How elements of the Indian state purchase drugs

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18th August 2021

Abstract

Quality problems in drug purchasing by Indian state agencies lie at the intersection of the field of drug quality in India and the field of government contracting in India. Improvements in the procedures used by state agencies when buying drugs can improve the working of public health care programs, and potentially also influence drug quality in the private market. The first step towards policy analysis and reform lies in careful description of how drug purchase works at present. In this paper, we describe how some elements of the Indian state buy drugs.

*This research was supported by a grant from the Thakur Family Foundation. We are grateful to Susan Thomas, Anjali Sharma, Diya Uday and Bhargavi Zaveri for useful conversations. All errors are our own.

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1 Introduction

Public procurement of drugs is undertaken at many elements of the Indian state. There are many concerns about the efficacy of public procurement of drugs, particularly on the problems of drug quality. If better procedures emerge in drug purchases in the Indian state, these could potentially have a valuable impact, directly in yielding better efficacy of public sector health care programs, and indirectly through potential impacts upon the much larger private market for drugs.

There is a need for a research program in this field, of assembling datasets, conducting research, and devising policy solutions through which these contracting mechanisms can be improved. This falls in the context of the larger research area of government contracting, of which the purchase of drugs is a special case. The field of government contracting for drugs in India can usefully take knowledge from the overall field of government contracting in India, and also feed knowledge back into this field.

A first building block that would be useful in this research program is a description of how various elements of the Indian state purchase drugs. This includes questions about the legal authority for procurement, the organisation of procurement activities across different levels of government, and the various process models followed to conduct procurement activities. The objective of this paper is to foster knowledge in the field by offering such description.

This paper is structured as follows. We provide a background of the drug procurement problem in India along with a brief overview of the existing literature on drug procurement. We describe the legal framework for public procurement of drugs in the country and attempt to organise the myriad rules and guidelines that govern this activity at different levels of government. We examine the landscape of public procurement in India, identifying the key elements of the procurement process and their application in different procurement frameworks at both the central and state level.

2 The problem of drug purchase by the Indian state

Government contracting is a homeostatic function performed by every state. It constitutes the pipeline from procurement to contract renegotiation to contract disputes to payments. This is of great importance all across gov-

ernment.[1]. In numerous areas, governments face "make vs. buy" decisions – the choice between recruiting civil servants to perform a certain task vs. contracting–out that task to a private person. The strengths or weaknesses in the specialised field of government contracting matter for (a) Efficacy in contracting out and (b) Undistorted decisions to make vs. buy. Examples where contracting capabilities hold the key to success in public policy include the purchase of defence equipment, the purchase of drugs and vaccines, the purchase of PPP or EPC infrastructure contracts, etc.[2]

Government contracting in India is affected by a range of issues such as lack of transparency and accountability, arbitrary power in the hands of civil servants which distorts the behaviour of private persons, and fear of harm to decision makers through future investigations.

These weaknesses manifest themselves in three classes of failure:

1. Some times, a decision is taken to contract-out, and this contracting fails, the expenditure is not made and the required tasks are not performed.

2. Some times, the goods/services purchased by the government are obtained at a higher price when compared with what a well-incentivised private person would have been able to buy. In the field of drugs, the simple comparison of price is inaccurate as there is also quality variation. While the tender and the payments by a government agency may appear to be efficient when compared with a private buyer, there may be an inefficiency in the government process in the form of sub-standard drugs. Conversely, if an efficient purchasing process set out to buy sub-standard drugs, it may be able to improve upon the pricing obtained through the government contracting process.

3. Some times, decision makers in government have a bias in favour of in-sourcing based on their assessment of the difficulties of contracting out, thus resulting in distortions in the make vs. buy decisions.

There is considerable executive discretion, in devising procedures and protocols of the procurement process. There is merit, in the field of government contracting, of legal foundations that are not excessively prescriptive

[1]This paper connects into the body of literature on government contracting, `https://xkdr.org/publicprocurement.html`, and builds on the questions articulated in Shah (2021)

[2]In this paper, we have concentrated on government purchase of drugs. Government purchase of vaccines became particularly important during the pandemic. A dataset about these purchases is `https://xkdr.org/releases/stategovt2021_vaccineprocurement.html` . However, in this paper, we do not analyse government purchase of vaccines.

Table 1 Result of the MoHFW drug survey, 2014-16

Samples	NSQ drugs	Spurious drugs
33656 (Retail)	1011 (3.16%)	8 (0.023%)
8369 (Government)	839 (10.02%)	5 (0.0597%)
1708 (Ports)	0	0

Source : Ministry of Health and Family Welfare, 2016.

in defining tendering procedure, bid evaluation, award of contracts, post-award monitoring and dispute resolution to enforce compliance (Roy and Uday, 2020). We must, then, understand and critique the ways in which the unique puzzles of drug procurement have been addressed, through the development of commensurate procedures, by persons in the executive who have wide-ranging discretion on the precise mechanism design.

The government of India (summing across all state agencies) is likely to be the biggest buyer of drugs in India. It is also the regulator of drug quality in India. Very little data is generated and published by the government with regard to the quality of drugs made available to the public through government and retail pharmacies[3].

A Central Drugs Standard Control Organisation, 2009 report, released nine years after it was performed, indicates that 0.046% of drugs in India are counterfeit while 0.101% are Not of Standard Quality (NSQ) (CDSCO 2009). In the following years, many researchers have reported less sanguine results. Weir et al., 2005 found that about 20% of the drugs tested were found to lack adequate potency. Bate et al., 2009 found that 6-12% of drugs sampled from Delhi and Chennai were reported to be NSQ. The Ministry of Health and Family Welfare (MoHFW) published findings in 2016, additionally classifying the source of drugs as private retail vs government samples in Ministry of Health and Family Welfare, 2016. In this pioneering work, government samples are taken from pharmacies that supply the drugs procured by various government procurement agencies. Table 1 summarises their findings: the extent of NSQ drugs in government samples are more than two times higher than those found in the private retail market.

Singh et al., 2012 undertook a qualitative comparison of the different drug

[3]The quality concerns in drugs are typically classified into a) Misbranded *(drugs that appear to be better than their therapeutic quality due to their labelling or branding)*, b) Adulterated *(contaminated by filty substances)*, c) Spurious *(likely to deceive public and could cause serious harm)*, d) Sub-standard drugs *(defects of serious nature caused by licensed manufacturers)*, and e) Not of standard quality *(NSQ Drugs, manufactured by licensed manufacturers having minor variations in quality)*

procurement models of five Indian states with a view to determine the effectiveness of each model using a set of 53 process and price parameters. The study highlights that autonomous procurement bodies fare better in ensuring timely payments, procuring drugs at lower prices and managing inventory. The study also lists a set of factors that determine the efficiency of a procurement model based on the objectives chosen for comparison. Chokshi et al., 2015 conducted a study of drug procurement in Bihar and Tamil Nadu. They analysed the practical differences between the procurement processes followed in both states by studying a range of financial and non-financial data such as budget documents, annual reports, tenders etc. The basis of comparison are parameters such as utilisation of budget, availability of suppliers and price of procurement. They argue that autonomous procurement agencies such as that of Tamil Nadu are better at ensuring access to medicines at lower prices. Chaudhury et al., 2005 and Veena et al., 2010 both study the Delhi and Tamil Nadu models of procurement in the context of the historical evolution of public procurement in India and attempt to identify emerging trends in procurement on the basis of this analysis. In addition to studies that focus on state-specific procurement models, reports examining the institutional framework for drug regulation such as Thakur and Reddy, 2016 and Agnihotri and Chandrashekaran, 2019 contribute to the literature by analysing and suggesting reforms in the legal framework for improving the drug regulatory system in India.

CUTS International, 2012 estimates the size of government procurement and describes the legal framework for procurement. Hazarika and Ranjan Jena, 2017 describe the institutional frameworks for public procurement in India. These papers lay the foundation for this work, where we narrowly focus on the problem of government buying drugs.

While studies on the drug regulatory framework and domain-neutral research on government contracting exist in the literature, a systematic review of the landscape of drug procurement and its relation with regulation of drug quality is absent. A thorough description of the public procurement framework for drugs is a necessary first step towards analysing the pathways for reform. In this paper, we aim to provide a greater description of how the Indian state procures drugs, specifically the effect that the legal and institutional framework for drug procurement has on the drug procurement process at the central and state level.

3 Legal framework for public procurement of drugs

There are various points of intersection between the legal and institutional framework for public procurement of drugs and the broader framework for drug regulation in the country. The public procurement system often relies on the resources and capacity of the central and state drug regulators to discharge its quality assurance functions. Hence, we need to view the overall interacting system, of government purchase and government drug quality regulation, viewed as a whole.

3.1 Who regulates drug quality?

Under the Drugs and Cosmetics Act, 1940 (DC Act), the regulatory function is performed by both the central and state governments. The union government is responsible for the approval of new drugs, regulation of drug imports, and laying down standards for drugs, cosmetics, diagnostics and devices. The quality standards for drugs sold in India are laid down in the Indian Pharmacopoeia under section 124 of the DC Act. The standards for manufacturing practices (cGMP) for manufacturing facilities are laid down in schedule M of the DC Act. The union government performs these functions through the CDSCO.

Meanwhile, state governments, through State Drugs Regulatory Authorities (SDRAs) are responsible for licensing and monitoring manufacturers for drug quality and initiating legal action against offenders [4]. This division of responsibilities is the result of the delegation of essential national functions by the union government to the states. While Section 33 of the DC Act empowers the union government to appoint the licensing authority for the manufacturing and sale of drugs, it has delegated such power of appointment to the state government using subordinate legislation, i.e., the DC Rules (Rule 59) (Thakur and Reddy, 2016). Therefore, licensing of drug manufacturing firms, and their regulation, is an exclusive function of the SDRAs.

Under the DC Act, the actual detection and prosecution of substandard quality drugs is the responsibility of drug inspectors (Sections 22, 23). Drug inspectors can be appointed by both the central and state governments (Section 21), and function under the control/directions of an officer appointed by the relevant government (Rule 50).

[4] SDRAs may be referred to as Food and Drugs Authority (FDA) in certain states.

However, the DC Act and Rules do not clarify the instances in which the drug inspectors are to be appointed by the central government and when they are to be appointed by the state government. Neither do they outline a scheme of accountability wherein the quality enforcement actions of the drug inspectors can be scrutinised or audited by either a state or central body. This results in a quality enforcement framework where there is no clear statutory body responsible for the failure in drug quality at the central or state level and therefore no incentive for individual drug inspectors to investigate and prosecute quality violations adequately. There are difficulties on the incentives of state government agencies engaged in regulation (Kaur, Roy et al., 2021).

The procurement agencies of various states rely on drug inspectors appointed under the DC Act for quality assurance of procured drugs. Therefore, these flaws of drug quality regulation adversely impinge upon the ability of state agencies to buy drugs.

3.2 What is the legal framework for public procurement of drugs?

While there is no central/state legislation specifically governing public procurement of drugs in India, such procurement is governed by the broader legal framework for public procurement in the country. The elements of the legal framework for public procurement are shaped and defined by many elements.

The Constitution of India The law pertaining to government contracts is specified in Article 299 of the Constitution of India. This provision authorises the union and state governments to contract for goods and services in the name of the President (or the Governor). It does not, however, stipulate any specific procurement policies or procedures. In addition to Article 299, Article 53 of the Constitution vests executive powers, including the financial powers, of the Union on the President of the country. The President, in turn, has vested the financial powers in the Ministry of Finance (by way of the Government of India (Allocation of Business) Rules, 1961). These powers have been further delegated to subordinate bodies under the General Financial Rules, 1947 (GFR Rules, revised in 2005 and 2017). The GFR Rules establish the principles and procedures for government procurement.

Legislative provisions A set of overlapping administrative guidelines, sector-specific manuals and rules shape public procurement. These are guided by principles-based central legislations such as the Indian Contract Act,

1872, the Sale of Goods Act, 1930 and the Arbitration and Conciliation Act, 1996. At the state level, procurement is usually governed by State Financial Rules/Codes issued by the Finance Department of the State. However, certain state legislatures such as those of Karnataka, Tamil Nadu, Andhra Pradesh and Rajasthan have enacted state-specific legislations such as the Tamil Nadu Transparency in Tenders Act, 1998, the Rajasthan Transparency in Public Procurement Act, 2012 and the Karnataka Transparency in Public Procurement Act, 1999. Modelled on the GFR Rules, these legislations give clarity and certainty to procedures and provide for grievance redressal thereby making the procurement procedures more efficient and transparent.

Administrative rules The GFR Rules are a compilation of rules and orders that are to be followed by all departments and organisations under the Government (as executive instructions) in matters involving public finances. The GFR Rules (vide Notification dated November 2, 2010 of the Department of Expenditure, Ministry of Finance, Government of India) now also apply to autonomous bodies except in cases in which the bye-laws of the autonomous body provide for separate financial rules. The Rules provide specific and detailed procedural instructions on the procurement of goods and services (in Chapter 6) as well as contract management (in Chapter 8). In addition to the GFR Rules, the Manual for Procurement of Goods, 2017 (MPG) and the Delegation of Financial Powers Rules, 1978 (DFPR) contain guidelines on the purchase of goods by the government and the delegation of financial powers by the government to ministries and other lower bodies. These are further supplemented by guidelines issued by the Directorate General of Supplies and Disposal (DGS&D) which is a purchase organisation formed at the central level to undertake procurement for departments/bodies that lack the facility to do so on their own.

Sector-specific rules Procurement of goods and services in several sectors is governed by sector-specific manuals and policies such as (a) the Defence Procurement Procedure, 2016 (DPP) governing defence procurement; (b) the Indian Railways e-Procurement Systems (IREPS) for railway procurement; and (c) the Pharmaceutical Purchase Policy, 2013 for pharmaceuticals.

CVC The Central Vigilance Commission (CVC), which oversees investigations under the Prevention of Corruption Act, 1988, has guidelines to prevent corruption and promote objectivity in the procurement process. It require that agencies prepare codified procurement manuals containing comprehensive step-by-step purchase procedures and delegating powers to relevant authorities/officials. However, it is pertinent to note that the MoHFW does not have a comprehensive, easily accessible procurement manual or other written procedures for procurement.

Accountability mechanisms The Comptroller and Auditor General of India (CAG) is a constitutionally appointed body tasked with auditing the accounts of the union and the states. This includes accounts relating to public procurement at the central and state level. Additionally, the Parliamentary Accounts Committee (PAC), Parliamentary Standing Committees (PSCs) and the Legislative Accounts Committees (LACs) of the states are all tasked with ensuring transparency and efficiency in use of public finances used for procurement. In terms of grievance redressal, the CVC has issued specific guidelines to curb corruption in public procurement. It is tasked with generally increasing objectivity and fairness in procurement activities.

To summarise, public procurement in India must broadly operate in compliance with the following framework (i) the GFR Rules; (ii) sector-specific legislation on tendering and procurement; and (iii) sector-specific manuals and orders published by the relevant sectoral department/ministry. The main stakeholders in the process are the procurement agency and the supplier whose legal relationship is documented in the tender and award contract.

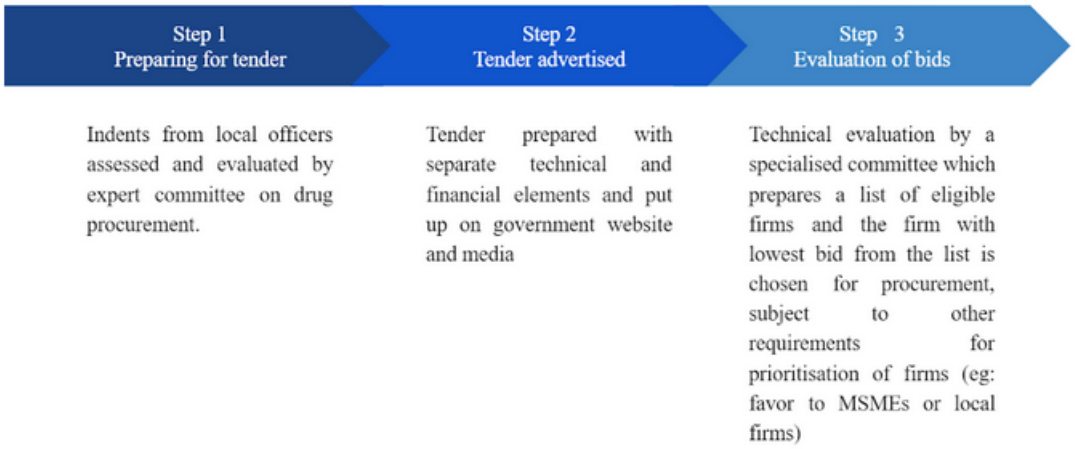
4 Organisation of the public procurement system for drugs in India

Drug procurement is undertaken at all levels of government, by many different government organisations, and follows diverse mechanisms. These mechanisms differ significantly in terms of their:

1. Procuring legal entity;
2. Financing;
3. Tenders;
4. Stocking and distribution;
5. Quality testing protocols;
6. Grievance redressal mechanisms; and
7. Blacklisting protocols.

The typical drug procurement occurs through a two-step tender process wherein technical and financial bids are separated, through the following steps (summarised in Figure 1):

Figure 1 Steps involved in a typical procurement process



1. A list of required medicines is chosen from the state or national list of essential medicines. For this purpose, indentation requirements from hospitals and warehouses etc. are assessed;

2. A specialised committee creates an annual procurement plan, i.e. an estimate of current requirement in the form of a periodic order. The estimation process differs from one agency to the next and may or may not be based on scientific forecasting protocols;

3. Budget allocation and release of funds is carried out based on the list of decided medicines and the annual procurement plan;

4. Tenders are designed basis the requirements in the GFR Rules or state specific requirements followed by bid submission and opening; and

5. Finally, an evaluation committee examines the bids which results in the award of a final contract.

We now turn to describing these processes at the union government and at the state government level.

4.1 Drug procurement by the Ministry of Health and Family Welfare (MoHFW)

At the union level, procurement of drugs is principally undertaken by the Ministry of Health and Family Welfare (MoHFW). The MoHFW is responsible for the procurement of drugs for government hospitals, dispensaries, disease control programmes and the Central Government Health Scheme

(CGHS) through the Medical Stores Organisation (MSO). The MSO, an attached office of the Department of Health, conducts its procurement activities through seven medical depots in different parts of the country using the centralised rate contract model of procurement. The centralised system enables the placement of one merged purchase order for a specific set of government hospitals, dispensaries etc. (collectively called the indenters) by the MSO. To facilitate this centralised order an agreement is entered into between the MSO and a successful bidder, setting the terms and conditions under which the procurement of specified drugs is to take place during the term of the agreement. This includes a rate contract form of agreement which may either be pre-determined or are determined at the time of procurement through a pre-decided process. No minimum quantity requirement is set for the term of the contract, and it is therefore in the nature of a standing offer by the chosen contractor. Under this model, the government finances purchase of drugs, procures the drugs and distributes them itself. The entire process of drug selection, procurement, stocking and distribution is owned and managed by the MSO. [5]

Under the centralised rate contract system, only manufacturers having a valid manufacturing license issued by the relevant state drug regulatory authority, and duly registered with the MSO are eligible to participate in the tender. Additional eligibility requirements such as the supplier having more than the prescribed minimum annual turnover (INR 0.50-1 Billion based on the type of drug being purchased), a non-conviction certificate, and a valid WHO GMP certificate for quality assurance is typically seen in MSO tenders. We study quality assurance mechanism by procurement entities in greater detail in an associated paper, Kaur, Shah and Srivastava, 2021.

[5]The budget allocation to carry out MSO procurement from 2013-14 is shown in table 2. This information was received as a response to Right to Information request filed with the MSO on 20 November 2020.

Table 2: Budget estimates and utilisation of MSO (Depots) from FY 2013-14 to 2019-20

S.No.	**Year**	**Budget Estimates (INR, in Billion)**	**Budget Utilisation (INR, in Billion)**
1	2013-14	0.45	Not Available
2	2014-15	0.50	Not Available
3	2015-16	0.52	0.51
4	2016-17	0.58	0.57
5	2017-18	0.56	0.56
6	2018-19	0.61	0.55
7	2019-20	0.64	0.56

The list of manufacturers that have been granted registration by the MSO is published on the MSO website along with the date and term of registration. This list reveals that a large number of registered manufacturers are large Indian pharmaceutical firms such as Cipla, Glenmark, Lupin etc. A possible reason for the overwhelming presence of big firms in procurement by the union may be the high value for the minimum annual turnover that is required to be eligibile to bid on contracts. We may note in passing that there *are* quality problems with drugs purchased by the union government (Ministry of Health and Family Welfare, 2016). This suggests that high values for the minimum annual turnover of a prospective drug supplier does not, in and of itself, solve the problem of drug quality.

Another mechanism used by the MSO to ensure maintenance of quality standards is blacklisting. As per tender requirements, the MSO reserves the rights to inspect drugs at the manufacturing facility as well as the final destination of the goods. A finding of substandard quality leads to blacklisting for a period of 3 to 5 years (depending on the type of drug) and forfeiture of a certain percentage of the performance security of the supplier. Blacklisting entails temporary debarment (based on the category of defect) of the firm from the supply of the product found to be substandard, and in case of repeated defects the debarment from supply of all products. The list of firms that have been blacklisted by the MSO for supply of all drug items for a period of five years is published on the MSO website. It may be possible that debarred companies obtain fresh registrations for their other divisions/sister companies during the period of disbarment

The MSO does not have a detailed blacklisting policy and simply includes a section on process for debarment in its procedural manual.

As noted by the CAG in its 2007 audit of the MoHFW, the execution of the rate contract system is characterised by the absence of an established procedure for placing and consolidating indents, issuing supply orders and distributing materials. This often leads to a failure on the part of the MSO to meet the demands of various indentors, in turn leading to reliance on local purchases of medicines by hospitals and dispensaries. The CAG estimates that during 2002-2008, the value of purchase of medicines from local chemists was almost 80% of the total purchase value of drugs procured during this period. To this extent, then, it appears that the centralised system works poorly, and de facto, there is a decentralised system of purchases from local chemists.

We note that the MSO only procures a small fraction of total drugs procured by the MoHFW since it primarily supplies drugs to hospitals run by the union

Table 3 Railways budget estimate from detailed demand for grants, 2021-22 (INR, Billion)

Actuals (2019-2020)	**Budget estimate (2020-21)**	**Revised estimate (2020-21)**	**Budget estimate (2021-22)**
9.10	10.71	9	9

government. A portion of budget of the Central Government Health Scheme, Ayushman Bharat scheme, National Health Mission are also used to procure drugs. Moreover, drugs are also procured under specialised programmes by the health ministry. For instance, in the year 2019-20, an expenditure of more than INR 2.25 billion was made on procurement of Oral Polio Vaccine under the Pulse Polio Program alone (Parliament of India, 2020).

Several estimates of the magnitude of government drug purchase are visible in this paper. All of them seem to be smaller when compared with prior beliefs of researchers, or when compared with bottom-up calculations about the magnitude of expenditure on drugs that would be required. This is a puzzle that requires further exploration.

4.2 Procurement by other Union ministries

In addition to the MoHFW, certain other central ministries such as the Ministry of Defence and the Ministry of Railways procure drugs for military/field hospitals and railway hospitals, respectively. The Armed Forces Medical Services (AFMS) through the Director General of Armed Forces Medical Services (DGAFMS) as well as the Director General of Railway Health Services (DGRHS) purchase drugs primarily through centralised rate contracts, with leeway given for local/decentralised purchase of certain drugs. For instance, in the railways, quantity assessment for all medicines is done on the basis of assessing the periodic requisition (annual or less) of all hospitals falling under the jurisdiction of a zonal chief medical director (CMD). The requisition amount from all zonal centres is then clubbed at the headquarter/central level. After consolidation, if the estimated demand is less than one lakh in value (or a similar amount, notified from time to time), then the individual indents are sent back to the hospitals, who can procure such low-demand drugs locally. The approximate budget estimate classification for the procurement of medicines for the railways for FY 2020-21 is given in Table 3.

4.3 Procurement by agencies of the union government

Certain autonomous/independent bodies such as the Employees State Insurance Corporation (ESIC) and the Bureau of Pharma PSUs of India (BPPI) undertake procurement activities as per their mandate. These procurement agencies may be formed either through legislation, a cabinet decision, or decision of the concerned ministry as an independent legal body or a government body. The CMSS was formed in 1991 as a society in order to streamline drug procurement and distribution under the Department of Health & Family Welfare (DoHFW) and to procure high quality health goods in line with the directives of the union government. It is a central procurement agency that manages its pooled drug procurement through 20 warehouses. The BPPI is an autonomous agency formed under the Department of Pharmaceuticals and is responsible for the implementation of the Bhartiya Janaushadhi Pariyojana (PMBJP) by undertaking procurement for and management of Janaushadhi Kendra's throughout the country. The BPPI procures medicines through open tender from private manufacturers as well as central public sector undertakings (CPSUs). The ESIC is formed under the Employees' State Insurance Act, 1948 and is responsible for procuring drugs for ESIC hospitals and dispensaries under the ESIC scheme through long term rate contracts.

Table 4 compares the features of three of these agencies.

4.4 Drug procurement by the state procurement agencies

At the state level, there is significant heterogeneity in procurement models across the country. These differences dictate the financial burden, drug quality, transparency, and efficiency of the procurement process in the relevant state. Specifically, some of the broad differences in procurement models arise in the following components of procurement:

1. **Legal status of the procurement agency** - Whether the agency is state-owned or autonomous? This determines the independence and capacity of the agency as well as the source of its funding.

2. **EDL and demand estimation**- Whether the agency maintains an EDL and if yes, then what is the frequency of its revision? Whether it undertakes demand estimation based on scientific methodology and if yes, what is the frequency of such estimation? This determines proper selection and timely availability of procured drugs.

Table 4 Some features of some procurement organisations

Features	**Central Medical Services Society (CMSS)**	**Bureau of Pharma PSUs of India (BPPI)**	**Employees' State Insurance Corporation (ESIC)**
Year of formation	2011	2008	1954
Incorporation status	Society approved by approval of the Cabinet under the MoHFW	Independent society under the Ministry of Pharmaceuticals	Corporation under a Union government legislation
Source of finance	Government	Government and trade margins	Government and (forced) contributions from employees and employers
Quality testing	Inspection and random testing of procured drugs	WHO prescribed cGMP certification and lab testing of each batch of drugs	Inspection and random testing of procured drugs
Information on blacklisted firms	Yes	Yes	Yes
Annual reports	Yes (last uploaded for 2018-18)	Yes (as part of the Ministry's annual report)	Yes

3. **Procurement process** - What is the tendering process and timelines? A well detailed and transparent tendering system determines the efficiency of the procurement process.

4. **Quality control criteria** - Are there pre-qualification criteria such as minimum turnover, GMP, production capacity requirements? Are there additional quality assurance requirements such as pre-testing, random testing etc? This determines the quality of drugs procured.

5. **Supply chain management** - Who is responsible for warehousing, inventory management and distribution? This determines proper distribution of the procured drugs.

6. **Penalties**- Does the model impose penalties for quality breaches, failure to provide adequate quantities of drugs etc? Is there a blacklisting procedure? This determines the deterrence framework in place to ensure maintenance of quality and efficiency in the procurement process.

While procurement models differ across states, most states have attempted to emulate the Pooled Procurement model followed by the state of Tamil Nadu. Therefore, we first examine the Tamil Nadu model of pooled procurement and then study the variations to this model adopted by certain other states.

The Tamil Nadu Medical Services Corporation (TNMSC) is an autonomous procurement agency consisting of government appointed IAS officers and qualified contractual staff. It procures drugs at the state level. The budget utilised by Tamil Nadu to procure drugs through the TNMSC for the years 2012-13 to 2018-19 is provided in Table 5[6]. It functions in accordance with the detailed tendering process outlined in the Tamil Nadu Transparency in Tenders Act, 1988. The agency maintains a localised EDL that is frequently updated and conducts centralised tendering and purchasing of drugs on this list for the entire state (Singh et al., 2012). The tendering is based on the criteria provided under the Tenders Act which contains comprehensive guidelines on bid evaluation. The drugs are delivered to state warehouses in pre-estimated quantities by the chosen supplier and are further distributed to medical facilities on the basis of a passbook system. As per the passbook system, each medical facility is assigned a specific amount and may requisition any quantity of EDL drugs within that amount (Singh et al., 2012).

A quality testing protocol is followed whereby the agency tests the first batch of each drug requisitioned and also conducts random testing of drug samples

[6]Source: Performance budget of Health and Family Welfare Department (2018-19), Government of Tamil Nadu Tamil Nadu, 2019.

Table 5 Budget utilised for procurement of drugs and medicines by TNMSC from FY 2012-13 to 2018-19

S.No.	Year	Procurement amount (INR, in Billion)
1	2012-13	3.27
2	2013-14	3.56
3	2014-15	4.82
4	2015-16	6.30
5	2016-17	5.71
6	2017-18	5.87
7	2018-19	6.92

from its warehouses. The TNMSC places regular orders throughout the year based on the inventory levels in its warehouses which are monitored in real time with the extensive use of information technology. Since every step of the process is streamlined and certain, the TNMSC model has been extremely successful in terms of competitiveness i.e., number of bidders, successful candidates and drugs supplied to medical facilities. The procedures followed under the TNMSC model are recommended as best practice for other states by organisations such as the World Health Organisation and the World Bank.

While pooled procurement is the favourable mode of procurement in most states, different states adopt this model with variations in the different components of procurement. It is important that state specific variations to the pooled procurement model be based on an objective analysis of the pros and cons of adopting each element of the model in the local context of the state in order to ensure an efficient and economical procurement process. After TNMSC worked well, several states such as Kerala, Odisha, Bihar and Maharashtra have adopted this model with state-specific variation. The extent to which the design of TNMSC works, all across India, is limited, and to some extent this approach has not delivered comparable results even after local adaptation.

Across procurement models, there exist a set of common challenges with some states faring better than others at managing these issues. Some of these challenges identified across states and procurement models are -

1. Lack of documented procurement procedure;
2. Lack of information on criteria for technical and commercial bids;
3. Lack of timely availability of drugs due to non-scientific demand estimation,

inventory management and distribution issues;

4. Inadequate quality assurance mechanisms in terms of pre and post testing, recall and blacklisting;

5. Lack of transparency in publication of tenders, bid evaluation criteria etc.

In addition to these procurement specific challenges, the MoHFW as well as various committees set up to examine public procurement have pointed to the less than optimal state capacity of the State Drug Regulatory Authorities across the country especially when it comes to ensuring drug quality. For instance, in 2010-11, the PAC noted that state drug laboratories do not have the capacity to test all types of drugs, the drug inspectors are grossly inadequate in number and ill-equipped in training, and the functioning of the drug controllers themselves is far from ideal. As such, the failure of the broader drug regulation regime in the states has significant repercussions on public procurement as well since there is a large amount of resource sharing (such as government laboratories and inspectors) between both frameworks.

5 Conclusion

Drug purchase by various elements of the Indian state is an important problem, both because the state is a large-scale buyer of drugs, and because improvements in these processes can potentially impose gains upon the overall private markets for drugs. There is a need for a research community, and a research literature, which will build the positive and normative insights into these questions. Three key puzzles require resolution in this field:

1. Is it possible to improve the general capabilities of government, in a wide variety of government contracting problems, or is it better to solve narrow problems such as purchase of drugs by one specialised organisation such as TNMSC?

2. Are there ideas through which progress can be made all across the country, or do local conditions vary substantially and the pathways for progress in (say) Kerala differ from those in (say) Uttar Pradesh?

3. How can improvements in drug regulation impose gains for state procurement, and how can improvements in state procurement impose gains for the private market?

In this paper, we have described the mechanisms through which elements of the Indian state buy drugs and given links into this literature. This helps

lay the foundations of descriptive knowledge for a variety of researchers to analyse these questions further, as we have in Kaur, Shah and Srivastava, 2021.

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