

An Overview on Pharmaceutical Tendering Process

Silpa Jalagam, Muddukrishna Badamane Sathyanarayana*

Department of Pharmaceutical Quality Assurance, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal, Karnataka, INDIA.

ABSTRACT

Objectives: World Health Organization (WHO) has implemented the Pharmaceutical tendering process for procuring the high-quality medicines from different firms to meet the needs of the countries which are having drug shortages. **Materials and Methods:** The main aim of the WHO is to get the quality products at low price which can be affordable by the patient. WHO constantly giving chance to different firms based on their qualification for tendering process. The pharmaceutical companies are inspected by WHO members to check whether the company is adhering with Good Manufacturing Practices (GMP) regulations and Quality Management system (QMS) requirements. **Results:** The WHO allows only prequalified pharmaceutical company for the tendering process (Restricted tender). By this process WHO allows the company which produces quality drugs at the affordable cost and complying with the all WHO regulations. Comparing the restricted to open tender, the direct procurement and competitive negotiations tender methods are little disadvantageous as the drugs are taken from highly reputed or single manufacturer which causes the price of the drug to be higher. In the open tender and restricted tender, the WHO can get the manufacturers who supply drug products at low prices.

Key words: Tendering process, Procurement, GMP, Pre-qualification, Bidding.

INTRODUCTION

Drug Products costs are increasing along with the expansion in Pharmaceutical Industry and they are expanding health systems in addition to their feasibility.¹ Several factors are responsible for the increase in pricing of the Pharmaceuticals products. Worldwide use on medications is assessed to reach US\$1.4 trillion by 2020, with up to 60% of this spent money are paid back by the WHO authority.^{2,3} For difference, the entire worldwide use on medical management in 2018 is assessed to be US\$9.3 trillion, with a normal multiplication.² Procurement of pharmaceuticals is a complex process which involves several steps, agencies, ministries and manufacturers.⁴ Some countries are not having proper regulations and distribution systems in-place for the pharmaceutical procurement which lead to drug shortages. Therefore World health Organization (WHO) published guidelines such as Operational principles

for good pharmaceutical procurement and Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies to help the countries for procuring pharmaceuticals by the tendering process. The inevitable objective of pharmaceuticals acquisition is to get a high-grade drug accompanied along with good provisioner administration together with most minimal conceivable costs.² The Formal Method has been introduced by the WHO for the tendering process, it enhances the competition between the Sponsors.^{2,5} World Health Organization (WHO) defined Pharmaceutical Tendering as “any formal and competitive procurement procedure through which offers are requested, received and evaluated for the procurement of goods, works or services and as a consequence of which an award is made to the tenderer whose tender/offer is the most favorable”.⁴ In many countries pharmaceutical products are purchased through the health budgets.⁶

Submission Date: 24-06-2020;
Revision Date: 09-10-2020;
Accepted Date: 25-11-2020

DOI: 10.5530/ijper.55.1.5

Correspondence:

Dr. Muddukrishna BS

Assistant Professor, Senior scale, Department of Pharmaceutical Quality Assurance, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal-576104, Karnataka, INDIA.
Phone: +91 0820-2922482
E-mail: krishna.mbs@manipal.edu



www.ijper.org

WHO uses the following procurement methods: a. Open tender; b. Restricted tender; c. Competitive negotiations; d. Direct procurement.⁶ Pharmaceuticals tendering process comprises of: Establishing format and its scope; estimated or fixed tender quantities; selection of suppliers to participate for bidding; In restricted tenders, the suppliers are invited for prequalification.; Invitation for tender; Preparing and sending the documents; Evaluation of bids and post qualification procedures.⁵ The techniques and practices may not just demonstrate the impact on the cost for a given drug yet in addition needs a unavoidable enrollment procedure to safeguard medicate standard is kept up on suppliers which were granted the tender for a specific drug.^{4,6} This article mainly gives emphasis on Pharmaceutical Tendering process by WHO which includes different methods used for tendering, supplier selection, prequalification of the suppliers for restricted tenders, bidding documents submitted during the tendering and post qualification of supplier by the WHO.

Repeated problems in drug procurement⁶

1. Once in a while, delivered drugs may not be in consistence with worldwide guidelines of ICH containing related to Quality, Safety and Efficacy.
2. It is very hard to get repayment for debased imported drugs that had been already paid by the government.
3. Procurement of pharmaceuticals depend on open international tender's shows a plenty proposal, which are of affordable cost but the low-grade drugs are delivered.
4. Slow-up in distribution's are regularly experienced while managing new and obscure sponsors through open tenders.

Tender Format for Suppliers⁶

WHO proposed the below methods for procurement which are being utilized in real practice:

Open tender

It is a formal technique where tenders are welcomed from a worthwhile manufacturer or sponsor. Even if it is for small quantities pharmaceutical companies generally respond to tenders. Hence, an excessive number of applications for tenders are submitted which over-burdens the constrained limit of acquirement organizations is small countries which prompts delay in the assessment of bidders and can't be attempted when the schedule of tender has been started.

Restricted tender

Prequalified suppliers can only participate in restricted tenders. Initial selection and assessment of suppliers is tedious, when prequalified providers has just been established, the selection procedure will be simple for the procurement agency. Drugs quality can be all the more effectively guaranteed through restricted tender.

Competitive negotiations

This strategy includes asking for price quotations from few selected organizations which results in more expensive rates.

Direct procurement

This strategy includes the open purchase from a single manufacturer either at supplier's tender cost or swing costs. This technique is best if there should be an occurrence of emergency situations, however isn't reasonable for routine orders. This method is simplest but it is the most expensive procurement method. (Table 1)

Types of tender quantities^{6,7}

The two extensively used tender quantity types are discussed below:

1. Fixed-quantity, scheduled delivery purchasing contract

This contract determines that the delivery of pharmaceuticals will be either in one shipment or a

Table 1: Advantages and disadvantages of types of tenders.

Procurement method	Open tender	Restricted tender	Competitive negotiations	Direct procurement
Advantages	Large number of bids, Low prices, Identify the new suppliers	Only minimum number of bids, Better quality assurance can be provided because suppliers are prequalified	Selection and evaluation of suppliers doesn't take much time, Suppliers are generally well known.	Direct purchase from single supplier which is easy and quick.
Disadvantages	Determination and assessment of suppliers is tedious on account of large number of bids	A system should be in place for the prequalification of suppliers.	Higher prices	High prices

few smaller shipments in fixed amounts. In the event that the amount surpasses actual requirement, the purchaser acknowledges the danger of overstocking. The purchaser should risk paying more expensive rates for additional orders if the amount requested is not exactly actual need.

2. Estimated quantity, periodic-order contract

Each drug contract price will be negotiated and the quantity is based on estimate. The amount really obtained may vary from the estimate which prompts the risk for supplier. Orders will be placed periodically.

Prequalification of suppliers for restricted tenders⁶

Profile of pharmaceutical companies should be established by the prequalification of suppliers. This method includes purchase of drugs from the local agents/wholesalers or directly from the manufacturer. If the purchase of drugs is from the local agents or wholesalers, the price will be high which includes a complicated negotiations. (Table 2)

The objective of the prequalification is to guarantee that the organization being referred to is a registered company and the manufacturing of the drugs is in consistence with Good manufacturing practices and the drugs offered by the supplier provide a certification that it has marketing authorization for respective country of origin. If the procurement agency knows the supplier, the assessment of past performance will be a part of the prequalification. Drug certificated dependent on WHO Certification Scheme on the drugs standard grade moving in the market are to be submitted at the time of Prequalification. These certificates guarantee that the products are manufactured by current GMP standards. These certificates additionally guarantee that the supplier is audited by National regulatory authority and the drugs are authorized for advertising in the country required by the officials.

Criteria for prequalification of suppliers⁶

- Use the questionnaires to obtain the supplier’s information.
- WHO certification scheme can be used.

- Obtain data from the exporting nation’s drug regulatory authority.
- For information exchange between drug regulatory authorities, existing networks can be used.
- Samples of the product should be evaluated.
- Performance of the suppliers should be monitored and recorded.

The Questionnaire for Prequalification of suppliers includes the following:

Business Information

It incorporates the information to survey the extent of the business as far as staff, turnover of the organization and trading practices of the organization.

It is fundamental to inquire the countries that the organization has marketing authorization approval for its drugs.

Manufacturing Information

Manufacturers should be inspected, but it is not feasible for some developing countries due to insufficient funds and qualified inspectors. The GMP compliance will be assured with the WHO Certification Scheme. Information should include the details about the products meant for exports which are being used for the sale in the country of origin. The manufacturing of pharmaceuticals includes different steps from procurement and preparing of raw materials, packaging of the final product and labelling the drugs which may incorporate more than one company in the entire procedure, the GMP compliance of all manufacturing plants engaged with the manufacturing of pharmaceutical must be documented. This section should also give information about the bioavailability testing and stability testing have done on products offered for export on a routine base. This information should also include the total number of drugs manufactured and manufacturing operations carried out by the company, manufacturing license.

Quality Control Information

Data report is utilized to assess the quality assurance system of the manufacturing company. Sponsors manufacturing facilities ought to maintain the quality

Table 2: Advantages and disadvantages depending upon type of supplier’s.

Supplier Type	Local Agent	Wholesaler	Manufacturer
Advantages/Benefits	Easy and fast communication	Easy and quick communication	Lower prices and communication on technical issues will be easy
Disadvantages	High prices and communication on technical issues will be difficult	High prices and communication on technical issues will be difficult	

control labs to be in compliance with GMP. For selected tests, external laboratories can be used.

Product Information

While procuring the drugs, the marketing authorization status of the drug in different countries both of developed and developing. This ensures that the product is complied with safety, efficacy and quality standards of those countries. If the products are not registered in well developed countries, investigation should be done on the safety, efficacy and quality issues. The Certificates of Pharmaceutical products dependent on WHO Certification scheme will guarantee a certain that the drug offered for export had enrolled in the country which it has marketing approval. And the manufacturer is in consistence with GMP measures with audits. The drug information ought to incorporate the Certificate of Suitability to the European Pharmacopoeia (CEP) or Drug Master File (DMF), finished product specifications, validation, Active ingredient assay limits, stability data, Label and insert data.

Tender invitation⁶

It is a vital document which gives data with respect to technical and legal prerequisites for acquiring products of high quality. If there is any problem with suppliers, tender invitation can be used as a reference. The choice on the final form of the invitation ought to be contemplated to convince about programme and necessity on the acquisition of drugs. The invitation for tender ought to incorporate the terms and conditions, terms of installment, Conveyance periods and timetable, specifications of the product, labelling, packaging, expiry date and how the quotation is to be submitted.

Documents to be submitted for bidding⁶

- The bid form which includes the specifications, size of the package, delivery mode, number of items and the cost for each item.
- A Pricing plan, presenting total and unit prices.
- Documentation evidences for good manufacturing practices (GMP) and manufacturing license.
- Procedures of quality control, equipment and manufacturer's capacity.
- For each item, the evidence for quality assurance documentation.

Evaluation of bids⁶

Price is the determining factor for awarding a tender. Amid assessment of bids, a pharmacist or an individual who is knowing about pharmaceuticals and its production will be an individual from the tender board which will grant tenders. Quality of the products must

be taken into consideration while evaluating the bids. Assurance of quality is plays a key role while evaluating the bids and the product prices. Transparency ought to be kept up all through the procurement cycle by following the terms and conditions. After the assessment, rundown of the contracts granted, alongside suppliers and cost for every pharmaceutical product will provide accessible to all candidate.

Post qualification procedures⁶

A supplier's performance and consistence with the terms and conditions ought to be checked and recorded, with noticeable quality on timely delivery, amounts conveyed according to the indent, quality and the shelf-life of the drug after delivery of the item. By the visual inspection, the quality of the consignment can be checked and an inspection checklist for drug receipt will be there which is used to compare the supplier's invoice against the original purchase indent.

ACKNOWLEDGEMENT

The author would like to thank Manipal College of Pharmaceutical Science, MAHE for providing the materials and instruments to conduct this work.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

WHO: World Health Organisation; **QMS:** Quality Management System; **GMP:** Good Manufacturing Practices; **US:** United States; **ICH:** International Council for Harmonisation of technical requirements for pharmaceuticals for human use; **DMF:** Drug Master File; **MAHE:** Manipal Academy of Higher Education.

REFERENCES

1. Petrou P, Talias MA. Price determinants of the tendering process for pharmaceuticals in the Cyprus market. *Value Health Reg Issues.* 2015;7:67-73.
2. Dranitsaris G, Jacobs I, Kirchoff C, Popovian R, Shane LG. Drug tendering: Drug supply and shortage implications for the uptake of biosimilars. *Clinicoecon Outcomes Res.* 2017;9:573-84.
3. Who. int. [cited 2020 Nov 25]. Available from: <http://apps.who.int/medicinedocs/documents/s18767en/s18767en.pdf>
4. Who.int. [cited 2020 Nov 25]. Available from: <https://www.who.int/3by5/en/who-edm-par-99-5.pdf>
5. Who. int. [cited 2020 Nov 25]. Available from: <http://apps.who.int/medicinedocs/documents/s19577en/s19577en.pdf>
6. Who.int. [cited 2020 Nov 25]. Available from: <http://apps.who.int/medicinedocs/pdf/h2999e/h2999e.pdf>
7. Who.int. [cited 2020 Nov 25]. Available from: http://apps.who.int/iris/bitstream/handle/10665/65175/WHO_DMP_RGS_98.5.pdf

PICTORIAL ABSTRACT



SUMMARY

Tendering is a potent system and various parameters can influence the process of tendering. The process of tendering for pharmaceuticals need to be safeguarded by supplying the quality assured products. Most of the developing countries follows tendering process given by WHO to procure pharmaceuticals. Even Pan American Health Organization (PAHO) follows the procedures given by the WHO for procuring pharmaceuticals with assured quality.

About Authors



Dr. Muddukrishna B.S is Associate Professor in Department of Pharmaceutical Quality Assurance, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education. He teaches pharmaceutical analysis to undergraduate students and pharmaceutical quality assurance and management to post graduate students of Pharmacy. He has 21+ years of total experience in academics, Research & Development, Laboratory Operations & Quality Assurance in an organization of high repute. He has published several papers in journals of high repute and have presented papers in national and international conference.



Jalagam Silpa was a student of Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education and completed her M. Pharmacy in Pharmaceutical Regulatory Affairs. She has presented papers in national conferences. She is presently working in one of the leading pharmaceutical company.

Cite this article: Jalagam S, Muddukrishna BS. An Overview on Pharmaceutical Tendering Process. Indian J of Pharmaceutical Education and Research. 2021;55(1):21-5.