Tendering and biosimilars: what role for value-added services?

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ABSTRACT
Background: Access to biologic medicines (including biosimilars) across Europe is largely governed by a process of tendering conducted by health authorities. Over-reliance on treatment costs in awarding tenders has the potential to hinder competition and undermine the long-term sustainability of biosimilars.

Objective: To assess the extent and impact of consideration of ‘value-added services’ (VAS) in tendering for biosimilars, we conducted a narrative review of published literature.

Results: Findings from survey-based publications indicated that tendering practices for biosimilars are widely used, with cost being the main determinant of success and little detail being available on other criteria where these apply. Criteria (of therapeutic and technical interest) beyond price were included in one tendering specification for infliximab (originator and biosimilars), while a separate tender for the same product included VAS in the form of therapeutic drug monitoring, measurement of antibodies and calprotectin.

Conclusions: Published evidence concerning inclusion of VAS in tendering for biosimilars is lacking. Development and implementation of standardized criteria and methods of assessment for tenders may avoid manufacturers facing segmented markets, encourage competition and the longer-term sustainability of biosimilars, and realize the healthcare system and patient benefits these treatments can bring.

Introduction

Procurement of pharmaceuticals in the European Union (EU) is mostly subject to a process of tendering [1]. This applies in the hospital sector as well as in outpatient care. In some countries, tendering for pharmaceuticals is also used in public functions (such as in pandemic plans or for pharmaceuticals against communicable diseases) and for defined groups (e.g., military personnel, pensioners, or prisoners) [1].

Tendering is a formal and often strictly defined procedure, carried out via competitive bidding for a particular contract [2,3], with the aim of containing expenditure on pharmaceuticals when alternatives or equivalents for a specific medicine are available [2,4]. Tendering can drive competition when it operates effectively, even in markets with few suppliers and where competition might otherwise be minimal. To ensure the continued involvement of prospective bidders and to maintain competitiveness, the tendering process should be transparent in terms of the award criteria and selection process. The successful contract should be for a fixed period that is open to repeat tendering, without advantaging the incumbent supplier. Tendering aims to ensure the necessary pharmaceuticals are provided at the required cost, quality, and quantities, thereby contributing to optimal patient outcomes and the economic sustainability of healthcare systems.

Value-added services (VAS) in the context of drug tendering are intended as a means to improve patient and overall health outcomes, as well as to give a competitive advantage to the manufacturer [5]. In this context, VAS are considered distinct from the elements typically included in health economic value assessments of medical technologies [6]. Such VAS include disease programs designed to enhance patient adherence, particularly in the treatment of chronic illnesses, where otherwise there is a considerable burden on patients and healthcare systems [7]. Others focus on improving hospital services and treatment delivery (e.g., infusion therapy), physician and/or patient education and support, and patient lifestyle management. VAS increasingly arouse interest of tendering bodies as shown by the results of a survey of over 30 companies in the life science industry. The survey found that while cost accounted for a high proportion of the award...
criteria, tendering bodies were increasingly incorporating more qualitative criteria, such as safety, efficiency, and supply and logistics, right across the sector, including in the supply of biologic drugs [8]. The influence of the provision of these services on clinician or payer decision-making will ultimately be driven by the availability and strength of the evidence in demonstrating that they meet their goal of adding value for patients and healthcare systems [7]. Nevertheless, some skepticism is perceived to exist amongst payers as to the motivation of the pharmaceutical industry in offering these services, and to the actual value they bring to the health care system and patients [5].

Biosimilars are biological products that are highly similar to an already licensed biologic, with no clinically meaningful differences in quality, efficacy, or safety [9–11]. The development program for a biosimilar is more tailored, but nevertheless just as rigorous as for a new biological medicine [12]. Since the approval of the first biosimilar to somatropin in 2006, over 50 biosimilars have been authorized by the European Commission for use in the EU, spanning a variety of biologic classes and a broad range of disease indications [13]. Many others are currently at an advanced stage of clinical development or undergoing regulatory assessment.

Biosimilars to originator biologics now also feature in drug-tendering processes for off-patent biologics in the EU. The regulatory approval of biosimilars and their subsequent availability offers the potential for increased treatment options for healthcare providers and patients. Although price-only and single-supplier (‘winner-takes-all’) tendering can generate the greatest short-term cost savings, as in other industries this approach could have a negative impact on the long-term sustainability of the biosimilar industry [14]. For instance, high investment costs and development risks, coupled with low profit margins, may discourage participation by biosimilar manufacturers and ultimately undermine competition [15]. In the Netherlands, for example, the low prices of off-patent outpatient-tendered medicines (generics and biosimilars) were perceived by stakeholder groups (including competent pricing authorities, public payers, patients/consumers, generic industry, and pharmacists) to discourage manufacturers and wholesalers from maintaining stocks, resulting in incidences of drug shortages [2,16]. Economic considerations alone may also lead to mandatory switching of patients from the originator biologic to a biosimilar, without patient or physician input. While such an approach has raised concerns as to the impact on patient outcomes [17], data from patient registries suggest that outcomes [18] and healthcare resource use [19] for patients are comparable for those who switched from the originator biologic to a biosimilar for mandatory reasons and those for whom switching treatments was optional.

European directives are in place to regulate and harmonize the use of tenders for public-sector procurements and the awarding of supply contracts, including for healthcare purchasing [20]. While selection of the most economically attractive (advantageous) tender is recommended (based on the best price:quality ratio as measured by predefined criteria) [20], there is considerable divergence between countries in terms of implementation [21]. In particular, definitions of the award criteria vary, including in relation to the role of VAS, and go beyond the cost and supply of the product [21]. With the increasing availability of biosimilars, the aim of this article is to explore whether, and how, VAS are considered in the tendering process for biosimilars in the EU.

Methodology

A search of PubMed was conducted for articles published up to 1 October 2018. Search terms included: tendering, procurement, value-added, qualitative criteria, and biosimilar. There was no restriction or exclusion on article type. The reference lists from articles identified in this search were reviewed and additional publications retrieved if considered within the scope of this review. A separate ‘Google search’ using the same search terms was performed to identify material relevant to the topic and not captured within peer reviewed literature, so called ‘gray’ literature. Relevant regulatory and policy documents were also identified and hand searched for material on VAS as they relate to tendering for biosimilars in EU countries. All the retained articles were qualitatively assessed and described in this review article. In addition, information acquired by the authors through their contacts with tendering authorities, and their awareness of or involvement in tendering processes, also contributed to the findings reported in this article.

Tendering practices for off-patent biologics across Europe

Tendering processes for off-patent biologics operate in several European countries, and current practice varies [22,23]. Authorities in some countries consider price only. Others consider VAS and have a formal ‘points’ system to evaluate them. For instance, a 2017 survey of pharmaceutical associations identified tendering for off-patent biologics in 26 (81%) of the 32 European countries covered by the survey [23]. Most tenders were
either at the national or hospital level. Twelve countries reported ‘single-winner’ tendering. Non-medical switching of treatment (i.e. for reasons other than efficacy or tolerability) because of tendering was reported as possible in 12/26 countries (46%). However, in eight of these 12 countries the physician can opt out, implying that in the other four countries (Bulgaria, Poland, Serbia, and Turkey), patients may be forced to switch treatment based on the outcome of tendering [23].

A 2017 policy overview of 31 European countries conducted by Medicines for Europe revealed similar findings regarding tendering for biosimilars [24]. In a separate literature review concerning 10 countries (Belgium, France, Germany, Greece, Hungary, Italy, Poland, Spain, Sweden, and the UK), tenders for biosimilars were reported to operate in all countries except Greece [25]. Tenders generally operate at the hospital level (except in Germany). Tenders in the outpatient setting were reported for Germany, Hungary, Poland, and the UK. Criteria other than price alone may be considered in Belgium, France, Spain, and the UK, including additional services (e.g. medicine training or delivery service) [25]. Non-exclusive tenders (i.e. those that result in the inclusion of the originator product and the biosimilar in the formulary) are widespread, although exclusive tenders operate in Poland [25].

An overview of policies for medicinal products used in the hospital setting (including biosimilars) in European countries (20 EU Member States, plus Iceland, Norway, Russia, and Serbia) found that tenders occurred in all countries, either at a national level or conducted by individual hospitals [26]. A white paper from EuropaBio (the European Association for Bioindustries) included a series of case studies from member organizations based on their experiences in bidding for tenders. In 5/15 cases, price was the only criterion for awarding the tender [22]. Limited information was provided in the case studies regarding the qualitative criteria that were considered in the selection process [22]. Findings from a questionnaire-based survey of biosimilar pricing and reimbursement practices in Central and Eastern European countries (Bulgaria, Czech Republic, Croatia, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia, and Romania) indicated that a tendering system/procedure existed in all countries except for Latvia, Croatia, and Romania (and only in inpatient care in Estonia and Lithuania) [27]. Price was reported to be the main criterion for tendering in Slovakia, Poland, and Hungary.

Thus, while tendering for off-patent biologics is commonplace across Europe, there is considerable variation between and within countries in terms of the process and assessment.

Consideration of VAS in tendering for off-patent biologics

Research conducted on behalf of Medicines for Europe across seven European countries identified ‘tenders should not only focus on price’ as one of 13 principles for a sustainable biosimilars market [28]. Similarly, the European Biosimilars Group found that among various stakeholders in seven European countries, most agreed that factors allowing biosimilar manufacturers to deliver value through product and service differentiation should be encouraged [29]. This may include elements such as support for education programs and improved drug packaging or delivery, with the use of multi-criteria tendering by payers to determine value.

A number of organizations have advocated against ‘single-winner’ or ‘winner-takes-all’ tendering in medicines. For instance, the white paper from EuropaBio discussed above recommended that ‘winner-takes-all’ tendering for biological medicines should be avoided, such that treatment options are not limited, and unintended switching of treatment does not occur [22]. Moreover, the document recommends that the contract is not allocated based solely on price or cost, but should take into account overall value (including for patients and healthcare systems). The European Federation of Pharmaceutical Industries and Associations has stated that the design of tenders for biologics should, among other criteria, always ‘contain a variety of selection criteria and not only focus on price, e.g. ability to supply’ [30].

An assessment of the elements that influence the sustainability of biosimilars, from the perspectives of multiple stakeholders across seven European markets with differing payer-purchasing mechanisms (Germany, Netherlands, France, Italy, Spain, Norway, and Denmark) and in which biologic medicines have recently faced biosimilar competition, has been reported [31]. The study concluded that having tender criteria that are broader than price (e.g. VAS, device design, inactive ingredients, traceability, and supply stability) was key to incentivizing biosimilar manufacturers to innovate, to address patient needs, and to support patients, physicians, and care institutions [31].

Based on an extensive analysis that drew on pricing and market-access policies, procurement and purchasing practices, savings derived from competition, and patient and health outcomes, Medicines for Europe has advocated that to achieve a sustainable environment for biosimilars, tendering decisions should be value-based rather than be determined by cost alone. Multiple influencing factors, such as supply guarantee, provision of education, or other VAS, should be taken
into account in assigning an overall tender rating for individual biosimilars (Figure 1) [32].

Examples and details of tendering processes that include consideration of VAS are scarce. Specific examples identified from a number of European countries are described below.

**Norway**

In Norway, the Drug Procurement Cooperation (nor. Legemiddelinnkjøpsamarbeid – LIS) operates as an agreement between all four regional health enterprises with the aim of managing the expenditure on drugs through tendering [33]. The physician experts and representatives who comprise the tendering panel take into account a range of factors when deciding to award a tender to a particular product [15]. For instance, in tendering for the use of biologics in the treatment of inflammatory diseases, aspects such as ease of use (including injection frequency and storage conditions) and safety are considered, in addition to disease-related factors (disease manifestations, response predictors, and comorbidities), unless there is a medical rationale for using a particular product [15].

**Italy**

Under the Public Procurement Code that applies in Italy, contracts for pharmaceuticals are awarded on the basis of the price:quality ratio or their cost-effectiveness [34]. However, for biological medicines, the provision of additional innovative services offered with the medicine, or that contribute to treatment of the condition, independent of the quality of the product, also contribute significantly to the decision to award a supply contract [34]. These services may include the manufacturer’s expertise and certifications, pharmacovigilance programs, and logistics support to benefit healthcare workers and patients indirectly. Formal consultative interaction between contracting agencies and providers is viewed as a valuable means of optimizing tender specifications, particularly in going beyond the lowest-price criterion. This is achieved by identifying and incorporating innovative services and qualitative aspects that competing companies can offer to deliver better treatment outcomes [34], while the principles of transparency, non-discrimination and equal treatment of providers underpin the Code.

**England**

In issuing the ‘Commissioning framework for biological medicines (including biosimilar medicines)’, the National Medical Directorate of NHS England recognized the opportunity for increased access and patient and clinician choice derived from competition between different biological medicines [35]. The group recommended that in striving for cost-effective prescribing, commissioners should consider VAS offered by manufacturers (e.g. homecare, outsourced outpatients, and patient-support services, including nursing support) [35]. With more biosimilar medicines becoming available, commissioners are viewed as having a pivotal role in ensuring the

| Criteria                        | Assessment |
|---------------------------------|------------|
| Cost                            | +          |
| Supply guarantee                | ✗          |
| Value-added services            | ✗          |
| Education provision             | +          |
| Patient-support services        | ✗          |
| Other (specified)               | ✗          |
| Overall ranking                 | 1          | 2          | 4          | 3          |

*Criteria met*  *Criteria not met*  *Criteria partially met*

Figure 1. Tender scorecard as decision instrument (Adapted from [32]).
uptake of the best-value biological medicines, which relies on their prompt reaction to the changing situation with respect to the availability of treatment options, in liaison with clinical reference groups, clinicians, providers, and patients [35].

France

A tender for infliximab at the University Hospital of Bordeaux, France (operated by UniHA, a cooperative purchasing network of 56 public hospitals) included both the originator (Remicade®, Janssen Biologics B.V., Leiden, Netherlands) and a biosimilar (Remsima™, Celltrion, Incheon, South Korea) [36]. The tender process comprised a points-based weighting system that addressed factors related to therapeutic and technical interest (Criterion 1) (Table 1), in addition to economic factors (Criterion 2) [36].

Ireland

A number of public-service tenders for the supply of infliximab in Ireland have been published [37–40]. While there was considerable variation between hospitals in the tenders, all included an element of VAS, either as an additional consideration or as a core criterion. For instance, in the tender for the supply of infliximab to Our Lady’s Children’s Hospital in Dublin, the provision of patient-support resources and therapeutic drug monitoring (TDM), antibody, and calprotectin measurements contributed 15% to the overall weighting (Table 2) [39].

Since treatment response to infliximab may differ between patients because of the formation of anti-drug antibodies, TDM can be considered to add value by facilitating treatment optimization [41], in helping clinicians identify patients who may benefit from dose tapering, treatment intensification, discontinuation, or switching [42].

Application of multi-criteria decision analysis

For tendering authorities to make meaningful and evidence-based decisions that take account of VAS, they will likely require some form of multi-criteria decision analysis (MCDA). MCDA is a decision-making process widely used in Health Technology Assessments (HTA), where the criteria are defined, ranked in terms of relevance and importance, and evaluated consistently [43–45]. As such, VAS are considered separately, or incorporated among other categories in MCDA. One systematic literature review identified an increase in the application of MCDA in HTA studies, with most emanating from the UK, Netherlands, Canada, US, Germany and Italy [46]. However, literature on the utilization of MCDA in tendering for biologics (including biosimilars) is sparse.

Tendering for procurement of hematopoietic growth factors by the 37 Public Assistance Hospitals of Paris is overseen by the General Agency of Equipment and Health Products (AGEPS) and is rerun every 2 years [47]. Following a scientific assessment, once products are listed on the hospital drug formulary, procurement is based on a multi-criteria tendering process comprising both a number of unspecified pharmaceutical and economic considerations, which contribute a maximum of 65 and 35, respectively, towards the overall score (100) for each product. In a case study of tendering for short-acting erythropoietins in April 2012, as a result of originator Epo-alfa scoring higher under both criteria and being the least expensive, it was favored over the originator Epo-beta and a biosimilar [47]. In contrast, in the tender for short-acting granulocyte-colony stimulating factors (G-CSFs) (March 2012), although not the

| Table 1. Criteria for VAS beyond price for tendering for infliximab at the University Hospital of Bordeaux [36]. |
| Criterion 1: Therapeutic and technical interest |  |
| --- | --- | --- |
| 1a Presentation of the product | Points | Total score (points) |
| Adaptation of the packaging to the use | 5 |  |
| Readability of labeling | 5 |  |
| Health traceability support | 5 |  |
| Stability data | 10 | 25 |
| 1b Contribution to the good use of the product |  |
| Information from the prescriber on the latest scientific data | 10 |  |
| Provision of information to the patient about the drug | 10 |  |
| Help in clinical follow-up of treatment for the prescriber, including the provision of kits for determining infliximab serum concentrations and anti-infliximab antibodies | 15 |  |

VAS, value-added services
cheapest product, a biosimilar of G-CSF was preferred over two other biosimilars as well as the originator product [47].

Discussion and conclusions

There is considerable variation in tendering practices for biologics and biosimilars across Europe, with cost dominating decision-making and little available evidence for consideration of VAS when awarding contracts. VAS could play an important part in the sustainability of biosimilar markets and better address patient needs where tendering predominates. Consideration of such services not only broadens the approach to tendering beyond one based largely on cost, which could ultimately be detrimental to long-term viability, but also has the potential to provide benefits for patients and providers that may otherwise not be routinely available.

Since a standardized or widely accepted approach to identifying and weighting criteria for tendering or in scoring bids is lacking, biosimilar manufacturers can face different challenges with each tender. Such a disjointed market discourages participation of multiple manufacturers and meaningful competition, thereby jeopardizing the sustainability of biosimilars.

Limitations of this study include the structured, non-systematic approach used and the scarcity of information that was identified on VAS in tendering for biosimilars upon which our analysis and conclusions are based. Tendering invites are mainly only available on regional or national health-authority websites in their native language. Information about the outcomes of tendering processes and details of successful bids are similarly not readily accessible.

There is a need for increased transparency and greater consistency between health authorities in the criteria included and in the weighting applied for consideration of VAS in tendering for biosimilars. Adoption of a more standardized approach to tendering for biosimilars, particularly one that includes consideration of VAS and their evaluation as part of a broader MCDA, may bring the greatest benefits for patients and healthcare systems while sustaining a market for biosimilars.

One approach to expand on the findings reported here and to obtain more robust information could be to develop a questionnaire on the role of VAS in tendering of biosimilars, and to conduct a survey of the relevant personnel with responsibility for this aspect within health authorities across Europe.

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