Process improvement for drug procurement by the Indian state

Harleen Kaur Ajay Shah Siddhartha Srivastava*

19th May 2021

Abstract

In India, drug quality is an important problem. Government agencies are an important buyer of drugs, and also face significant problems with drug quality. In this paper, we examine the mechanisms used for drug purchase by four Indian states – Rajasthan, Punjab, Bihar and Gujarat. We establish a taxonomy of 13 design elements that are found across these four states. We engage in deductive reasoning about the design elements that appear to be useful and those that are less so. This work would help policy makers placed in an Indian public sector context in devising better procedures for drug purchase.

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

Contents

1 Introduction

There is a major drug quality problem in India. Within this overall problem, there is an important sub-problem: the purchase of drugs by various elements of the Indian state. There is a possibility that the endemic problems of drug quality in India, coupled with the endemic problems of low state capacity, could result in particularly daunting outcomes in drug procurement.

It is thus important to identify pathways for better mechanisms for Indian state organisations to purchase drugs. This could potentially be useful in and of itself – as the government is an important buyer of drugs. In addition, there are some pathways through which state purchase backed by high quality standards, coupled with transparency, could create greater market pressure in favour of higher drug quality.

Proposals for change can be relatively ambitious or they can be relatively modest and incremental. In this paper, we take an incremental approach:

1. We study four state government: Gujarat, Punjab, Rajasthan, Bihar.
2. We form the set union of all the elements of process design that are used in these four states.
3. We engage in deductive reasoning about the elements that appear to be useful and the elements which are not likely to be useful.
4. We propose a process design which puts together the good elements.

We consider the proposals of this paper to be relatively small and easily adopted modifications. Most elements of the proposed path only involves established elements of the process design used in one or more state organisation at present. As a consequence, it is particularly easy for any Indian state organisation to adopt these desirable design features.

The rest of the paper is structured as follows: Section 2 briefly describes the quality assurance drug procurement in India. Section 3 locates the problem of designing a government purchase process for drugs within modern Indian thinking on state capacity. In section 4, provide an intellectual framework for studying the procurement process. We classify the process in three stages; pre-tender, tender, and post-award stage for the purpose of this paper. We then identify common quality assurance mechanisms adopted by state procurement agencies. From this information, we evaluate better practices and enumerate guidelines for improvement in quality assurance in drug procurement in section 5. Section 7 concludes.

2 Quality concerns & measurement problem in public procurement of drugs

Drug purchases take place at the union and state level across various departments. In an associated paper (Kaur, Shah and Srivastava, 2021), we classify these models on the on the basis of purchase models into centralised & decentralised procurement types and on the basis of the procurement agency into union, state, autonomous and local procurement. States usually procure drugs through their respective departments of health or through specia1lised procurement agencies. Within a state, the drug procuring agency may adopt a centralised or a decentralised procurement model. While a centralised procurement model places a merged purchasing order for a defined set of hospitals and dispensaries, in a decentralised model, drugs are procured based on the local needs at the level of a health facility.

India is characterised by low state capacity across a large number of state activities. It is not surprising that the Indian state has low capabilities in purchasing drugs also. Drug quality is one bottleneck: state agencies face the risk that a vendor will deliver sub-standard drugs. There is a need for adequate process design in order to confront and address this problem.

At present, the processes are deficient. Many times, we see designs of procurement mechanisms in India where the burden of proof of drug quality is left to the supplier of drugs. The procurement agencies that do conduct quality testing have transparency mechanisms, where they share information regarding the bad quality drugs at their own websites. This information usually contains details of the batch number, manufacturer, sampled place, date of test report and findings of the test report. The drugs that fail quality tests are classified into Not of Standard Quality (NSQ) or spurious drugs. Around 2009, the government launched a central database for drug manufacture licensing and quality assurance called *XLN - Xtended Licensing, Laboratory & Legal Node*. At the time of writing, this website is partly functional, it provides information on substandard drugs only. About five states actively share information regarding drug quality results through XLN database.[1]

This disclosure comes in the context of low information about drug quality in India. For instance, Weir et al., 2005 wherein about 20% of the drugs tested were found to lack adequate potency and Bate et al., 2009 wherein 6-12% of drugs sampled from Delhi and Chennai were reported to be NSQ. If state

[1]We studied the substandard drug quality reported at XLN for the years 2019 and 2020 and find that Gujarat, Kerala, Goa and Chattisgarh actively contribute to this database.

systems created good information on the quality of drugs made by various firms, this could potentially induce positive effects upon the working of the private market. However, the information on quality of drugs generated by the government is sporadic and even contested.[2]

The present literature on state procurement of drugs is focused on description of procurement processes in states (such as Singh et al., 2012) and description of the regulatory framework for public procurement (such as CUTS International, 2012; Kamala Dawar and Seung Chul Oh, 2017). There is a need for a greater focus on the problem of drug quality in public procurement. We aim to contribute to this knowledge through Kaur, Shah and Srivastava, 2021 and this paper.

3 Policy design for government procurement of drugs

At the outset, we need to engage in some foundational reasoning about the Indian state and the ways in which it engages with private persons when purchasing drugs. In the India of old, there was a certain world view that was brought to bear upon this question.

It was felt that government officials fundamentally mean well, and that private firms come in two kinds: good ones and crooked ones. From this point of view, the problem of procurement consisted of excluding the crooked ones and buying from the lowest bidder among the good ones.

This world view is fraught with difficulties. The analytical construct for thinking about government officials is now grounded in public choice theory, the idea that government officials will primarily pursue their own self-interest. A system of checks and balances is required to channel the energy of self-interested actions by officials into outcomes that are aligned with the larger good. In contemporary thinking, we are skeptical about the intentions of officials and politicians, and we are highly conscious that good intentions generally do not map to good outcomes unless elaborate mechanisms of check-and-balance are put into place.

Similarly, modern thinking in Indian economics does not view firms as good or bad; firms merely respond to incentives. Most firms will try hard to maximise profit, and if a system of checks and balances is put into place, this

[2]Please see CDSCO drug quality reports, Central Drugs Standard Control Organisation, 2009; Ministry of Health and Family Welfare, 2016.

energy will be channelled into innovation and cost-reduction. On the other hand, if the checks and balances are weak, then firms will behave badly. Bad behaviour by firms it not seen in a moralistic way; it is merely a response to the wrong incentives.

In the old intellectual framework for policy design, officials were seen as good and some firms were seen as bad, so a key lever that was placed into the mechanism design was analogous to a death sentence: Debarment or "black listing". It was argued that the problem in drug procurement is that some firms are bad, and alongside this it was felt that officials are always good, so officials were given high executive discretion in wielding this death sentence, of pushing some firms out of the pool of eligible firms, forever.

In modern Indian policy thinking, however, the very power of writing a death sentence creates bad incentives for officials and undermines their work. Self-interested officials who wield large powers are more likely to use this in ways that cater to their own interest. The threat of a death sentence can elicit enhanced corruption. This is particularly the case when the legal foundations of debarment are not specified in great detail, in a rule of law framework, thus conferring enormous powers upon officials.

High powers tend to corrupt government organisations, and result in reduced state capacity. When firms face a low probability of facing sanctions for delivering low quality drugs, the quality of drugs is reduced, whether by "good" or "bad" firms.[3]

From the viewpoint of policy design, it is better to generate a *regime* of sanctions, where bad behaviour is punished and incentives are constantly created for firms to produce high quality drugs at a low price. We must recognise that firms will try to squeak past quality requirements at the lowest possible cost, and every now and then, some firms will fail to make the bar. Faced with sufficiently high monetary sanctions, firms will be pushed back into the correct zone of quality, without requiring disbarment.

4 Quality assurance procedures in drug procurement

We studied the practices by agencies of four states – Gujarat, Bihar, Punjab and Rajasthan. Gujarat Medical Services Corporation Limited (GMSCL),

[3]Modern thinking in Indian public policy, as articulated here, roughly maps to the Mark 3 framework of Kelkar and Shah, 2019.

Rajasthan Medical Services Corporation Limited (RMSCL) and Bihar Medical Services & Infrastructure Corporation (BMSIC) are the procurement agencies for Gujarat, Rajasthan and Bihar, respectively. These are autonomous agencies registered under the Companies Act and are fully owned and operated by the state governments. The state of Punjab conducts its procurement through its state government department, the Punjab Health Systems Corporation (PHSC).

A procurement agency has to ensure that the quality and integrity of drugs are preserved while maintaining batch traceability and possibility of stock rotation. This role is not limited to the procurement stage only, but extend to post procurement storage and distribution stage as well, as improper storage or handling can lead to deterioration of quality of drugs.

We set out to carefully examine the processes followed by these four states, with an emphasis on the problems of quality both at purchase and after.

4.1 Principles that guide normative analysis

In order to engage in normative analysis of design features, we used the following set of principles to guide the thinking.

Transparency Greater ex-ante transparency about the process that will be used is a desirable thing. An updated procurement manual with description of processes, publication of annual reports and a reasoned explanation of criteria applied by agencies can help firms and general public in understanding the significance of the qualification criteria chosen by the agency, such as the minimum annual turnover of a manufacturer. When legal disputes come about, such documentation helps reduce legal risk, by shaping the minds of rival lawyers and of judges.

Quality testing The primary responsibility for product quality reports should be on manufacturing or supplier firms, and the claims that they make should be derived from a sound and audited data gathering process. At the same time, procuring agencies should be responsible for random testing of drug quality in different steps along the supply chain. We found that while none of the state procurement agencies or Medical Stores Organisation (MSO) had any random testing protocol available, certain other agencies such as the Tamil Nadu Medical Services Corporation Ltd. (TNMSC) have a prescribed mechanism for random and blind testing of every batch of drugs received by them.

Reducing friction Various procurement processes in India contain elements of the process design which are hard to justify; these elements which may have

crept in over the years appear to merely add process overhead and are worth removing.

Scientific methods of quality assurance The methods used by agencies should have adequate statistical sampling at various elements of acquisition, storage and supply chain management.

Unambiguous legal processes When a procurement agency finds that it has been delivered a consignment of defective drugs, there must be predictability about the legal process that will be followed: e.g. it could inform the Food and Drug Control Authority (FDCA), or it could take legal action against the seller including mechanisms like blacklisting / debarment. One puzzle here lies in the inter-relationship between a state buyer, the state FDCA and the state State Drugs Laboratory (SDL) labs which also do testing for the state FDCA.

Single source of information The procurement agencies and the FDCAs perform similar functions within their jurisdiction. The information available within these entities is currently available in silos. A person who is a resident of a state 'A' has to examine the list of drugs declared NSQ or spurious under atleast three different databases (procurement agency, FDCA and Central Drugs Standards Control Organisation (CDSCO) updates) to check quality alerts for drugs sold in their own state. To the extent that procurement processes induce simplification of information flows to the public, this is a desirable feature.

There are three stages wherein quality of procured drugs are tested by procurement agencies. These stages are pre-qualification, tender and award & post-award stage. We now study the common methods of quality assurance used by state agencies to identify best practices.

4.2 Pre-qualification stage

In an ideal world, it would be possible to purchase from the open market, and impose quality standards at the point of acceptance. This imposes a greater burden upon the purchaser in terms of effort and expenditure on quality assurance. It also creates greater risk of failed procurement attempts. In order to address these constraints, pre-qualification criteria are employed, to reduce the field to reputed sellers. The three standard pathways for pre-qualification criteria are (a) Compliance with Good Manufacturing Practices (cGMPs) prescribed by a regulator or the World Health Organisation (WHO), (b) A minimum annual turnover and (c) A "non-conviction certificate" from the state FDCA. At the same time, an excessive push with

stringent pre-qualification criteria can result in a less than competitive purchase process.

The design elements that we see at this stage are:

E1: License and cGMP certificate are standard criteria across most procurement agencies. These help in establishing the minimum standards of drug manufacturing/import of suppliers participating in the tender process.

E2: Minimum experience for manufacture This criterion is generally set to three years. As the procurement process involves large consignments of drugs, a minimum experience may help in choosing suppliers with the necessary bandwidth to provide quality drugs expeditiously. At the same time, it constitutes an entry barrier against young firms which may or may not correlate with high quality drug manufacture.

E3: Market standing certificate issued by state governments is used by procurement agencies as a qualifier which looks at the financial performance of the drug.[4] Physical inspections of lab testing by agencies are usually not performed at this stage while they are recommended by the World Health Organisation, 2007 A participating agency has to obtain a certificate from either CDSCO or a state drug regulator and submit the same to the procuring agencies. There are concerns about the usefulness of this criterion, as these regulatory agencies have low capabilities and lack standard protocols about how these certificates are issued.

E4: Non-conviction certificate is issued by a state drug regulator for use with state procurement agencies. In practice, the state drug regulators issue the certificate on the strength of an assertion by the private firm. Even if the information management were sound, there is a deeper issue: should one conviction generate debarring from public procurement forever? This is somewhat like a death sentence. Generally, in economic law, softer penalties are more effective in reshaping incentives.

E5: Minimum annual turnover varies considerably amongst the states studied. There is little published rationale about the thresholds that are chosen. Once minimum experience, cGMP and manufacturing licenses are in fray, it is hard to see the extent to which minimum turnover adds value.

E6: Blacklisting disclosure by supplier The supplier is asked to provide a certificate to the procuring agency stating that it has not been blacklisted elsewhere in the country. Since procurement occurs at various union and state level agencies, it is important to obtain this disclosure by the supplier before allowing them to participate in the bidding process. This puts the

[4]For instance, a similar process is described in CDSCO, 2019.

Table 1 Pre-qualification criteria for quality control during drug procurement

Design element	GJ	BR	PB	RJ
E1: Valid manufacturing or import license	Y	Y	Y	Y
Valid WHO-GMP/COPP certificate	Y	Y	Y	Y
E2: Years of experience of manufacturer	Y	Y	Y	Y
E3: Market standing certificate	Y	Y	N	Y
E4: Non-conviction certificate	N	Y	Y	Y
E5: Min. avg. annual turnover (Last 3 years)	2 Cr	25 Cr	2 Cr	20 Cr
E6: Blacklisting disclosure by Supplier	Y	Y	Y	Y

burden on proof on the supplier, thereby helping the procurement agency obtain relevant information without expending resources.

Table 1 compares the design features of the four states on these six criteria.

4.3 Tender stage

Once the pre-qualification stage is complete, we come to the tender stage. Sometimes, features that are absent in the pre-qualification stage (e.g. cGMP certificates) are placed at the tender stage. Quality test certification of random samples can be made a condition precedent to grant of the contract. Tender documents can include a requirement for conducting an inspection and technical audit of supplier's premises by the procurement agencies. Sometimes, the *same* provision is found in the pre-qualification stage as in the tender stage. The criteria seen at this stage include:

E7: Testing drugs batch-wise before supply States can require testing of all batches of drugs, putting this burden on the manufacturer. This is either done by demanding a report by government labs/government certified labs or through being made responsible for payment of getting tests conducted by the procurement agency.

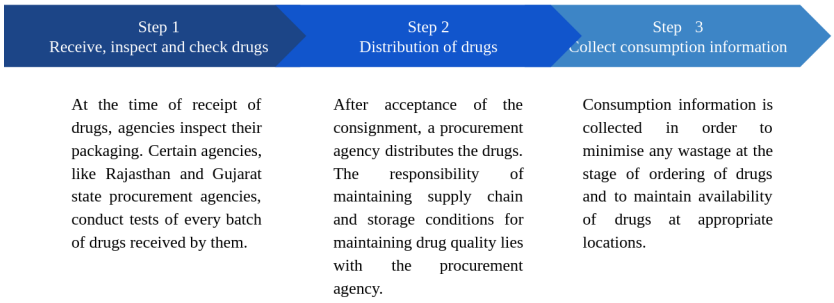
E8: Testing of samples by procurement agencies is done by only few states at SDLs themselves. However, policies for random testing of samples are usually not well defined. A detailed policy on random testing of drug samples by procurement agencies was not present in publicly available documents of our sampled states.[5]

[5]The Tamil Nadu Medical Services Corporation services, however, had declared the basic process of random testing of their drug consignment such as stating that random samples from each batch are sent to TNMSC Quality Control department where common batch of each item are eliminated, the tablets and capsules are removed from the strips

Table 2 Qualification criteria at the tendering stage

Design element	GJ	BR	PB	RJ
E7: Testing every batch before supply	Y	Y	N	Y
E8: Pre-testing of samples at qualified labs	Y	N	N	Y
Testing of random samples (at point of supply or distribution/storage)	Y	Y	Y	Y
Policy for testing of random Samples	N	N	N	N
E9: Evidence of stability of drug	Y	Y	N	N
E10: Submission of Reference Standards/Quality Protocols for Testing	Y	Y	Y	Y

Figure 1 Drug management by procurement agencies



E9: Evidence of stability of a drug is a criterion that is places the burden upon the supplier to show test results on stability.

E10: Reference standards and quality protocols for testing These refer to pharmacopoeial chemical reference substances which are usually set up by countries. In absence of such standard being present, a manufacturer should establish a primary reference substance for the drugs supplied by it so that any random testing can be conducted against such a specification.

Table 2 shows the process design used in the four stages at the tendering stage.

4.4 Award and post-award stage

After a tender is granted, the burden of quality assurance largely shifts to the procurement agencies. Figure 1 shows the steps that take place at the

and blisters, labels of vials, ampules and bottles are removed and coded with the secret code (Sample Code) and automatically empanelled laboratory is allotted (randomly with equal weight-age) to each sample by software (DDMS). Accordingly the decoded samples are sent to the respective laboratories for analysis.

procurement organisation after the tendering process.

Formal processes, transparency and accountability are weak at this stage. For instance, a procurement manual that defines the process followed by agency after the receipt of consignments is absent in many states. The process of blacklisting or debarment is not well defined in policy documents. Updated names and details of blacklisted/debarred firms are unavailable. The annual report of agencies is unavailable in most cases. We see three important elements at this stage:

E11: Manual for drug testing and blacklisting process Once the contract is awarded and after the drugs have been procured, quality is usually assured by way of drawing samples from each consignment and getting them tested at laboratories approved by the state FDCA or random testing of the consignment. While some states conduct random tests of procured drugs at empanelled labs, others like Punjab and Maharashtra do not. Predictable and rule of law procedures require that there should be a manual that drives this stage, and that the manual should have sound procedures.

E12: Transparency about blacklisted/debarred firms A publicly available list of debarred/blacklisted firms, with details about the circumstances that led to this drastic measure, would increase knowledge with the public about the reputation of alternative firms. It would also create checks and balances surrounding the executive discretion in the blacklisting process. It would also create greater pressure upon firms to sell high quality drugs to government agencies.

E13: Updated annual report Procurement agencies are a part of the Indian state. The release of a detailed annual report is one essential element of the transparency and accountability mechanisms which create checks and balances in favour of better owrking of the agency.

Our findings about the four states at this stage are presented in table 3.

5 A normative perspective

A surprising feature of the above examination, of elements of the state level drug procurement process, is the extent of variability between the procedures used by the four states under examination. To some extent, this variation could reflect differences in local conditions. At the same time, each element present in at least one state represents a precedent which could be utilised by other states.

Table 3 Quality assurance post award

Design element	GJ	BR	PB	RJ
E11: Procurement policy/manual published	N	Y	N	Y
Procedure for blacklisting/debarment published	Y	N	N	Y
E12: Blacklisted/debarred firms visible for last financial year	Y	Y	N	Y
Reasons for blacklist/debarment available	Y	Y	Y	Y
E13: Updated annual report	N	N	N	Y

Based on the arguments above, we argue that the following features are desirable:

1. Minimum Average Annual Turnover (Last two years): In government contracting, it is often a problem when the dominant activity of a given firm is made up of the order magnitude associated with the government contract under examination. It is, hence, helpful to have a minimum average annual turnover which is three times of the estimated contract value that is being purchased. Such a requirement would inevitably require a minimum of two years of experience.

2. Valid WHO-GMP/COPP certificate : A sound GMP process is of great importance in achieving greater quality.

3. Evidence of stability of drug : The manufacturer should need to supply this evidence.

4. Submission of Reference Standards/Quality Protocols for Testing : When the relevant pharmacopia does not have the reference substance, the manufacturer should have to establish the primary reference substance for the drugs supplied by it.

5. Testing of Random Samples (at point of supply or point of distribution/storage) : This is the most important checkpoint where drug quality will be assured for government purchasers.

6. Policy for Testing of Random Samples : In a rule of law system, every detail about how the recipient of the consignment will engage in random testing needs to be disclosed.

7. Valid manufacturing or import license: While the concept of licensing may have limited value in the modern Indian economy, mapping substandard

or NSQ drugs with the State Drug Regulatory Authorities (SDRAs) providing license may lead to improved checks and balances between the drug procuring agency and the SDRAs.

8. Procurement policy/manual published : The purchasing agency should release comprehensive information about all aspects of its purchase process.

9. Procedure for imposing sanctions upon faulty suppliers : In particular, when random samples reveal the lack of adequate quality, there must be a written manual which generates sanctions upon the seller. This would generate predictability, and create incentives for sellers to be more careful.

10. Name and address of firms, with details about the infractions, where sanctions were imposed in the last three years : The public should know all the details about the firms which were sanctioned, and every detail about what went wrong in those transactions. This would generate reputational damage for these firms, and induce greater quality in the private market for drugs.

11. Annual report of procurement organisation : Every state organisation must be obliged to release a detailed annual report about its own work.

On the other hand, the criteria that appear to be less useful in the procurement process, that are used in one or more of the four states under examination, are:

1. Minimum experience of manufacturer: Once the minimum average annual turnover requirement is in place, it automatically imposes a minimum years of experience in the field.

2. Testing every batch before supply by the supplier : The right pathway for testing lies with random samples at the point of delivery, with a testing process that is controlled by the recipient.

3. Pre-testing of Samples at procurement agency qualified laboratories by the agency : This is also less important once random testing is done by the recipient of drugs.

4. Market standing certificate, Non-Conviction Certificate, the concept of blacklisting : Economic law should not have death sentence clauses. When firms make mistakes, they should not be thrown out of business. Instead, a system of monetary penalties needs to be created, which creates incentives for firms to behave better.

Table 4 The quality of drug procurement procedures

State	Sound elements	Weak elements
Gujarat	+8	-4
Bihar	+8	-3
Rajasthan	+5	-1
Punjab	+9	-1

6 Ranking procurement agencies

So far, we have proposed a taxonomy of design elements, that are observed from government procurement of drugs in four states, and made certain normative claims about each of these elements. Some design elements are considered useful and others less so.

This can be turned into a numerical scoring system as shown in Table 4. As an example, Punjab looks better than the other states, in that it has 9 positive elements and one negative element in its design of the procurement procedure. Such measurement systems can encourage weak states to review their procurement frameworks and potentially adopt sound design features visible in other states in India.

Such design, of course, has to be undertaken in a cautious way, with a recognition that the ground realities in the different states of India are highly heterogeneous. There is no one-size-fits-all formula for effective procurement and no two states function alike. Such simplistic numerical scoring is limited in that some design elements are enormously more important than others; e.g. the most important design element may be testing of random samples at the point of receipt. Similarly, such simplistic numerical scoring suffers from the illusion of linearity, while the design elements actually interact with each other in a nonlinear way.

7 Conclusion

Drug purchase by the government is an important element of the drugs industry and of government contracting. At present, there is a problem of drug quality in government drug purchases. Addressing these problems will induce many positive benefits: Better drugs in the government system, and greater incentives for manufacturers / importers to deliver higher quality into the private market for drugs.

In this paper, we have undertaken a detailed description of the processes used

in four states: Gujarat, Bihar, Punjab and Rajasthan. There is significant heterogeneity in the mechanisms that are used in these states.

We go on to engage in deductive normative reasoning about the elements of the procurement process. The set of design elements which are present today contains some elements which appear to have limited usefulness. There are other elements which are more useful, and can be potentially modified to become stronger. This work will help designers of the processes of government procurement of drugs achieve a birds eye view about the systems in use in India, and foster debates about the reform of these systems.

References

Bate, Roger et al. (2009). "Pilot study of essential drug quality in two major cities in India". In: URL: https://pubmed.ncbi.nlm.nih.gov/19547757/ (visited on 8th Jan. 2021).

CDSCO (2019). *Guidance document for obtaining market standing or non conviction certificate of notified medical devices*. URL: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/mscmd.pdf (visited on 29th Oct. 2020).

Central Drugs Standard Control Organisation Directorate General of Health Services, Ministry of Health & Family Welfare (2009). *Report on country-wide survey for spurious drugs*.

CUTS International (2012). "Government procurement in India: Domestic regulations and trade prospects". In: URL: https://cuts-citee.org/pdf/Government-Procurement-in-India_Domestic-Regulations-Trade-Prospects.pdf (visited on 19th June 2020).

Government of India (2020). *XLN - Xtended Licensing, Laboratory & Legal Node*. URL: https://xlnindia.gov.in/GP_FailedSample.aspx (visited on 29th Oct. 2020).

Kamala Dawar and Seung Chul Oh (2017). "The role of public procurement policy in driving industrial development". In: URL: https://www.unido.org/api/opentext/documents/download/9921981/unido-file-9921981 (visited on 24th Jan. 2021).

Kaur, Harleen, Ajay Shah and Siddhartha Srivastava (May 2021). *How elements of the Indian state purchase drugs*. Tech. rep. todo.

Kelkar, Vijay L. and Ajay Shah (2019). *In service of the republic : The art and science of economic policy*. Penguin Allen Lane. ISBN: 9789353057138,9353057132. URL: https://www.mayin.org/ajayshah/books/isotr2019.html.

Ministry of Health and Family Welfare (2016). *Survey of extent of problems of spurious and not of standard quality drugs in the country*. URL: https://main.mohfw.gov.in/documents/reports/drugs-survey-report (visited on 23rd May 2020).

Singh, Prabal Vikram et al. (2012). "Understanding public drug procurement in India: a comparative qualitative study of five Indian states". In: URL: https://bmjopen.bmj.com/content/bmjopen/3/2/e001987.full.pdf (visited on 21st May 2020).

Weir, R E et al. (2005). "Variability in the content of Indian generic ciprofloxacin eye drops". In: URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1772805/pdf/bjo08901094.pdf (visited on 24th July 2020).

World Health Organisation (2007). "A model quality assurance system for procurement agencies". In: URL: https://www.who.int/medicines/publications/ModelQualityAssurance.pdf?ua=1 (visited on 22nd Jan. 2021).