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PRACTICAL APPLICATION

Shaping Pharmaceutical Tenders for Effectiveness and Sustainability in Countries with Expanding Healthcare Coverage

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Abstract

Policy makers in countries, aiming to build and expand their healthcare systems and coverage, need effective procedures to support the most efficient use of limited financial resources. Tendering is commonly deployed to minimize and fix the purchasing price for the contract duration, especially for off-patent pharmaceuticals. While tenders can reduce acquisition costs, they may also expose the healthcare systems to risks including drug shortages, quality trade-offs, and ultimately, compromised patient health outcomes. Careful planning is therefore required. The effectiveness and impact of tendering were examined in different healthcare settings to establish good tender practices and to develop guidance for tender stakeholders in countries with expanding healthcare coverage for the effective conduct. The literature was reviewed for tender practices and outcomes in all countries, and tender experts from one multi-national pharmaceutical company in 17 countries with expanding healthcare coverage were surveyed on current tender practices. Tendering is a common practice for multisource pharmaceuticals in most countries worldwide. However, countries with expanding healthcare coverage specifically are vulnerable to the risks of defective tendering practices. Risk factors include non-transparent tender practices, a lack of consistency, unclear tender award criteria, a focus on lowest price only, single-winner tendering, and generally, a lack of impact monitoring. If well planned, managed, and conducted, tenders can be advantageous. Countries with expanding healthcare coverage should approach tenders strategically to achieve the desired improvements in healthcare. The good tender practices derived from this study may guide policy makers and purchasers in countries with expanding healthcare coverage on how to expand access to healthcare at an affordable cost. These include the use of multiple selection criteria and performance monitoring.

Plain Language Summary

Decision makers in countries aiming to expand their healthcare systems must best use the limited money available for healthcare. Tendering is commonly deployed for pharmaceuticals produced by multiple manufacturers (so-called multisource pharmaceuticals), to choose the product with the lowest price. Through tenders, purchasers request offers from suppliers for the needed products.

The ultimate purpose of our research was to develop a guidance on robust tender processes. Therefore, we reviewed the literature to examine the effectiveness and impact of current tendering practices. In addition, we conducted a survey among tender experts from one pharmaceutical company in 17 countries with expanding healthcare coverage.

In both the survey and the literature review, we confirmed that worldwide, tendering is a common practice for multisource pharmaceuticals. However, defective tendering practices may increase the vulnerability for some risks including abuse due to intransparent processes, lack of consistency, unclear tender award criteria, a focus on lowest price only, single winner tendering, and generally, a lack of impact monitoring after the end of the tender process.

Hence, tenders must be well planned, managed, and conducted to be advantageous. Countries with defined and transparent tender frameworks and processes will be better equipped to achieve the desired improvements in the healthcare systems. ‘Good tender practices’ include the clear definition of requirements to be used as selection criteria in addition to acquisition costs, and for monitoring of the tender success. ‘Good tender practices’ may help to manage cost and improve healthcare at the same time.

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Extended author information available on the last page of the article

1 Background

In countries that are building and expanding their healthcare (HC) systems, pharmaceutical products often represent a considerable part of the total HC expenditure, ranging from 20 to 60% [1, 2]. In addition, most countries with expanding healthcare coverage (CEHCs) are low- and middle-income countries, which still rely significantly on private health expenditure in the form of out-of-pocket payments and voluntary health insurance [3]. However, as many CEHCs strive towards universal HC coverage and to expand the access to HC including pharmaceuticals and decrease out-of-pocket spending, increased expenditure and burden on the public HC budgets can be expected [4, 5]. The payers and purchasers in such countries are under high pressure to develop effective procedures and mechanisms supporting more efficient use of the limited financial means by attaining maximum health benefit at a minimum possible cost. Single-source products are mostly protected through patents with limited options for cost containment through competition. Therefore, cost-containment policies often target off-patent multi-source products. For off-patent pharmaceuticals, tendering is one of the procedures commonly deployed to achieve the lowest possible purchasing price and to have it fixed for the time of the resulting contract.

Tendering can be defined as: "The acquisition of pharmaceuticals based on a competitive bidding process where the contract is granted to the pharmaceutical supplier who offered the best bid following strict criteria" [6, 7]. Tenders for medicines offered by competing suppliers are also conducted in many countries with developed HC systems. While tenders can be powerful in minimizing acquisition costs, they may also expose the HC system to some risks [8]. An important aspect in conducting tenders effectively is the criteria used for selecting a winner. Even, if containing the same active ingredient, there may be important differences between product alternatives relating to, for example, regulatory approval process, data available, formulation, dose, or manufacturer reliability, and manufacturing regulatory and quality standards [9]. If all products in a tender were equal and completely interchangeable, the winner should be the product with the lowest cost.

In many CEHCs, however, there is a high variability in the products offered in tenders. Differences can relate for example to quality, manufacturer reliability or capability to deliver, the formulation, or intended or unintended effects at the patient level. Moreover, when additional costs are incurred when using the product, it is important to take the total cost into consideration. When only focusing on price in the supplier selection, factors related to product value and health outcomes for the patients are neglected. However, most patients are currently treated with off-patent pharmaceuticals and therefore, tendering for off-patent pharmaceuticals must be conducted in a manner that protects these patients against potential negative consequences of the methods used for procuring pharmaceuticals. By ensuring good tender practices, purchasers and decision makers of CEHCs, alongside efficiently using the financial resources, can make an important contribution to the stability and accessibility of the HC services in their country.

2 Objective

This research aims to examine the effectiveness and impact of tendering practices in different HC environments and to make recommendations as to good tender practices for CEHCs based on a literature review of all countries and a survey with current tender experts from one multi-national pharmaceutical company in a number of CEHCs. These can guide policy makers and purchasers in CEHCs on how to make choices that improve accessibility and health outcomes in their country at the lowest possible overall cost.

3 Methods

A systematic review was conducted following the Centre for Reviews and Dissemination guidance for systematic reviews [10] to describe tender practices and to identify, evaluate, and summarize the findings of relevant individual studies regarding tender practices in compliance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement [11]. Relevant reports published between 1995 and December 2017 were retrieved through electronic searches (performed in August 2017 and January 2018) in PubMed, Google Scholar, and the Cochrane Library databases. The search strategy was based on combinations of two groups of keywords as follows: Group 1: 'drug' or 'pharmaceutical' or 'medicine' or 'medication'; Group 2: 'tender(s)' or 'tendering' or 'bid' or 'bidding' or 'buy' or 'buying' or 'purchase' or 'purchasing' or 'procure' or 'procurement'. In further screening, only those publications were retained where the titles and abstracts suggested that they would contain information on the following items: tender system in place (year of introduction, setting); types of procured pharmaceuticals; methodology, frequency, and criteria used and the legal basis for tendering systems. The reference lists of eligible articles were hand searched for further relevant publications meeting the same criteria. Data synthesis involved the collation, extraction, and categorization of the findings of the selected studies included in the systematic review. The publications were categorized and summarized by developed and developing HC systems, the latter generally representing CEHCs.

In parallel, an online survey was conducted to describe current purchasing practices, and more specifically those related to tender practices in CEHCs. The questionnaire [available as Appendix A1 of the Electronic Supplementary Material (ESM)] was completed between March and July 2017 by individual experts in CEHCs such as Algeria, China, Egypt, Indonesia, Lebanon, Malaysia, Pakistan, Philippines, Republic of Korea, Russian Federation, South Africa, Thailand, Turkey, Ukraine, United Arab Emirates, and Vietnam. All responders were market access professionals working in the country affiliates of Abbott (Established Products Division), who are all trained and experienced in purchasing, pricing, and reimbursement mechanisms of off-patent pharmaceuticals. The advantage of sourcing the information from this group of individuals was that it was possible to have a 100% response rate with a level of intra-company semantic consistency. The responses were evaluated and summarized by the research team.

4 Results

The literature search in PubMed and Cochrane resulted in a total of 9546 publications. After the selection of relevant abstracts according to predefined criteria, 14 papers were selected. After hand searching the reference lists of the eligible articles, another 14 publications were added, thus a total of 28 publications were included in the present review.

Tendering for pharmaceutical products is a common practice in many developed countries and, increasingly, also in developing countries. Tender practices have been analyzed and reported in European and other developed countries by academic or institutional researchers, whereby most of these reports comes from European research institutions [7, 12–14]. Such work was much less undertaken for the experiences with tender practices in developing countries and, therefore, the description of the tender practices in developing countries was drawn from our survey. The findings for tender practices in both developed and developing countries are summarized subsequently. The first part of this Sect. (4.1) focuses on describing the characteristics of tender systems, while the second part (4.2.) focuses on the impact of tendering in developed or developing countries as reported in the published literature.

4.1 Characteristics of Pharmaceutical Tendering

4.1.1 Developed Healthcare Systems

The approaches for pharmaceutical tendering in developed countries, and especially for Europe, have been reported by several authors and these reports are summarized here. In most of the developed countries, tendering is used primarily in hospital settings and public services (e.g., pandemic plans or military service), but in some countries, tenders are also applied for the purchasing of pharmaceuticals in the ambulatory care sector [7, 12]. Many countries apply the tendering process for a selection of vaccines, pharmaceuticals included in pandemic plans, or pharmaceuticals against communicable diseases.

In general, the tendering methodology depends on the volume of the tender. Tenders are invited from the specific country or from across the European Union. Switzerland is the only country where tenders are limited to pandemic supplies and vaccines for military hospitals. A recent report on tendering concluded that tendering in Europe can contribute to cost containment if embedded in a robust legal and organizational framework with appropriate stakeholder management protecting the users against potential risks [13]. There are European directives, which regulate the use of tenders for public sector procurements in general and specifically, for HC purchasing in Europe [14].

4.1.1.1 Reward Criteria Lowest price is the prevailing award criterion, but some countries have advanced to select the *Most Economically Attractive (Advantageous) Tender* (MEAT) [14–16]. This is also the approach recommended across all sectors including HC in recent European Union regulations [14]. Criteria such as quality standards or ability to deliver may serve as conditions (i.e., prerequisites) for access to tenders or alternatively, tender selection criteria may include quality, availability, or supply reliability. Tender invitations can be released by single hospitals, regional consortia, or by central governmental organizations. Germany and the Netherlands apply tender-like processes for the selection of preferred providers. In Germany, these are conducted by the health insurance funds on a regional basis. The pharmacists should dispense only drugs from those manufacturers who have been selected as preferred providers by the patient's health insurer [12, 17].

4.1.1.2 Frequency of Calls for Tenders Mostly, tenders are conducted in a 1-year cycle, but they may occur less frequent (e.g., 2–3 years in Germany) or on an irregular basis as in the case of Lithuania [7, 13].

4.1.2 Pharmaceutical Tenders in Countries with Expanding Healthcare Coverage

In many countries, tendering systems have only recently been introduced and the introduction is usually not well documented and reported. Therefore, the information for this section was drawn from the survey answered by individuals from Algeria, China, Egypt, Lebanon, Malaysia, Pakistan, Philippines, Republic of Korea, Russian Federation, South Africa, Thailand, Turkey, Ukraine, United Arab Emirates,

Table 1 Survey results on procurement characteristics and institutions in countries with expanding healthcare coverage

Country	Tender regulation	Scope	Institutions involved	Legal basis
Algeria	Yes	Hospital market and military health needs	Central pharmacy of hospitals	PCH: price and quality (CE, ISO, FDA) Military: quality of product and investment in continuous training and prices
China	Yes	All pharmaceuticals	Provincial tender authorities	NA
Egypt	Yes	All pharmaceuticals in public sectors	All governmental sectors (e.g., MOH, university hospitals, educational institutes)	Financial threshold
Lebanon	No	–	Military entities, MOH, hospitals	Financial threshold
Malaysia	Yes	All pharmaceuticals	MOH	NA
Pakistan	No	–	Public hospitals, army	Price
Philippines	Yes	Vaccines	Private, Department of Health, and government hospitals	General Appropriations Act of current year
Russian Federation	Yes	All pharmaceuticals	Hospitals, national tender agency, MOH	Financial threshold, government program
South Africa	Yes	All pharmaceuticals in public sectors	National Ministry of Health	Any registered product can be submitted for tender
Thailand	Yes	Pharmaceuticals and vaccines	GPO (for NHSO), DDC	NA
Turkey	Yes	All pharmaceuticals but only 1–2% of total sales	Hospitals and pharmacies	NA
Ukraine	Yes	Pharmaceutical (mostly hospital segment) and vaccines	MOH (for vaccines) and hospitals	For some medicines, government program
UAE	Yes	Pharmaceuticals and vaccines	MOH, DHA, and Seha healthcare	NA
Vietnam	Yes	Pharmaceuticals, vaccines, and medical devices	Hospital or service of health depending on the assigned list of products	NA

CE cost effectiveness, *DDC* Department of Disease Control, *DHA* Dubai Health Authority, *FDA* US Food and Drug Administration, *GPO* Group Purchasing Organization, *ISO* International Organization for Standardization, *MOH* Ministry of Health, *NA* not applicable, *NHSO* National Health Security Office, *PCH* Pharmacie Centrale Des Hôpitaux, *UAE* United Arab Emirates

and Vietnam. The results of these responses are summarized in Tables 1 and 2.

While Pakistan, Lebanon, and the Republic of Korea did not report any use of tender systems for the purchasing of pharmaceuticals, all other responders indicated the use of tendering for pharmaceuticals in some form. In most of the countries, all medicines are purchased through a tendering procedure. In addition, five countries also purchase vaccines through a tendering procedure, and only Vietnam also purchases medical devices through tenders (see Table 1). In most countries, the Ministry of Health and hospitals are the key institutions procuring pharmaceuticals through tenders. Some countries mention military entities or the army (Pakistan, Lebanon, and Algeria). In Egypt and the Russian Federation, tendering can happen throughout all governmental sectors (e.g., Ministry of Health, university hospitals, educational institutions). In Turkey, the Social Security Institution is the single payer; the drugs are sold to the wholesaler first and then, the pharmacies procure drugs from the wholesaler.

4.1.2.1 Reward Criteria Where tenders are conducted, the lowest price is the key criterion for selecting the winning supplier. Some countries, however, apply additional criteria such as 'performance' (not further defined) in Thailand; the ability to supply quantities in South Africa; product categories differentiated by product quality standards as defined in Vietnam [18]; supplier quality and investment by suppliers in Algeria; local manufacturing in Malaysia; or innovation and brand value in some cases in the United Arab Emirates (see Table 2).

4.1.2.2 Frequency of Calls for Tenders In several countries, calls for tenders are issued annually (Table 2: Vietnam, Thailand, Philippines, Egypt, United Arab Emirates, and Algeria). In other countries, tenders occur every 2–3 years. In Ukraine, many mid-sized and small tenders occur throughout the year, usually in spring and autumn. In Malaysia, tenders are called for products exceeding a budget of US$250

Table 2 Survey results on tender characteristics in countries with expanding healthcare coverage

Country	Criteria considered for winner	Criteria differences between single source (SS)/multi-source (MS) products	Criteria differences for patented (P)/off-patent pharmaceuticals (OPP)	MCDA or differentiated categories beside tender	Tender frequency	Tender duration	Upcoming changes
Algeria	Best price (price and quality and some investment and notoriety of suppliers)	SS: importance of the product for the patient as anesthesia, oncology, hematology, psychiatry, respiratory, diabetology, and cardiovascular	OPP: advantages for local products	No	Annual for some and every 3 years for PCH	1–3 years	No changes
China	Differentiated categories and lowest price	No	Yes (not further specified)	No	2–3 years	Not fixed time	More frequent with internal reference price cut
Egypt	Lowest price	No	No	In some sectors (e.g., air hospital)	Once per year but purchasing based on demand	1 or 2 years; may extend longer	MCDA included in the new tender law
Lebanon	Lowest price	No	No	No	Two to three times per year depending on need	Yearly	No changes
Malaysia	Lowest price and locally manufactured products preferred	MS: Lowest price and locally manufactured products preferred	Where possible, OPP (Gx) are favored	No	Tender called upon products achieving at least US$250 million per hospital	2 years	Increased procurement of Gx. They will be favored over patented products. Price negotiation is expected to intensify
Pakistan	Lowest price	No	No	No	Variable	NA	–
Philippines	Lowest price	No	No	No	Annual	1 years	Evolving mechanisms for drug price reference index for government health facilities; potential Drug Price Board that will put price ceiling on drugs
Russian Federation	Lowest price	No	No	No	Daily	1 years	Stricter limitation to INN and price
South Africa	Lowest price and ability to supply quantities	No	No	No	2 years	2 years	Online tender submission
Thailand	Lowest price or price performance	MS: suppliers have to offer for e-bidding	No	Engineer model, IT	Mostly annual	1 years	New CGD Procurement Act will be forced around June 2017
Turkey	Lowest price	No	No	No	–	–	–
Ukraine	Lowest price	No	No	No	Many middle and small tenders during the year	1 years	Implementation limited prices by IRP regulation

Table 2 (continued)

Country	Criteria considered for winner	Criteria differences between single source (SS)/multi-source (MS) products	Criteria differences for patented (P)/off-patent pharmaceuticals (OPP)	MCDA or differentiated categories beside tender	Tender frequency	Tender duration	Upcoming changes
UAE	Lowest price, but innovative molecules and some brands may be considered	SS: negotiation is possible MS: lowest price	P: negotiation is possible OPP: lowest price principle	Brand name and patient preference may be considered in specific tenders	MOH (GHC each year), DHA (every 3 years), Seha (every 2 years)	–	New molecules and innovative technologies have a great chance in tender winning
Vietnam	Lowest price	No	No	Differentiated categories	Annual	1 years	Expansion of centralized procured list, MCDA application, simple scoring

CGD Comptroller General's Department, *DHA* Dubai Health Authority, *GHC* Gulf Healthcare Council, *Gx* generics, *INN* International Non-Proprietary Name, *IRP* international reference pricing, *IT* Information Technology, *MCDA* multi-criteria decision analysis, *MOH* Ministry of Health, *NA* not applicable, *PCH* Pharmacie Centrale Des Hôpitaux, *UAE* United Arab Emirates

million per hospital. In Egypt and Algeria, the duration of the tender contracts may extend for longer than 1 or 2 years.

4.2 Analysis of Impact of Tender Systems

4.2.1 Tendering Policies in Developed Healthcare Systems

Twenty-one publications relating to the use of tendering in European or other countries with developed HC systems and the key benefits and risks that were reported are extracted into Table 3. Broad experience exists with procurement through tendering in hospitals or for vaccines or pharmaceuticals for the military, but increasingly, tendering is also applied in the ambulant sector [7]. However, there is little 'European' agreement on best practices for tendering, each tender system is a 'homebrew' by the individual member state institutions [19]. Generally, the focus of the studies is on price management rather than health or other outcomes [20, 21] and too little attention is paid to monitoring the success of the policies [22].

Many authors agree that tendering effectively reduces prices and contributes to cost containment in the short term [6–8, 13, 17, 20, 21, 23–29]. This seems to be more evident when there is more competition in the tender [30]. Cost savings were also observed with a tender process used for the selection of preferred providers, such as in Germany [12, 31]. Here, however, it is primarily the insurance companies that benefit [12]. Increased transparency was mentioned as another benefit [7]. In contrast, the long-term impact of procurement through tenders is not yet very well known [12, 29]. There is some evidence that the growth in pharmaceutical expenditure may not be reduced sustainably [25]. Dylst and Simoens reported a phenomenon called "reallocation of demand", which means that savings are offset by prescribing medicines with a similar therapeutic indication that does not fall under the tendering procedure [32]. In some cases, even increased government budgets were described [8].

Several additional risks and potential negative consequences have been identified. Tendering is challenging for manufacturers and when bidding prices eventually are reduced to marginal costs [17, 23], they will be less motivated to compete and may move away from the business, which may be detrimental for product availability [17, 23, 27]. This will be even more critical for manufacturers of branded products [31]. In particular, tenders selecting only one supplier will lead to monopolist supply situations [24]. Overall, the capacity to produce and supply the products at affordable prices may be reduced [8]. This will lead to decreased competition and consequently, to less pressure to offer the lowest price. Additionally, a reduction in the number of players will make the market more vulnerable for special events and may increase the risk for drug shortages, meaning restricted access to effective medicines for patients

Table 3 Benefits and risks relating to tendering for off-patent pharmaceuticals in Europe and other developed healthcare systems. Summary of the published information

Source	Geography	Benefit	Risk
[7]	EU Member States and EEA countries	Positive experiences with tendering in hospital settings Lower prices for the medicines Increased transparency relating to the use of public funds	Forecasting the necessary quantity of the products to be tendered is difficult High level of expertise and resources required for an effective tendering process
[12]	The Netherlands, Germany	Appointing preferred providers through a tender process in combination with rebate policies led to significant cost savings Short-term benefits to health insurance were identified	Risk of monopsony formation across insurers Lack of evidence about the long-term implications of such policies on overall economic and health outcomes for the patients
[17, 23]	The Netherlands, Germany	Significant reduction in prices	Markets are very challenging for manufacturers: (1) Prices were reduced to marginal cost; (2) Price reductions and the increased implementation of rebate contracts provoked changes in business models and overall market structure; (3) Several manufacturers have diversified their portfolio to stay on the market
[31]	Germany	Preferred supplier contracts are a powerful strategic instrument for Gx manufacturers	Manufacturers of branded products appear to be more vulnerable to tendering
[24]	New Zealand	Achieved major savings and cost control Among lowest pharmaceutical prices worldwide	Anti-competitive sole-supply monopoly for selected supplier Grouping of patented medicines with Gx within therapeutic subgroups eroded intellectual property Restricted access to effective medicines owing to the strong financial imperatives, increased occurrence of drug supply issues Compromised quality of care as a result of extensive substitution and switching policies Compromised quality of the products because of lowest-price prioritization
[25]	New Zealand	After 3 years, the annual savings were NZ$7.84 million to NZ$13.45 million (2003–2004 to 2005–2006) Growth in in-patient hospital pharmaceutical expenditure slowed in the first year	Growth in in-patient hospital pharmaceutical expenditure was higher than the growth in total hospital pharmaceutical expenditure Availability problems with new contract items (‘out-of-stocks’; products perceived as inferior)
[26]	Serbia	Tender achieved 4.6%= and 17.2% cost savings vs. the minimal tender price and the free-market price	Drug tender was resource consuming, laborious, and risky Did not provide a fair balance between domestic and foreign manufacturers
[8]	EU	May lead to short-term price reductions	Negative impact on patient healthcare quality, government budgets, Gx industry sustainability, and the capacity to continue to supply affordable prices
[32]	Europe	Gx pricing policies supported effect	Offset of savings by prescribing of medicines with a similar therapeutic indication that did not fall under the tendering procedure (‘re-allocation of demand’) Short-term absences of some medicines because of logistic shortages in Germany Reduction in pharmaceutical investments (negative impact on employment and income taxes)
[6]	Europe	Potential for savings	Variety of shortcomings

Table 3 (continued)

Source	Geography	Benefit	Risk
[33]	Europe		For Gx, internal or external reference pricing, tendering as well as price capping may affect drug shortages
[27]	Canada	May lead to major savings for off-patent drugs	Reduced redundancy abetted shortages Less patent litigation by Gx companies delayed availability of lower cost Gx Less manufacturing of Gx drugs in Canada (closure of some Gx manufacturing Less competition in Gx markets in Canada Less pharmacy service by Gx suppliers Lower profitability and closure of pharmacies
[30]	Italy	The higher the competition, the higher was the price reduction (about 10% per additional competitor)	
[28]	Cyprus	60.6% value reduction and 39.39% mean price reduction were achieved with tendering systems Gx saw the greatest reduction both in value (94.8%) and in mean price (62.97%)	
[20, 21]	Cyprus	Statistically significant long-term price reduction, superior to reduction reached with official external price referencing scheme	
[13]	Belgium, Denmark, The Netherlands	Tendering can contribute to cost containment for off-patent medicines	Possibly leading to availability limitations (drug shortages)
[29]	Europe (Germany, The Netherlands)	Tendering works in the short term to reduce prices for off-patent pharmaceuticals in the European in-patient and ambulant sector	Long-term impact and low-price sustainability have not yet been analyzed Potential risk: reduced competition owing to market withdrawal of manufacturers

EEA European Economic Area, *EU* European Union, *Gx* generics

Table 4 Benefits and risks relating to tendering for off-patent pharmaceuticals in countries with expanding healthcare coverage. Summary of the published information retrieved in the literature review

Source	Geography	Benefit	Risk
[38]	Middle- and low-income countries	Originator and generic prices reduced by 42.4 and 35% Reduced quality uncertainty (if quality standards imposed) Even manufacturers of originators displayed a comparably high price flexibility	
[37]	Jordan	Joint procurement in Jordan, which resulted in estimated savings of 2.4–8.9% in the first year	
[34]	Chile	Reduced corruption and less supplier collusion Greater aggregation of purchases lead to 2.8% lower prices (volume effect) Electronic tendering overall lead to a greater than 8% reduction in prices	
[36]	Brazil		The requirement for bioequivalence and/or bioavailability tests increased costs by more than 100% for the basic pharmaceutical services component
[35]	China, Ghana, Indonesia, Mexico	Formularies, bulk procurement, standard treatment guidelines, and separation of prescribing and dispensing are broadly applied Increased transparency through publication of tender agreements and procurement prices	Few strategies targeting quality improvement were identified Lack of performance monitoring strategies was observed in all schemes
[54]	China, Guangdong province	High competition level and more winning experiences induced more aggressive bidding behavior of manufacturers	Bidders in low competition were less sensitive to other potential bidders and the experience of past wins

[13, 24, 25, 27, 32, 33]. A possible negative impact on HC quality has been red-flagged [8, 24]. Alternatively, manufacturers may choose to cut costs in their production processes, which ultimately may provoke quality compromises [24].

From the administration perspective, procurement through tendering requires a high level of expertise and resources for managing effective tendering processes [7, 26]. The smaller the volumes, the more burdensome and complex are the tenders. Planning and forecasting are demanding, and can be error prone and challenging [7]. It has also been observed that procurement through tendering can lead to an imbalance between foreign and domestic suppliers [26]. Additionally, with decreasing margins, manufacturers will invest less into the growth of the company in this market, which negatively impacts employment and the domestic economy [27, 32]. The reduced investment will be true for both branded and generic manufacturers, and the profitability in pharmacies may also be impacted negatively [27].

A few recommendations resulted from the research and observations in developed HC systems. Among the key success factors of tender programs are a strong legal basis, criteria to grant the tender, the number of winners, and the duration of the tender [6, 13, 28], but also the collaboration of buyers and pooling to achieve larger volumes [26], and the importance of fostering broad competition [30]. Finally, impact assessment is recommended for all pricing and reimbursement policies including tenders [13].

4.2.2 Tender Policies in Countries with Expanding Healthcare Coverage

Research on the impact of procurement by tendering in CEHCs is extremely scarce and only six publications relating to this were retrieved and summarized in Table 4. Often, when such policies are introduced, there is only a limited capacity to establish the processes themselves and only a small amount of interest, time, or ability exists for measuring the consequences.

Cost reduction [34] and improved transparency [34, 35] were observed as key benefits. Kaplan et al. recognized the power of competition and the lack of motivation to reduce prices, when competition was low [35]. On the risk side, compromises in quality were emphasized, especially if the legal and structural framework was unable to protect the system [35]. However, setting the appropriate quality standards increased the resulting prices substantially [36].

Finally, there was some evidence that pooling or joint tenders were more effective in attracting bidders and in reducing the prices [34, 37]. Recommendations for the CEHCs included that strict quality standards should be imposed

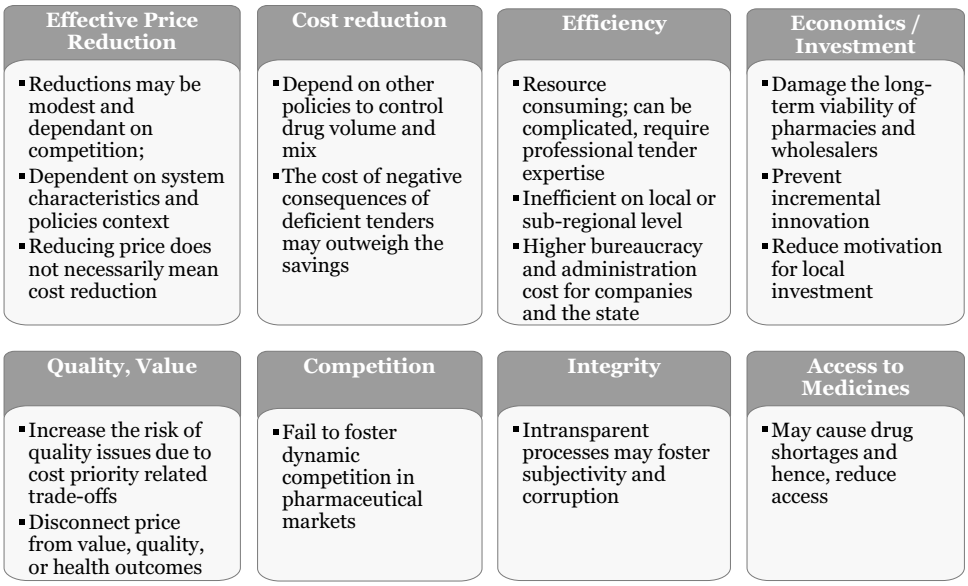

Fig. 1 Risks associated with tender practices as identified in the literature review

for tender inclusion [38], procurement should be pooled to address larger volumes [39], and a prudent practice for tendering should be followed by CEHCs to achieve their objectives in building their HC systems [38, 40, 41].

5 Discussion and Recommendations

5.1 Process and Prerequisites

Evidence from the literature review suggests that tendering is a well-established tool for purchasing pharmaceuticals or a predictable large volume of products such as vaccines. Especially in CEHCs, tendering is more broadly applied for the acquisition of any HC services in the public sector. In general, tenders seem to be somewhat effective in lowering prices for the purchasers and using public funds more transparently. However, tendering for ambulatory care seems to be relatively new and less evidence is available concerning long-term effects. Tendering procedures require expertise and resources and must be applied to each country's operational health policy framework. However, the side effects of tendering as summarized in Fig. 1 have also been reported on many occasions.

Our survey revealed specific behaviors or characteristics of procurement through tenders in CEHCs, which may elevate the risk for the occurrence of undesirable side effects. Such risk factors include the following: (1) products for public HC are procured through tenders without differentiation concerning value characteristics; (2) the lowest price criterion defines the tender winner; (3) tendering systems are applied for the on- and off-patent drug segments; (4) no consideration of the quality of the product or reliability of the manufacturer; (5) high frequency and short duration of tenders; and (6) single winner tenders, as reported from almost all CEHCs. These observations confirm those shortcomings, which had caused the World Health Organization to propose guidelines for pharmaceutical purchasing in low- and middle-income countries [42, 43].

Healthcare policy makers and purchasers are faced with the challenge to create systems, which allow them to maximize in the short term the amount of medicines bought within the frame of limited budgets while also maximizing the value in terms of health outcomes and overall HC costs. Any policy impacts HC for many millions of patients and should be designed to support HC system sustainability. This is of special relevance to CEHCs, which are more susceptible to the risks of flawed polices than countries with more developed HC systems [44]. Transparent and clear tender procedures will help to conduct tenders successfully and the general process is described in Fig. 2.

In the initial PLANNING step, the need for goods or services is identified to develop the procurement plan and budget for the required purchases. This very important preparation phase starts by talking and listening to the users of the product to exactly define the need. It also includes desk research on the market and the inherent risks. Based on this, the scope can comprehensively define the expectations relating to the product and the auxiliary services [45]. Subsequently, the REQUIREMENTS are SPECIFIED through clear and measurable criteria, serving as evaluation criteria as described further below. The criteria may be weighted by importance for achieving the overall goals. The CALL for TENDER will inform potential suppliers about the procurement conduct including a submission checklist and tender specifications. It is useful to develop a standardized approach; in the ESM, we have suggested an example for a checklist for the components (Appendix A2) to be included

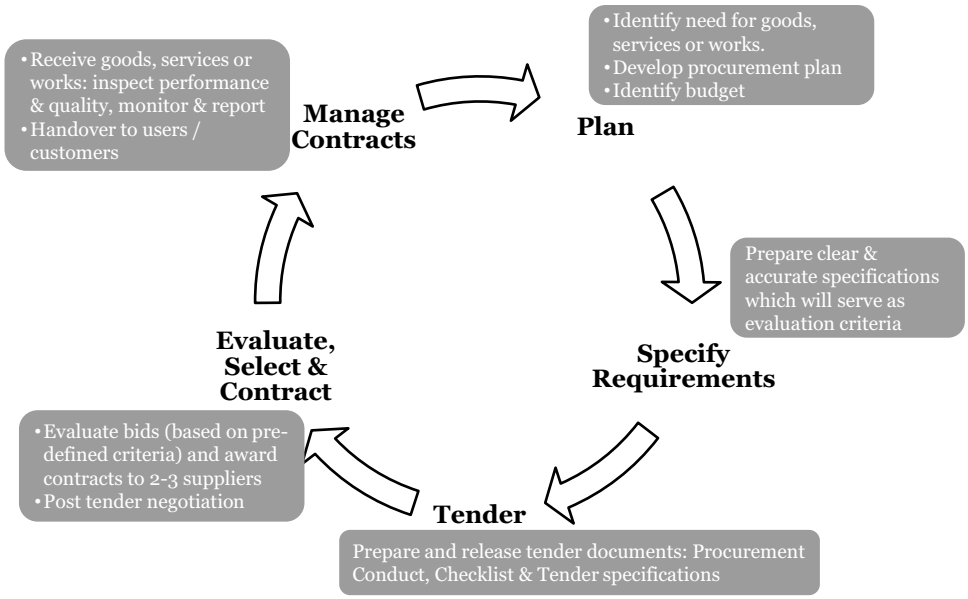

Fig. 2 Good tender practice; overview of tender process

and characteristics of good specifications (Appendix A3). The incoming bids will be EVALUATED using the predefined criteria in a (weighted) scoring exercise and the CONTRACT will be awarded to the two to three best-scoring suppliers. This step may include additional negotiation of the contract details. Finally, the contracts will have to be MANAGED over the time of the tender contract, which will include inspection of performance and quality, monitoring, and reporting.

5.2 Using Multiple Criteria for the Tender Decision

Most health systems, especially in CEHCs, tend to purchase medical products (including devices, supplies, and equipment) with the primary focus on up-front purchasing costs, not only failing to address patient needs, primarily, but also the needs of providers, health systems, and the society. In contrast to the prioritization of lowest price, there is a universal trend of value-based HC and consequently, value-based procurement: delivering the best possible health outcomes at the lowest possible overall HC cost.

It has often been emphasized that tender evaluation and contractor selection is "one of the most critical undertakings performed by clients, the effectiveness of which is directly related to project success and the achievement of specified objectives" [46]. Making judgments about suppliers and their ability to deliver to the requirements comprises high levels of ambiguity, uncertainty and, sometimes, trade-offs in conflicting objectives. Therefore, criteria supporting the fair and effective assessments of the offers are of eminent importance (e.g., price, experience, capability, quality, performance). Furthermore, the relative importance of the criteria for the selection must be defined [46].

In some developed markets, the MEAT approach makes purchasing processes fit for value-based HC [47]. The MEAT approach integrates, in addition to cost, more criteria for the supplier selection. Tenders are scored on each criterion, and an overall score is computed, to determine the winning tender. Alternatively, the ratio of the score in the criteria over cost is computed. For example, the UK National Health Service clearly define in their 'Principles of NHS Procurement' [15] that as the first principle 'Value for Money' should be applied in undertaking a procurement exercise and this is determined through the MEAT approach.[1] The European directive 2014/24/EU suggests in article 67 to select those product(s) with the best price-quality ratio as measured by pre-defined criteria, including cost and outcomes as well as qualitative, environmental and/or social aspects, linked to the subject matter of the public contract in question [14].

Even if the objectives and scope of tenders in developing countries might differ from those in developed countries such as those of the European Union, the risks and potential weaknesses of tendering are the same for any tender process within HC or other industries. In HC in developing countries, however, the users of the products purchased as a result of the tendering process are specifically vulnerable and therefore, should be protected as much as possible against

[1] "Price shall not be the sole or over-riding factor in the decision-making process. The Most Economically Advantageous Tender (MEAT) approach should be used in tender appraisal. Providers will be required to demonstrate that their services offer the best possible value for money. This assessment must be based on a number of criteria for evaluation including price, quality, sustainability, innovation and technical merit" ('Principles of NHS procurement'[15]).

the risks. Our literature review and the survey suggest that clear principles should also guide tenders for pharmaceuticals in CEHCs to foster a sustainable and affordable supply of pharmaceuticals with a minimum risk of unwanted side effects. Tenders for off-patent pharmaceuticals in CEHCs could include criteria such as: (1) costs including acquisition costs and any additional cost that could differ between the alternatives; (2) outcomes documented by evidence (data) on the effectiveness of the product for the target population; (3) other benefits such as patient preferences, application forms, devices, and support services; (4) the broader impact on society in terms of meeting local health policy priorities: local investment, employment, distribution and accessibility, risk management; and (5) quality standards in manufacturing and approval.

Tenders in developing countries often fail to define the prerequisites in the same way as public tenders in the European Union, for example. Therefore, what may be a prerequisite for being able to participate in the tender in the European Union (e.g., Good Manufacturing Practice production or proof of bioequivalence) may sometimes be a criterion for value assessment in a developing country. A range of such potential criteria has been defined in a recent publication by Brixner et al [48].

One option to reduce the complexity of the evaluation is to define narrower tender categories, which confine a fair competition within each of the categories. An example for this was introduced in Vietnam, where five categories of off-patent pharmaceuticals have been defined (see Fig. 3) with a dedicated budget for each category [48]. The competitive evaluation and supplier prioritization occurs within each product category and therefore, the differential value between the categories is recognized and preserved.

A more advanced approach or value-based tender evaluation that can be applied in tenders for off-patent pharmaceuticals in CEHCs is outlined in Fig. 4. Tender specifications and requirements are converted into measurable criteria. Not more than 10–12 criteria should be used. Those criteria more important in the decision (e.g., cost, quality) may be weighted stronger than those of secondary importance (e.g., local employment, added value services). The evaluation of each submission follows a simple multiple criteria decision analysis (MCDA) calculation:

$$\text{Total score} = \left(w_{\text{cost}} \times \cos t + \sum_{k=1}^{n} \left(w_k \times c_k \right) \right),$$

where w indicates weight, c indicates criterion rating, k indicates criteria count, and n indicates the total number of criteria. Two examples for such a calculation are shown in Tables 5 and 6.

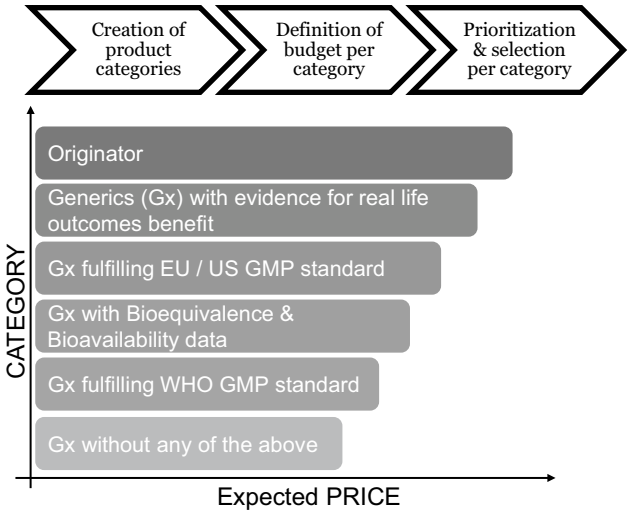

Fig. 3 Categorization approach to tendering as applied in Vietnam [48]. *EU* European Union, *GMP* Good Manufacturing Practice, *WHO* World Health Organization

A case where this approach was applied in Indonesia was described by Inotai et al [49]. Starting from the criteria suggested by Brixner et al. [48] all important stakeholders in the Indonesian medicines tender worked together to define those tender criteria that are relevant in a local context. These authors list criteria related to the product (e.g., proof of bioequivalence, product formulation, stability), the manufacturer (e.g., quality certification level, supply track record, local investment), the services related to the product (e.g., pharmacovigilance, product enhancement services), or the value evidence (e.g., cost effectiveness in the local environment, health outcomes, cost consequences beyond price). Which criteria are appropriate and effective in the setting of a specific country will have to be defined by the stakeholders involved in the specific HC system as shown by Inotai et al. in the example of Indonesia [49], Tuan et al. for Vietnam [44], and by Nurgozhin et al. for Kazakhstan [50]. Other examples for using MCDA in decision making for off-patent medicines in developing countries in a broader sense (price, listing, or formulary decisions) are emerging in several countries such as China, Thailand, or Egypt [48, 51, 52].

As an alternative to calculating an overall performance score from all criteria including acquisition costs, the cost-quality ratio may be calculated and compared:

$$\text{Total score} = \left(\text{Cost} / \sum_{k=1}^{n} \left(w_k \times c_k \right) \right).$$

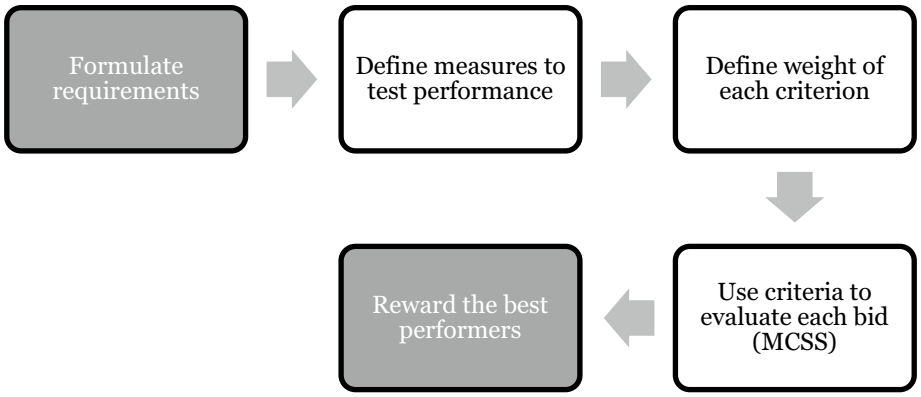

Fig. 4 Prioritization of bids by *m*ultiple *c*riteria *s*imple *s*coring (MCSS)

Table 5 Example for the comparison of two competitive products (Product A and Product B) in a multi-criteria decision analysis based on the European Most Economically Advantageous Tender (MEAT) criteria. The criteria need to be adapted, prioritized, and weighted according to the local requirements and specifications

	Criteria (requirements)	Importance factor[a]	Weight W (%)[a]	Product A		Product B	
				Rating C (0–2)[b]	Score ($W \times C$)	Rating C (0–2)[b]	Score ($W \times C$)
Cost	Acquisition cost	12	24				
	Additional cost (e.g., transport, import duties)	3	6				
Outcomes	Effectiveness	6	12				
	Patient-reported outcomes	2	4				
Other benefits	Quality	5	10				
	User preference	2	4				
	Application form	3	6				
	Support service	3	6				
Broader societal benefit	Local investment	4	8				
	Distribution and accessibility	5	10				
	Risk management	5	10				
		50	100		Total score A		Total score B

[a]The weighting is computed from the importance factor, which is adapted according to the local requirements, specifications, and priorities

[b]The rating scale used here is from 0 (bad performance vs. requirement) to 2 (perfect performance vs. requirement). Each rating must be clearly defined before the evaluation to avoid inter-rater variability

The cost-quality-ratio approach to tender prioritization has the advantage of linking price and value of products, the latter being defined in ways that are meaningful for the HC policy priorities. It does not discriminate against higher quality products and incentivizes investment in outcomes and quality. Both the resulting total scores and the cost-quality ratios can be compared and used for prioritization of the alternative bids.

Finally, the literature review and survey have resulted in important recommendations (see Table 7) relating to the preparation, conduct, and follow-up of the tender, which should be guiding the establishment of a structured and transparent process. Learning from the current shortcomings

Table 6 Example for the comparison of two competitive products (Product A and Product B) in a multi-criteria decision analysis based on the Evidence Framework for Off-Patent Pharmaceutical Review criteria [48]

	Criteria (requirements)	Importance factor[a]	Weight[a] W (%)	Product A		Product B	
				Rating C (0–4)[b]	Score ($W \times C$)	Rating C (0–4)[b]	Score ($W \times C$)
Product	Equivalence with reference	10	12				
	Pharmaceutical technology	2	2				
Manufacturer	Quality assurance	10	12				
	Supply track record	8	9				
	Local investment	5	6				
Service	Pharmacovigilance	8	9				
	Product-related value-added services	2	2				
Value assessment	Pharmaceutical acquisition cost	35	41				
	Real-world patient outcomes and cost	5	6				
		85	100		Total score A		Total score B

[a]The weighting is computed from the importance factor, which is adapted according to the local requirements, specifications, and priorities

[b]The rating scale used here is from 0 (bad performance vs. requirement) to 4 (perfect performance vs. requirement). Each rating must be clearly defined before the evaluation to avoid inter-rater variability

of sometimes short-sighted purchasing procedures across the world and designing more robust tender processes will enable CEHCs to further develop their HC offerings while stabilizing the HC systems.

As described by Brixner et al., Inotai et al., and others, a simple multiple criteria process can be introduced by involving the key stakeholders in a country in the adaptation to the local context [9, 48, 49, 53]. Introducing this concept will not only sensitize decision makers to important value aspects of buying off-patent pharmaceuticals but it will also help to increase the transparency and documentation level of decisions in the purchasing process.

In conclusion, tenders can be advantageous if they are well planned, managed, and conducted. This review shows how to consider value criteria in addition to price for the procurement of off-patent pharmaceuticals. In CEHCs, product value categorization, a multiple criteria (weighted) scoring mechanism, or MCDA may be incorporated into the tender for off-patent pharmaceuticals. Important pillars for tender mechanisms that help to ensure sustainability and consistency of supply are: (1) transparency at all stages; (2) an established, accepted, and publicly known process; (3) an audit trail along the entire decision chain; (4) compliance with the country's and organization's policy framework; (5) mechanisms such as product value categorization or MCDA to ensure fairness to all parties; (6) the encouragement of competition; (7) written quotations, along with relevant supporting information, against pre-defined requirements; (8) a structure that allows easy comparison of offers; and (9) selection of multiple winners.

6 Limitations

This study is based on a literature review and a survey. Scant research has been performed specifically on tender effects as related to off-patent pharmaceuticals in CEHCs. Therefore, the underlying evidence was drawn from the small amount of research on tender effects in other applications such as hospital tenders or vaccine tenders in developed HC markets. The survey was limited to the viewpoint and experience of one specific company active in the off-patent pharmaceutical sector and may be biased by the respondents' unique viewpoint. However, great care was taken to avoid such bias and to not guide the respondents in their answers. By suggesting monitoring as a standard part of future tender processes, more evidence should be generated that can be used to refine and improve the overall effectiveness of this purchasing procedure.

Author Contributions NM conceptualized the research and manuscript, developed the survey, reviewed all material, and reviewed and revised the manuscript including the discussion and recommendations. APH reviewed and summarized the literature, contributed to the manuscript concept and flow, integrated the findings from the survey and the literature, and drafted and revised the manuscript including the discussion and recommendations. JOC supported the survey development and evaluation, critically reviewed the manuscript from the perspective of

Table 7 Recommendations for good tender practice

Recommendation		Why
Tender preparation		
Tender is part of an integrated strategy	Take a comprehensive approach to controlling cost and volume. Use a mix of policies aimed at the same objectives (e.g., reimbursement policies, prescription control policies, substitution policies, claw back, pay backs, rebates, and managed risk agreements)	A wholistic approach eliminates loopholes that may counter the goals of cost-control policies such as shifting prescriptions to non-tendered products
Legal framework	National legislation and regulations provide the necessary legal foundation for procurement procedures, contract enforcement, financial authority, staff accountability, and other critical aspects of procurement of pharmaceuticals	Relevant legal and financial authorities recognize and apply the special requirements for pharmaceutical procurement
Capacity building	Prudent tender practices require well-trained and capable personnel. Capabilities may be built through national or international qualification programs, apprenticeships, or exchange programs with leading supply agencies in other countries, or through support from experienced external technical advisers	Better educated personnel will help to avoid simplistic and badly organized tender practices as well as reduce ambiguousness and the risk for corruption
Reasonable tender size	Pooling of purchasing needs across organizations and over the time horizon to achieve higher tender volumes	Larger procurement volumes increase suppliers' interest in bidding and thus, competition
Reasonable time horizon	The tender duration should be at least 1 years	Stability of supply processes, improved stock management, consistent therapy
Tender conduct, evaluation and contract award		
Clear specifications and quality standards	Pre-qualification: the supplier capacity, manufacturing standard, and reputation are evaluated before bids are solicited for specific products. Post-qualification: verify the adherence of manufacturer and products to the bid specifications	Pre- and post-qualification procedures help to eliminate substandard suppliers and confirm that the goods are received as defined in the specifications
Total cost	Consider total cost rather than price only. There may be hidden cost (consumables, side effects, monitoring, distribution)	Fair comparison of the total expenditure related to each offer
Multiple winners	Award contracts to the two to three best scoring suppliers	Avoid shortages and monopolies
Tender follow-up		
Purchasing and inventory control	Continuous inventory control processes are established and will tightly manage the stock and restocking	Ensures that products are available in the right amounts at all points of usage throughout the entire contract duration
Monitoring	Tenders should be monitored for performance vs. all requirements and non-compliance should be penalized	Increased supplier responsibility, learning for future tenders

tenders in developing countries and globally, and reviewed the manuscript. FG performed the initial literature search and extraction, and reviewed the manuscript. KW distributed the survey to the tender experts in 17 affiliates in the Middle East, Asia, Russia, and Latin America, and summarized the survey results, reviewed the manuscript, and provided critical input.

Compliance with ethical standards

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Conflict of interest Kalman Emry Wijaya and José Otávio Corrêa are employees of Abbott Products Operations AG. Nikolaos Maniadakis, Anke-Peggy Holtorf, and Fotini Gialama received payments for the research from which this manuscript resulted, and Anke-Peggy Holtorf received payments for coordinating the work on the manuscript.

Data availability The following material is available online as Electronic Supplementary Material: (A1) Survey questionnaire and (A2–A3) Checklist for writing a tender specification.

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