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Price Determinants of the Tendering Process for Pharmaceuticals in the Cyprus Market

Panagiotis Petrou, MBA, PhD*, Michael A. Talias, PhD

HealthCare Management Programme, Open University of Cyprus, Nicosia, Cyprus

ABSTRACT

Background: Tendering has been a promising approach for procuring pharmaceuticals. Significant price reductions have been well documented by several authors. To our knowledge, there are limited data detailing the impact of variables in the tendering process. **Objectives:** In this article, our objective was to evaluate the impact of potentially exploratory variables, which included innovation status, total value and volume of sales of each product, health care setting administration (hospital/outpatient), patent status (branded/generic), tendering type, and wholesale price, on price reduction in the tendering process. **Methods:** Financial data of public sector sales during 2011 were analyzed. On the basis of these data, we selected 178 medicines with corresponding sales of €49 million, out of a total market value of €104 million. Medicines were selected according to volume, value, and therapeutic value across all therapeutic areas. We performed a beta regression for the assessment of impact of variables and applied the same methodology to different subgroups. **Conclusions:** The generic

status of medicines is statistically significantly associated with a higher price reduction. Tendering type by alternative, high wholesale prices, and high volume are robust estimators for price reduction. Innovation status does not have any effect on price reduction. Out-patient medicines reach lower prices as compared with hospital medicines. A rather unexpected finding is the negative correlation of high sales value with price reduction. These findings will lead to better understanding of the tendering framework, enabling us to further evolve its operational capacity, aiming to generate more savings. Moreover, our study indicates areas in which a more optimized approach is needed.

Keywords: health expenditure, innovation, pharmaceutical pricing and reimbursement, pharmaceuticals, tendering.

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Introduction

Pharmaceutical expenses are rising beyond the increase in productivity, and they are stretching health systems beyond their viability. Currently, pharmaceutical expenses constitute the fastest growing sector of total health expenses, being just second to personnel expenses in term of recurrent costs [1].

Several factors contribute to this increase. The pharmaceutical market is a highly heterogeneous and flawed market [2], imputed to its domination—value wise—by products enjoying monopolistic and oligopolistic status. Factors that determine the market nature are new expensive products, brand loyalty, and increased asymmetry of information due to the level of uncertainty [2].

In this context, steep price reductions stemming out of the market exclusivity that tendering offers to successful bidders have made tendering a necessary medicine procurement method [3,4]. Nevertheless, this attribute is mediated by the imperative need of a strict and detailed legal framework and the inherent hazard of relying on one or a few suppliers for the entire market, while at the same time sustaining the dynamic efficiency of the

industry. Consequently, in Europe, tendering has been used principally in procuring bulk quantities such as vaccines and dispensable products for hospitals, which are characterized by low differentiation. Currently, only a few countries such as Cyprus, Malta, and Iceland apply tendering in the outpatient sector, whereas some other countries such as The Netherlands and Belgium implement tendering selectively [3–6].

Cyprus is heavily fragmented into public and private health sector care sectors, an attribute that applies to the pharmaceutical market as well. Official prices of pharmaceuticals are set by the Ministry of Health (MoH) at the wholesale level through external reference pricing (ERP) based on a basket consisting of one cheap, two medium, and one expensive European Union (EU) countries. The retail price is set by adding a regressive mark-up pharmacy profit margin to the wholesale price. Cyprus is the only EU country without a universal coverage national health system (NHS). As a result, private health care costs burden patients unless they are covered by an optional private health insurance [7]. The long anticipated NHS has been postponed for 2017 because there are significant debates regarding its structure and operational mode [8]. The MoH provides free health care, in

* Address correspondence to: Panagiotis Petrou, HealthCare Management Programme, Open University of Cyprus, P.O. Box 12794, 2252, Latsia, Cyprus.

E-mail: panayiotis.petrou@st.ouc.ac.cy.

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public health care centers, to 85% of the individuals, based on criteria such as income, public servant employment tenure, socioeconomic status, and disease severity. Because some of the eligibility criteria for free public health beneficiary status are rather biased, this has ultimately led to a grossly uneven access to free public health care. The MoH procures all the medicines for public health care beneficiaries through tendering. All procured products must be registered in Cyprus, which implies that they carry an official wholesale price as well apart from the procurement price (the tender price). *Tender outcome* is defined as the price reduction compared with the wholesale price of the product. On average, tender prices achieved by tendering are 95% lower for generics and around 25% lower for branded products. (This refers to the tender price—the winning bidding price—compared with official wholesale price) [9]. The public sector does not apply pharmacy mark-up profit because public pharmacists are public servants and they are remunerated by a fixed monthly salary. Because prices to the tender process are submitted by marketing authorization holders (MaHs), the maximum price they can submit is the official wholesale price. The key cost drivers of Cyprus's public sector include oncology, neurology, and immunosuppressive agents, whereas the corresponding key cost drivers of the private sector are branded statins, branded angiotensin receptor blockers (ARB), branded proton pump inhibitors, and lifestyle products [10].

Despite the longstanding implementation of tendering in Cyprus, there is no documented analysis of exploratory variables that influence price reductions. The field of price determinants in the tendering process has been largely overlooked mainly because of the perception that tendering is a short-term approach and not a long-term health policy [11]. This is imputed to fears raised about industry sustainability, failures in some countries such as Belgium, and overestimated savings in The Netherlands due to the counterpoising increase in pharmacists' fees. All these factors, along with legal issues, hindered further dissemination of tendering [11]. Consequently, no studies have considered the dynamics of tendering and most specifically none of these studies so far has measured the impact of the variables and the extent of their impact on the tendering outcome. Recently, an Italian study analyzed the impact of tendering on biosimilars, with regard to the number of bidders [12]. Other studies dealt with the conceptual framework of tendering and with its quantitative impact [9,11]. In contrast, cross-country variations in the prices of prescription medicines have been studied by many authors and the field of price determinants raised considerable interest in the recent years [13,14].

The goal of this study was to examine which factors influence the outcome of the tender, and to what extent. By identifying key variables, we can capitalize on these, further augmenting the efficiency of tendering.

Methods

Study Design

We identified seven exploratory variables that may influence the outcome of tendering and are associated either with intrinsic attributes of the product or with extrinsic attributes of the product stemming out of its positioning and its uptake in the market. Price is the leading characteristic of a medicine and one of the decisive factors for its reimbursement. Pricing is a context-sensitive topic because a standoff must be achieved between affordable prices for the payer and profitable prices that will warrant the R&D projects of the industry, the balance between static and dynamic efficiency [15]. It was extensively argued that prevailing pricing schemes such as ERP may reduce short-term

expenditure, but they are blunt instruments with regard to rewarding the true added value of a new pharmaceutical product [16,17]. This was the rationale behind the anticipated introduction of the value-based pricing scheme, that is, the alignment of price with the real value of the product [18]. In this direction, innovation status was defined as another variable [19]. Cyprus currently does not have a dedicated health technology assessment agency. Because of this gap, and to assess the impact of innovation on price reduction through tendering, we adopted the *Amelioration du Service Medical Rendu* ([ASMR] [Improvement of Medical Benefit]) classification of Haute Autorité de Santé in France [20,21]. In France, pharmaceutical products are assessed by the Commission of Pharmaceutical Evaluation on the basis of five pillars:

1. Efficacy and safety;
2. Position of the medicine in the therapeutic strategy and the existence or absence of therapeutic alternatives;
3. Severity of the disease;
4. Type of treatment: preventive, curative, or symptomatic; and
5. Public health impact.

After the assessment is concluded, each product is awarded an improved medical benefit level ASMR classification ranging from I to V as follows:

1. ASMR I major improvement (new therapeutic area, reduction in mortality);
2. ASMR II significant improvement in efficacy and/or reduction in adverse effects;
3. ASMR III modest improvement in efficacy and/or reduction in adverse effects;
4. ASMR IV minor improvement; and
5. ASMR V no improvement.

We adopted the French improved medical benefit level classification for the products included in our sample to assess the impact of innovation status. Tender type is also another important variable and currently, three types of tendering are applied in the Cyprus health setting. The first type is the "International Nonproprietary Name (INN) sole." This tender type asks for a specific medicine, by its INN name. There is virtually no competition in this setting; therefore, we do not anticipate any significant price reduction. This, however, has to be counterbalanced by law provision, which may reject the procurement of a product should the Drug's Committee decide that the submitted price is high. The second type is the "INN group." This type applies for the procurement of several products of a specific therapeutic category such as aromatase inhibitors and anti-tumor necrosis factor agents and the elaboration of treatment guidelines based on the results. This is applied in expensive and specialized products in categories with high dropout rate and/or low compliance, primarily for secondary care. In this tender type, the cheapest product is set as a first-line therapy while the other products are set in subsequent treatment lines according to prices. The third type is the "INN alternative." This tender type is used in high-volume primary care products that are perceived to be interchangeable such as statins, angiotensin-converting enzyme inhibitors, nonsteroidal anti-inflammatory drugs, and proton pump inhibitors (e.g., omeprazole or lansoprazole) and asks for only one product (usually among three or more).

We also assessed the impact of value and volume of sales on the basis of assumption that a higher volume may yield significant savings, according to current literature in the field of price-volume agreement [22]. In addition to the above, the hospital or outpatient administration status and the potential interrelation with price reduction have not been studied. In Cyprus, current

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