, it will direct the Executive Committee of TNIDB to finalize the scope and structure of the project.

Financial Support from TNIDF

In finalizing the scope and structure of the project, the Executive Committee shall, following Rule 12 of TNID Rules, either approve its own accord or secure the Board's specific approval for the extent and form of public financial support for the project.

Financial Support from State Government

In case of the State financial support, the possible extent and form of state support proposed shall be reported to the State Government forthwith, including whether such state support is proposed to be a tender criterion.

Financial Support from Central Government

In case where the public financial support is to be support from the Central Government, the concerned Administrative Department and the Sponsoring Agency shall be advised to directly approach the agencies concerned in the Central Government.

3.4.2 Procurement – Planning and Process

(1) Stage I: Preparatory Stage

On approval of the scope of work and structure, the Sponsoring Agency shall initiate the procurement process. Preparatory stage of the procurement consists of the following steps.

- (a) Step 1: Formation of "Tender Inviting Authority", "Tender Scrutiny and Evaluation Committee" (TSEC) and "Tender Accepting Authority"
- (b) Step 2: Engaging consultants or advisors to assist the TSEC, etc. including preparation of tender documents (optional)
- (c) Step 3: Consideration on procurement process modalities
- (d) Step 4: Preparation of tender documents
- (e) Step 5: Selection of basis for tender evaluation criteria
- (f) Step 6: Approval of tender documents and Concession Agreement by TSEC

(2) Stage II: Approval of Tender Documents and Concession Agreement by TNIDB

Once the project approvals, project structure, method of concession and application for state support are in place, the project is ready to be bid out. Upon receiving the approved tender documents from TSEC, the tender documents are sent to the Board of TNIDB for final approval.

(3) Stage III: Notice Inviting Tenders

In accordance with Rules 9 through 13 of PPP Procurement Rules, the Tender Inviting Authority shall publish Notice Inviting Tenders. From the date of publication of Notice Inviting Tenders, the tender documents shall be available both in soft and hard copies.

(4) Stage IV: Bid Process Stage

PPP Procurement Rules and TNDB Manual describes in detail the bidding process and necessary documentations which consist of the following procedures:

- Request for Expression of Interest (REOI) Chapter III, PPP Procurement Rules
- Request for Qualification (RFQ) Chapter IV, PPP Procurement Rules
- Request for Technical Proposal (RTP) Chapter V, PPP Procurement Rules
- Request for Proposal (RFP) Chapter VI, PPP Procurement Rules

(5) Stage V: Bid Finalization Stage

Bid finalization stage consists of the following steps:

- (a) Opening of tenders Procurement Rules Rules 21~24, PPP
- (b) Selection and evaluation of lowest tenderer Procurement Rules Rules 55~58, PPP
- (c) Finalization and award of project Procurement Rules Rule 59, PPP

After the selection notification has been made, the Procuring Entity shall issue the Letter of Award (LOA) to the lowest bidder. The Sponsoring Agency shall forward to TNIDB the Concession Agreement to be signed with tenderer. Subject to the conditions precedent in the RFP and LOA, the lowest tenderer shall execute the Concession Agreement with the Procuring Entity.

3.4.3 Implementation and Monitoring

(1) Step 1: Appointment of Project Managers/ Project Management Facility

After the selection of a successful bidder, it is necessary to monitor the project implementation during and after the construction period. TNIDB is authorized to monitor the project during implementation with a view to ensuring that the project is proceeding as envisaged. To this end, TNIDB may request for periodic reports from the sponsoring agency as well as recommend corrective action to the State Government. The Board of TNIDB may recommend appointment of a Project Management Facility, which is an entity in case of large projects or a designated individual in the case of less complex projects in accordance with Section 20 of TNID Act.

(2) Step 2: Preparation of Project Management Plan

The Project Management Facility or the Project Manager shall prepare the Project Management Plan in accordance with the Project Management Principles as per Appendix V of TNIDB Regulations, upon the signing of Concession Agreement.

(3) Step 3: Project Monitoring

The Project Management Facility or Project Manager shall submit to the Board of TNIDB the following:

- An Achievement and Exception Report on a quarterly basis, within 30 days of the end of every quarter
- Periodic reports during the construction phase on status of project implementation, including time, cost, safety, and other factors.
- Periodic status reports during the operational phase on achievement of key performance indicators, other contractual, social, economic and financial indicators.

The Project Management Facility or Project Manager shall also be responsible for certifying the eligibility of the Concessionaire for release of the state support in accordance with the terms of the Concession Agreement.

(4) Step 4: Exit Strategy

The Project Management Facility shall be responsible for implementation of exit strategy at the end of contract term as prescribed in the Concession Agreement. In accordance with Regulation 21 of TNIDB Regulations, the Sponsoring Agency shall ensure that the Concession Agreement provides for the asset handover and exit strategy for the project including the following:

- Review of options to ensure service continuity
- Testing and valuation of assets
- Resource allocation for implementing the exit strategy
- Obligation of the parties in relation to the exit strategy.

3.5 Foreign Direct Investment Regulation and Taxation System

3.5.1 Foreign Direct Investment Promotion and Facilitation Agencies

On the national level, “National Investment Promotion and Facilitation Agency of India”, or “Invest India”, acts as the first point of reference for investors in India. Invest India is set up as a non-profit venture under the Department of Industrial Policy and Promotion, Ministry of Commerce and Industries, Government of India.

“Guidance Tamil Nadu” (formerly “Tamil Nadu Industrial Guidance and Export Promotion Bureau”) is the investment promotion and single window facilitation agency of the Government of TN. It is mandated under the Tamil Nadu Business Facilitation Act, 2018 and Tamil Nadu Business Facilitation Rules, 2017 to promote TN as the most preferred investment destination by reaching out, helping, and improving the ease and cost of doing business.

3.5.2 Foreign Direct Investment Regulation

Foreign direct investment (FDI) in India is regulated under Consolidated FDI Policy, 2020 of Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India. Eight sectors such as gambling and betting, real estate business and construction of farmhouses, etc. are listed in the said Policy as the prohibited sectors for FDI. In addition, foreign technology collaboration in any form is also prohibited for Lottery Business, Gambling and Betting activities. Section 5.2 of Consolidated FDI Policy also provides the lists of sectors and activities that FDI up to the limit indicated against each sector/activity is allowed, subject to applicable laws and regulations. According to Section 5.2 (a) of Consolidated FDI Policy, FDI in sectors and activities not listed is permitted up to 100% on the automatic route for approval, subject to applicable laws, regulations, etc. Therefore, since the medical sterilization business or medical instrument rental business is not mentioned in the said lists in Section 5.2 of Consolidated FDI Policy, it is considered that FDI up to 100% in the proposed project is permitted, subject to further consultations and confirmation with authorities in the next phase of the survey. Parenthetically, as a sector related to the proposed project, it is also noted that the aforementioned

lists of permitted sectors include “pharmaceuticals”, for which the automatic approval is granted in case of greenfield FDI up to 100% or brownfield FDI up to 74%, whereas the government approval process is required in case of brownfield FDI beyond 74%. Besides, according to the notes on the same section about the pharmaceuticals in Consolidated FDI Policy (Section 5.2.27.3), it is stated that “FDI up to 100%, under the automatic route is permitted for manufacturing of medical devices”; and it is defined that “medical device” includes any instrument, appliances, etc. for the purpose of “disinfection of medical devices”.

3.5.3 Taxation System

(1) Corporate Income Tax

Corporate income tax rates for domestic companies are summarized in Table 3-2.

Table 3-2 Corporate Income Tax for Domestic Companies

FY 2019-2020 Turnover or gross receipts	Taxable Income	Corporate Income Tax (CIT)
Not less than INR 4 billion	Not exceeding INR 10 million	Corporate Income Tax 30% Health and Education Cess 4% of CIT Total: 31.2%
	Not less than INR 10 million and not exceeding INR 100 million	Corporate Income Tax 30% Surcharge 7% of CIT Health and Education Cess 4% of CIT and Surcharge Total: 33.38%
	Not less than INR 100 million	Corporate Income Tax 30% Surcharge 12% of CIT Health and Education Cess 4% of CIT and Surcharge Total: 34.94%
Not exceeding INR 4 billion	Not exceeding INR 10 million	Corporate Income Tax 25% Health and Education Cess 4% of CIT Total: 26%
	Not less than INR 10 million and not exceeding INR 100 million	Corporate Income Tax 25% Surcharge 7% of CIT Health and Education Cess 4% of CIT and Surcharge Total: 27.82%
	Not less than INR 100 million	Corporate Income Tax 25% Surcharge 12% of CIT Health and Education Cess 4% of CIT and Surcharge Total: 29.12%

Note: Lower tax rate of 22% or 15% is also applicable to corporate entities subject to certain conditions (surcharge 10% of tax applicable)

Sources: Survey Team based on website information of Income Tax Department, Government of India as of Mar 2021

(2) Japan-India Tax Treaty

The Japan-India Tax Treaty provides the following withholding tax rates:

- Interest income 10%
- Dividend income 10%
- Royalty 10%
- Fees for technical service 10%

(3) Goods and Services Tax

Goods and Services Tax (GST) is an indirect tax used in India on the supply of goods and services. Different GST rates (5%, 12%, 18% and 28%) are applicable to various goods and services respectively.

3.6 TN's Foreign Direct Investment and Investment Incentives

3.6.1 India's business environment

India is moving upward year by year in the World Bank's annual ranking of the business environment in 190 countries and regions around the world³⁸. In the most recent 2020 report, India ranked 63rd, up 14th from 77th in the previous year's survey, in the overall ranking, which is the result of the individual evaluation of 10 items in all. India, together with China, Nigeria and others, is named as one of the countries with the most notable improvements in the business environment.³⁹

India has also been mentioned as one of the few countries with notable improvements for three consecutive years, and the World Bank has praised the efforts of the Government of India in light of its economic scale. In fact, it was ranked 23rd in the previous year as well, and the Indian business environment in recent years has seen remarkable improvement due to ongoing efforts such as regulatory reform.

Turning to individual evaluation items, the company ranked 13th in the "Protecting minority investors" category, and from the minority shareholder's point of view, it is regarded as a highly regarded business environment. In addition, "Getting electricity" (22nd), "Getting credit" (25th), and "Dealing with construction permits" (27th) are highly evaluated.

On the other hand, "Registering property" ranked 154th, and "Enforcing contracts" ranked 163rd. When the registration of real estate is accompanied, and from the standpoint of fulfillment of contracts, it is expected to improve in the future, and when business development in India is considered, more cautious investigation is required.

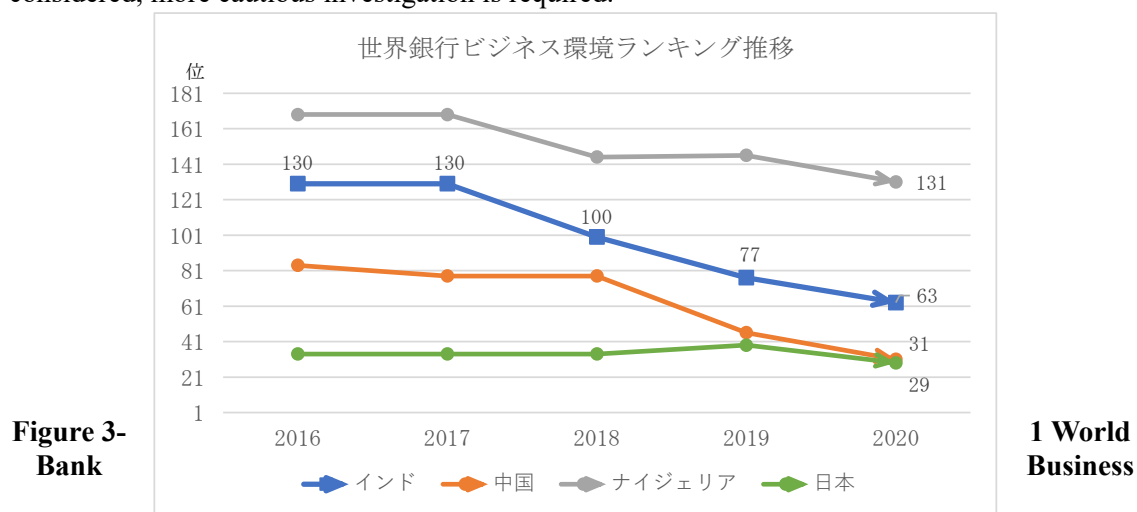


Figure 3-
Bank

1 World
Business

Environment Ranking 2016-2020

Sources: World Bank, Doing Business 2020

³⁸ World Bank, Doing Business 2020 Dataset

³⁹ World Bank, Doing Business 2020 Dataset

Table 3-3 World Bank Business Environment Ranking among Four Countries

2020年 世界銀行ビジネス環境ランキング				
	インド	中国	ナイジェリア	日本
総合順位	63	31	131	29
評価項目別順位				
①起業のしやすさ	136	45	105	106
②建設許可	27	33	55	18
③電力	22	12	169	14
④不動産登記	154	28	183	43
⑤信用供与	25	92	15	92
⑥投資家保護	13	28	28	57
⑦納税	115	105	159	51
⑧輸出入	68	56	179	57
⑨契約執行	163	5	73	50
⑩破綻処理	52	51	148	3

Sources: World Bank, Doing Business 2020

3.6.2 Foreign Direct Investment in India

Along with the improved business environment, the amount of foreign direct investment in India (Foreign Direct Investment: FDI) has been increasing year by year. Although it started to decline from the previous year in 2017, it has started to increase again since 2019. As a consequence, the FDI value in 2013, which was \$36.3 billion, increased to \$79.2 billion in 2020, and according to UNCTAD's most recent 2021 report, the FID value to India was ranked third, up from eighth in the previous surveys, to fifth.^{40,41}

Table 3-4 FDI Flow to India 2013-2020

インドへのFDI流入金額推移								
	2013	2014	2015	2016	2017	2018	2019	2020
US\$ (Bln)	36,396	44,877	53,429	59,406	62,220	64,165	69,631	79,232
		+ 23.3%	+ 19.1%	+ 11.2%	+ 4.7%	+ 3.1%	+ 8.5%	+ 13.8%

Sources: Department for Promotion of Industry and Internal Trade, FDI Fact Sheet

The Modi administration has adopted Make in India scheme and is focusing on promoting the domestic manufacturing industry. In the healthcare field, the government of India is highly interested in medical devices and medical materials, and it is also focusing on attracting foreign capital, and it has established operations in Europe, the United States, and Japan.

For foreign direct investment in India, the Ministry of Commerce and Industry of the Government of India has provided guidelines (Consolidated FDI Policy: Integrated FDI Policy, hereinafter referred to as "FDI Guidelines"). The FDI Guidelines have been revised repeatedly in 2015, 2016, and 2017 under the Modi administration, and there is a clear trend toward relaxing regulations and welcoming foreign investment on each revision, such as increasing the number of business areas that fall under the so-called "automatic route," which does not require prior approval by the Indian government agency. The latest revision was made in 2020 for the first time in three years.

The FDI Guidelines stipulate maximum foreign capital ratios and necessary procedures for each field of investment. When considering investments in India, the content of the FDI guidelines

⁴⁰ Department For Promotion of Industry and Internal Trade, FDI Fact Sheet

⁴¹ UNCTAD, World Investment Report 2021

needs to be closely reviewed.

For example, the FDI Guidelines specify business areas in which foreign capital investment is prohibited. It also provides for business areas in which equity investment is permitted under certain conditions (e.g., maximum equity stake regulation). In the case of business fields that do not fall under these categories, up to a maximum equity stake of 100% is authorized under the automatic route. For example, it is described in particular that an investment of up to 100% in the manufacturing of medical devices will be approved under the automatic route.⁴²

Table 3-5 Sectors prohibited from foreign investment

Sector/Activity
Lottery Business including Government/private lottery, online lotteries, etc.
Gambling and Betting including casinos etc.
Chit funds
Nidhi company
Trading in Transferable Development Rights
Real Estate Business or Construction of Farm Houses
Manufacturing of cigars, cheroots, cigarillos and cigarettes, of tobacco or of tobacco substitutes
Activities/sectors not open to private sector investment e.g. (I) Atomic Energy and (II) Railway operations (other than permitted activities).

Sources: Department for Promotion of Industry and Internal Trade, FDI Fact Sheet

Table 3-6 Sectors subject to automatic approval

Sector/Activity	外資上限	備考
Mining and mineral separation of titanium bearing minerals and ores	100%	
Food Product Retail Trading	100%	
Defence	100%	外資49%以下：政府承認不要
Broadcasting Content Service	49%	
a) FM Radio		
b) Up linking of 'News & Current Affairs' TV Channels		
Uploading/ Streaming of News & Current Affairs through Digital Media	26%	
Print Media - Publishing of newspaper and periodicals dealing with news and current affairs	26%	
Print Media - Publication of Indian editions of foreign magazines dealing with news and current affairs	26%	
Publishing/printing of scientific and technical magazines/ specialty journals/ periodicals	100%	
Publication of facsimile edition of foreign newspapers	100%	
Air Transport Service - Scheduled, and Regional Air Transport Service,	100%	外資49%以下：政府承認不要
Investment by Foreign Airlines	100%	外資49%以下：政府承認不要
Satellites- establishment and operation	100%	
Telecom Services	100%	外資49%以下：政府承認不要
Private Security Agencies	74%	外資49%以下：政府承認不要

Sources: Department for Promotion of Industry and Internal Trade, FDI Fact Sheet

⁴² Indian Ministry of Commerce and Industry, Consolidated FDI Policy Effective from October 15, 2020

Table 3-7 Government-approved sectors

Sector/Activity	外資上限
Agriculture	100%
Plantation Sector	100%
Mining and Exploration of metal and non-metal ores	100%
Mining - Coal & Lignite	100%
Manufacturing	100%
Broadcasting Carriage Services (Teleports, DTH, Cable Networks, Mobile TV, HITS)	100%
Broadcasting Content Service - Up-linking of Non- 'News & Current Affairs' TV Channels/ Down-linking of TV Channels	100%
Airports - Greenfield	100%
Airports - Brownfield	100%
Air Transport Service - Non-Scheduled	100%
Air Transport Service - Helicopter Services/ Seaplane Services	100%
Other services under Civil Aviation Sector - Ground Handling Services	100%
Other services under Civil Aviation Sector - Maintenance and Repair organizations; flying training institutes; and technical training institutions	100%
Construction Development	100%
Industrial Parks -new and existing	100%
Trading - Wholesale	100%
Trading -E-commerce activities	100%
Trading - SBRT	100%
Duty Free Shops	100%
Railway Infrastructure*	100%
Asset Reconstruction Companies	100%
Credit Information Companies	100%
Intermediaries or Insurance Intermediaries	100%
White Label ATM Operations	100%
Other Financial Services	100%
Pharmaceuticals - Greenfield	100%
Petroleum & Natural Gas - Exploration activities of oil and natural gas fields	100%
Petroleum refining by PSUs	49%
Infrastructure Company in the Securities Market	49%
Insurance	49%
Pension	49%
Power Exchanges	49%

Sources: Department for Promotion of Industry and Internal Trade, FDI Fact Sheet

In considering investment from overseas to India, it is important to confirm and consider the form of entry. In the case of business areas where there is a limit on the investment ratio with respect to foreign capital, it is necessary to establish a joint venture with local capital. There is also room to consider the possibility of entering the infrastructure business field using the PPP method.

PPP projects in India can be broadly divided into projects affiliated to the federal government and projects affiliated to state governments. Regarding the former, the Economic Bureau of the Ministry of Finance of India (Department of Economic Affairs) lists and publishes past PPP projects on the website (India PPP database). The latter is compiled by each state government, and a survey is individually required to grasp the actual situation. According to the Indian PPP database, 1514 PPP infrastructure projects had already been implemented as of December 2019. According to the database, the number of PPP infrastructure projects has been on a downward trend over the past 10 years.⁴³⁴⁴

Table 3-8 Number of PPP Infrastructure Projects in India 2010-2019

PPP事業件数推移										
	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
件数	121	102	99	65	59	51	62	37	2	1

Sources: India PPP Datanase, Public Private Partnerships in India, <https://www.pppinindia.gov.in/>

According to JICA, there are no special preferential measures set for foreign capital in India. In this survey, for example, the preferential measures for participation in PPP projects by foreign capital have not been confirmed. On the other hand, preferential measures such as corporate tax

43 India PPP Database, Public Private Partnerships in India(Link), <https://www.pppinindia.gov.in/>
44 Extract under construction (under construction), in operation (O&M stage), and completion (completed) from the Indian PPP database

reductions and exemptions have been established for specific business fields without relying on foreign or domestic capital.⁴⁵

Regarding the next-generation medical logistics centre business, which is the subject of this investigation, it can be seen that it does not fall into either the business field in which foreign capital is prohibited from investing or the business field in which it is conditional under the FDI Guidelines. In addition, it is considered that there are aspects of infrastructure projects that have been targeted by PPPs in many India up to now. Needless to say, at the time of full-scale commercialization verification in the future, it is necessary to hire experts as necessary, keeping in mind more specific business plans, such as the anticipated investment structure and the presence or absence of local partners, and to conduct more in-depth investigations, such as interviews with local officials, as much as possible, in light of the situation surrounding the Corona crisis.

3.6.3 Foreign Investment Regulation and System in TN State

(1) TN's business environment

India consists of 28 states and eight direct federal jurisdictions. With regard to foreign direct investment in India, the policy trends of these state governments also need to be closely checked.

Under the Modi administration, the Indian government has established Business Reform Action Plan: BRAP and is focusing on improving the business climate in each state. The 2020 BRAP provides for 301 items to be improved across 15 areas.⁴⁶

In addition, the Government of India's Office for Domestic Trade Promotion (Department for Promotion of Industry and Internal Trade: DPIIT) of the Ministry of Commerce and Industry (METI) ranks and publishes the business environment in each state and in the direct jurisdiction of the federal government in cooperation with the World Bank. This ranking reflects the degree of achievement of each improvement item set forth in BRAP, which allows us to identify the business climate and the degree of improvement in each state.

The Government of India aims to raise India's ranking in the World Bank's Annual Business Environment Ranking by working to improve these items by each state.

According to this ranking, the TN, which is the area subject to this investigation, ranked 12th in 2015 and a little lower thereafter, ranked 15th in 2017 and 14th in 2019. However, according to the survey results in 2017, the difference between the score in TN (90.68), ranked 15th, and the score in Andhra Pradesh (98.3), ranked No. 1, is about eight points, indicating that the business environment in TN is not significantly inferior to that in the top-ranking states.^{47,48}

⁴⁵ JICA "Encouraging Foreign Investment | India (Link)"

https://www.jetro.go.jp/world/asia/in/invest_03.htmlhttps://www.jetro.go.jp/world/asia/in/invest_03.html

⁴⁶ India Ministry of Commerce and Industry, Ease of Doing Business Reforms Booklet

⁴⁷ Reserve Bank of India 『Handbook of Statistics on Indian States 2020-21』

⁴⁸ Reserve Bank of India 『Handbook of Statistics on Indian States 2020-21』

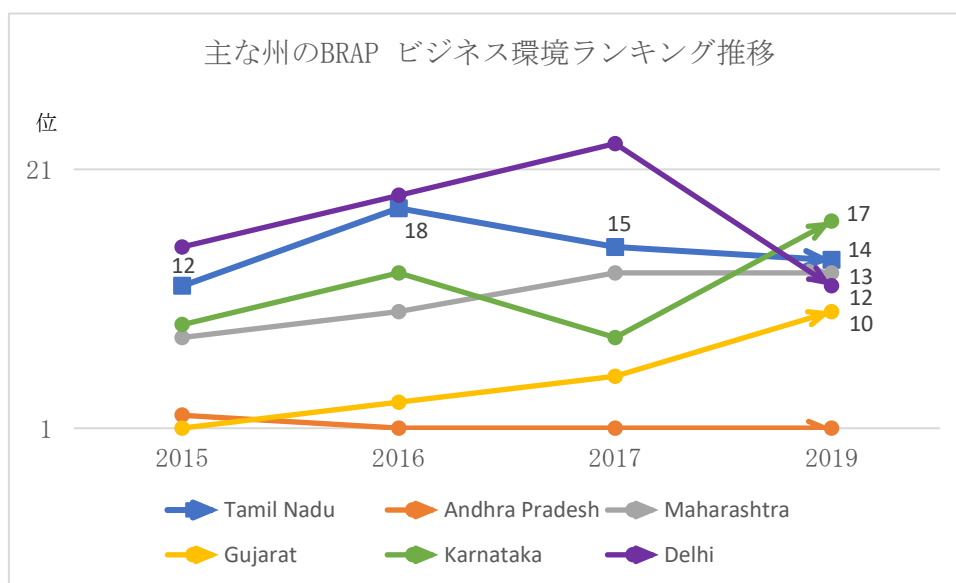


Figure 3-2 India's Business Reform Action Plan Business Environment Ranking of major States

Sources: Department for Promotion of Industry and Internal Trade, FDI Fact Sheet

According to the trend of FDI to each state published by the Government of India, the amount of FDI to TN in the past five years has remained stable at over \$200 billion. On the other hand, in Gujarat, where major industries such as the automobile and other manufacturing industries and petrochemical industries are concentrated, and in Karnataka, where high-tech industries are concentrated and Bangalore, which has been called the Indian version of Silicon Valley, the FDI amount has grown significantly over the past five years.⁴⁹

Table 3-9 FDI Inflow to major States 2016-2020

US\$ (mil)	2016	2017	2018	2019	2020
Tamil Nadu	2,218	3,475	2,613	2,354	2,323
Andhra Pradesh	2,195	1,246	3,457	718	86
Maharashtra	19,654	13,423	11,383	10,880	16,170
Gujarat	3,367	2,091	1,803	6,052	21,890
Karnataka	2,132	8,575	6,721	8,938	7,670
Delhi	5,884	7,656	10,142	11,144	5,471

※Equity Capital Components Only

Sources: Department for Promotion of Industry and Internal Trade, FDI Fact Sheet

(2) TN Investment Preferential Policies

Under such circumstances, the TN government is focusing on attracting investment, and many overseas companies, including Japanese companies, have established operations and have established manufacturing bases. Incidentally, there are three industrial parks in which Japanese companies participate in the project.

In 2018, Tamil Nadu Business Facilitation Act, 2018 and Tamil Nadu Business Facilitation Rules, 2018 took effect to promote investment in the state. This clearly defines previously unclear investment procedures and the necessary time period, and increases the transparency of procedures and the required time period for investment in the State of TN. In addition, operations

⁴⁹ Department For Promotion of Industry and Internal Trade 『FDI Fact Sheet』

have been introduced which are deemed to have been approved if the procedure period is exceeded without justifiable reason.

In addition, the TN government has established a one-stop portal website to handle investment procedures in the state. According to the website, 161 applications have been accepted and 93 applications have been approved as of February 2022.⁵⁰

In 2021, the state government of TN announced Tamil Nadu Industrial Policy 2021. It has set goals, including attracting \$135 billion in new investments by 2025, and is focusing on attracting investment to the manufacturing industry. It should be noted that preferential treatment that may be effective from the viewpoint of this initiative, which does not apply to the manufacturing industry, has not been confirmed at present.⁵¹

The policy defines four categories according to investment size and three categories according to location. Chennai is included in Category A of this project. Specific preferential items are defined in preferential packages such as "FDI" and "Logistics Infrastructure," and the categories applicable to each package are defined.

Table 3-10 Priority category by amount of investment

投資金額による優遇カテゴリー		
カテゴリー	投資金額 (IDR mil)	投資期間
Sub-Large	500 ~	4年
Large	3,000 ~	4年
Mega	5,000 ~	4年
Ultra-Mega	50,000 ~	7年

Sources: TN state, Tamil Nadu Industrial Policy 2021

Table 3-11 Priority category by location

ロケーションによる優遇カテゴリー	
カテゴリー	ロケーション
District A (4地区)	Chengalpattu, Chennai, Kancheepuram, Tiruvallur
District B (12地区)	Coimbatore, Erode, Karur, Krishnagiri, Namakkal, The Nilgiris, Ranipet, Salem, Tiruchirappalli, Tirupattur, Tiruppur, Vellore
District C (22地区)	Ariyalur, Cuddalore, Dharmapuri, Dindigul, Kallakurichi, Kanniyakumari, Madurai, Mayiladuthurai, Nagapattinam, Perambalur, Pudukkottai, Ramanathapuram, Sivagangai, Tenkasi, Thanjavur, Theni, Thiruvarur, Thoothukudi, Tirunelveli, Tiruvannamalai, Villupuram and Virudhunagar

Sources: TN state, Tamil Nadu Industrial Policy 2021

In the future, when a full-scale investigation and detailed commercialization study is to be conducted, it is necessary to conduct more in-depth investigation activities, such as grasping the actual status of the transparency of TN investment procedures, usability of portal websites, and whether or not preferential investment treatment is applied, through interviews with local officials, etc. with a consideration of more specific business plans.

(End)

⁵⁰ TN-state Single Window Portal's <https://tnswp.com/DIGIGOV/>

⁵¹ TN State Tamil Nadu Industrial Policy 2021