

White Paper

From Regulated Prices to Prices Set in Tenders

Tendering landscape in Europe

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Introduction

Historically, the tender market had been limited to only a few segments of the life sciences industry with lead by generic medicines. Now the major growth segments in the pharmaceutical market leverage tenders: specialty medicines, biosimilars, medical devices, and vaccines. Countries in Europe have either explored, implemented, or are expanding the use of tenders to achieve cost savings for healthcare payers and budgets which are subject to continued financial pressure.

Tendering has become an increasingly integral and vital part of the pharmaceutical market in Europe. Tenders can take many forms and are subject to European as well as local regulations, making them complex processes for both tendering bodies to implement and bidders to perfect. Despite the high formalization and complexity of the process, IQVIA estimates tendering accounts for around 40% of drug purchases in Europe, and in many countries accounts for almost 100% of drug purchases in the hospital channel.

The mostly open nature of tenders (especially in the public sector) increases competition and can significantly affect the price of products. Depending on the subject of the contract, tenders make it possible in some cases to obtain up to 98% discounts on list prices. Yet lower prices for a buyer are not the only benefit of competing in tenders. Additional benefits for the tendering authority includes security of supply, ability to maintain multiple manufacturers within the market or, for example, the promotion of environmental protection through the application of Environmental, Social, and Governance (ESG) criteria.

IQVIA has undertaken this study to support the healthcare industry, and to provide greater clarity in this increasingly important segment of the market. Covering the definitions, steps, and systems that govern the tendering system for the benefit of commercial stakeholders, and for the creators of tenders in Europe.

The findings of this report highlight the variability in the usage, type, and process of tendering. It showcases some of the best-in-class approaches, and provides a landscape for the tendering market in a time when commercial decision making is critical to success, as well as to the long-term sustainability of the healthcare system in Europe. This study describes the tendering market in the area of drugs understood as original medicines, biosimilars, generic medicines and vaccines. For the most common tenders in Europe relating to drugs the scope is defined by the CPV (Common Procurement Vocabulary) classification. This study does not cover medical devices and other life sciences products.

40%

Tendering accounts for around 40% of drug purchases in Europe

80%

More than half of the pharma companies surveyed said that over 80 per cent of their business comes from tendering

What are tenders?

Tenders in Europe are referred to in diverse ways, partially due to the diversity of local markets and to the different systems and market segments they operate within. The definition(s) and core concepts related to tenders and to the process of tendering are outlined below.

DEFINITION OF TENDERS

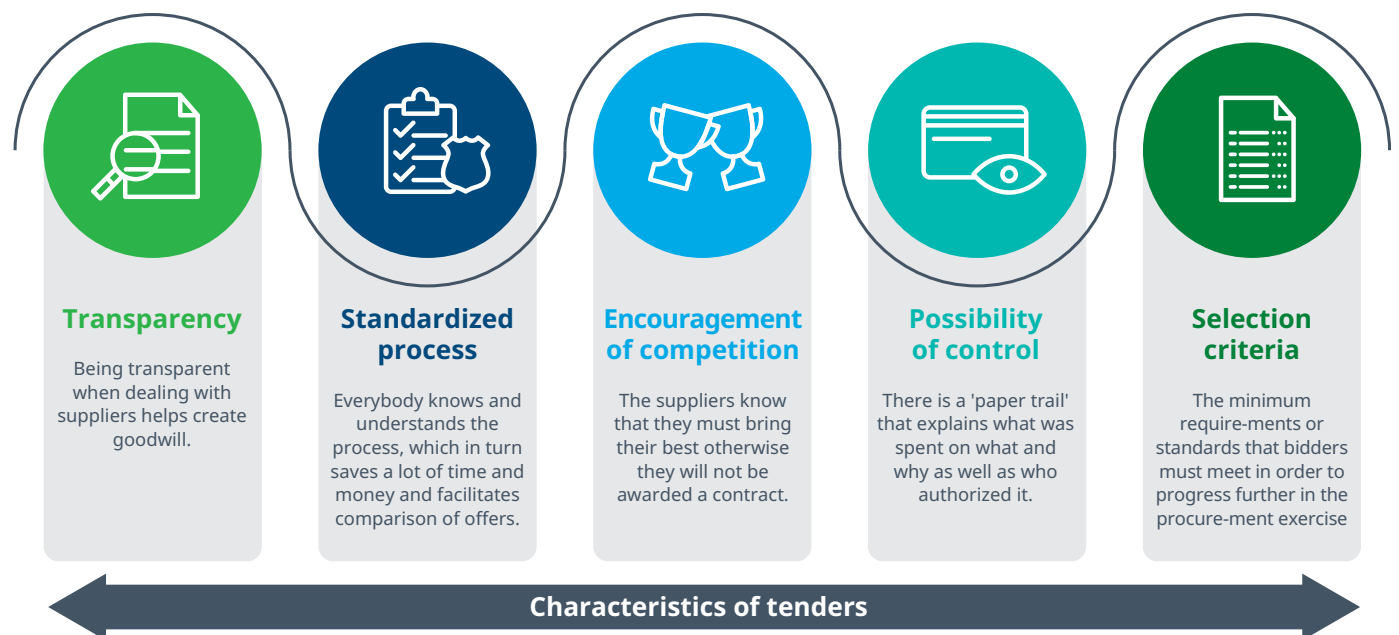
Tenders are formal, structured procedures by which bids (offers to set a price for a product or service) are invited from interested bidders (suppliers) to provide goods or services (or both) to a contracting body (buyer). In simple terms, tenders can be called “The mass purchase of goods and services through a competitive bidding process.” It is worth noting how formalized this process is.

When it is done in the healthcare sector by the government (e.g., Ministry of Health, National Health Fund) or government-affiliated entities (e.g., public hospital) it is known as ‘public contracting’. By its very nature, the public sector needs to be open to public scrutiny, which means that public sector contracts must be carried out through a tendering process. Depending on the value of the contract, public sector contracts must also be advertised in the Official Journal of the European Union.

Tenders also occurs in the private sector (e.g., private insurance companies or private hospitals), where they are called ‘private tenders’. As the private sector is less regulated when it comes to the tendering process, companies are not obliged to disclose the details of the tender, the contracts awarded, or their value. Business partners in the private sector are expected to carry out a fair and transparent procurement process, and the sector is also considered to be more flexible in terms of tender evaluation and selection and may be open to more innovative solutions that provide a commercial return on investment with cost and operational efficiencies. A private company may already have established suppliers it extensively uses and will negotiate directly with them for the supply of the products or provision of the services they offer.

High formalization of the tendering framework results also in standardization of the process, to ensure transparency for participants in the bidding process, clearly defines the rules, selection criteria and allow comparability of bids. Although the health sector is increasingly using a combination of multiple bid selection criteria (see Win/Award criteria section), tenders are mostly used to minimize price.

Figure 1: Characteristics of tenders



Source: IQVIA expertise

This practice is expected to reduce costs because of price competition and achieve economies of scale. It also reduces some of the inefficiencies caused by the segmentation of distribution systems. Private sector procurement is focused on driving value to the business and its shareholders, although social value is becoming higher on the agenda for companies to demonstrate how they use their expertise to benefit the communities in which they operate. For this reason, commercial factors relating to drug price, drug or service quality and efficiency, innovation, expertise, drug delivery terms and conditions, relationship management, along with supplier environmental, social and government responsibility are strong influences behind purchasing decisions, and the ultimate selection of the preferred supplier. A summary of tender features is shown in Figure 1.

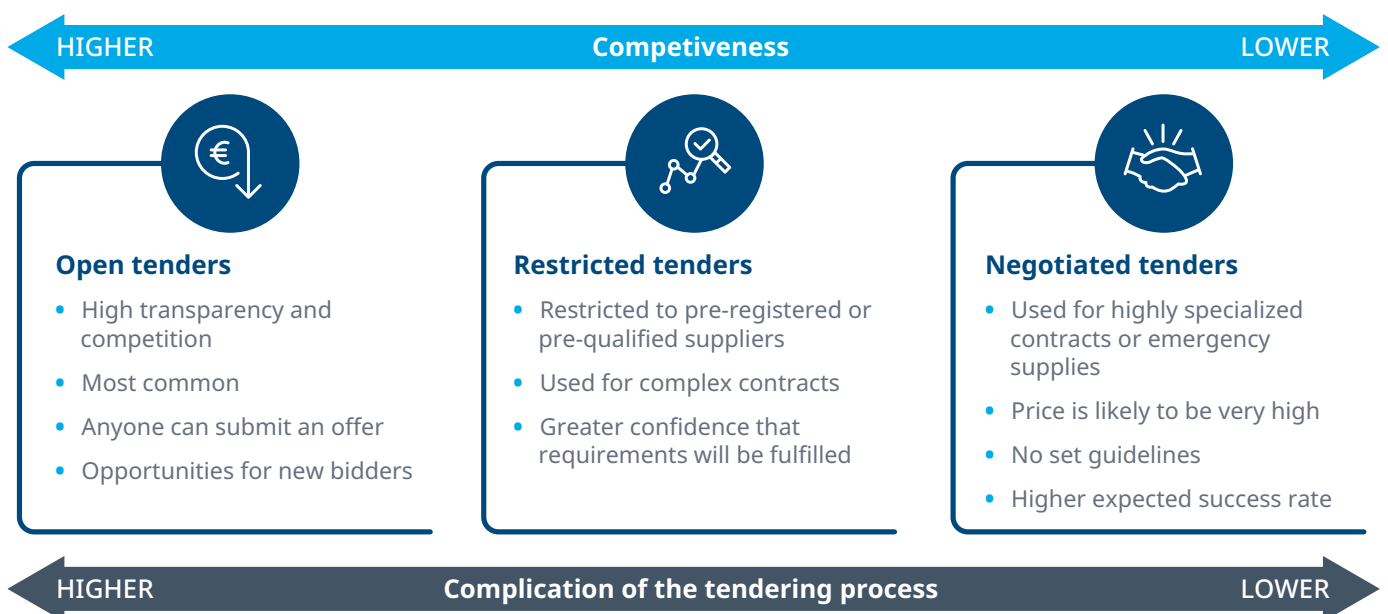
DIVERSE TYPES OF TENDERS

Tenders come in a range of formats, such as open tenders, restricted tenders, or competitive negotiation. Local regulations in each country may limit or expand the types of tenders permitted, but the three types of tenders are the most common: open, restricted, and negotiated. Their characteristics are defined in Figure 2.

In some countries, local regulations distinguish more varieties of tendering procedures. Poland is a case in point, where, in addition to open, restricted, and negotiated tendering, public procurement also uses competitive dialogue, innovative partnership, negotiations without an announcement and direct agreement. However, for the sake of simplicity, this report will focus on the three predominant types of tendering in Europe.

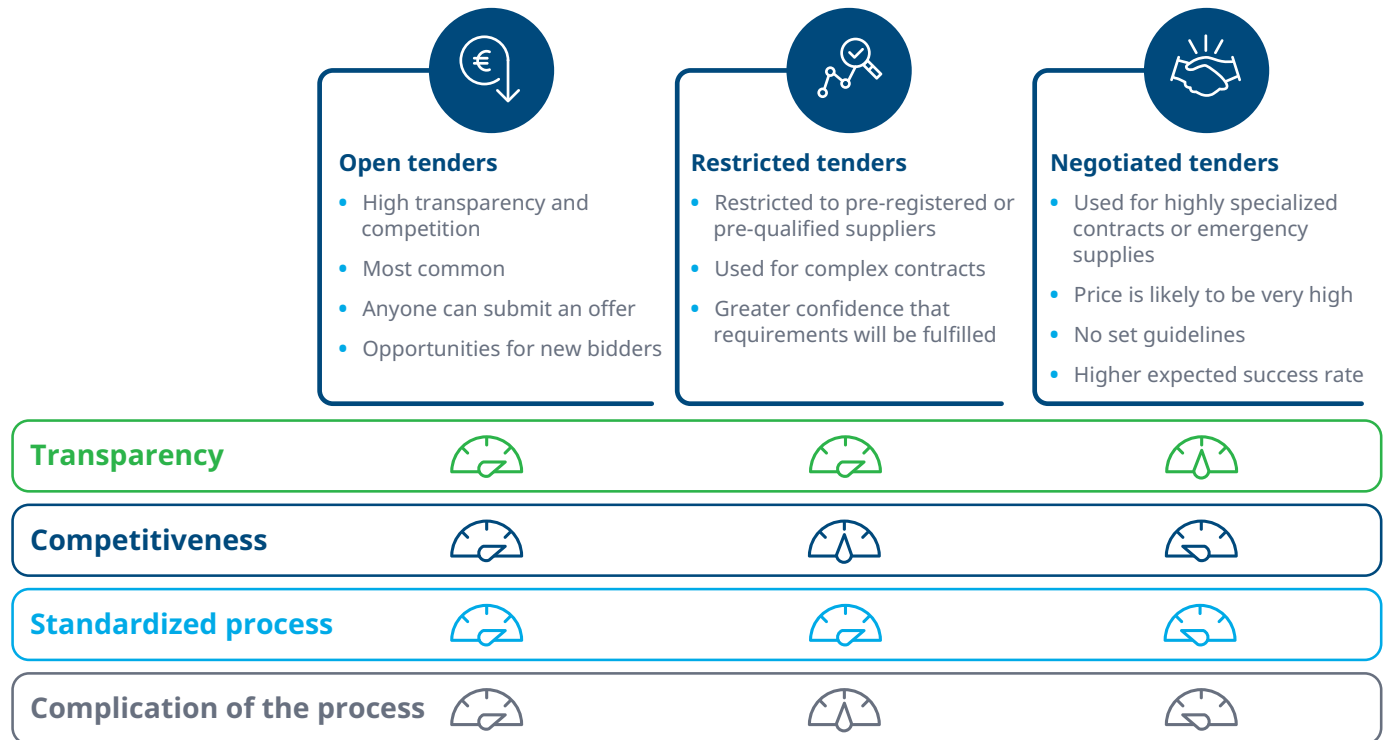
Each type of tender has its own characteristics, its own advantages, and disadvantages, so it is important to choose the right process for the object and purpose of the purchase. In the case of open tenders, it is worth highlighting great transparency and a high level of competition, where there are no restrictions on the entities submitting bids. This is the most common type of tendering which brings many challenges for the entities organizing tenders, due to the necessity to verify many bidders and risks, and the selection of the bidder who, despite offering the lowest price, will not be able to fulfil the contract for example, due to the inability to provide the required quantity of drugs or the required staff training. Such risks are eliminated by restricted tenders, which allow only verified bidders to participate in the process, which reduces the risk of the

Figure 2: The most common types of tenders



Source: IQVIA expertise

Figure 3: Types of tenders and their characteristics



Source: IQVIA expertise

bidder’s failure to fulfil the contract, and thus increases patient safety. In such proceedings, however, there is a lower level of competition and the prices obtained in the tender may be higher than in open tenders.

For complex tendering procedures, where drugs have no equivalents or where time is of the essence (e.g., emergency supply of drugs in a pandemic situation), negotiated tenders may be applicable. In this case, the whole purchasing procedure is simpler, and the chances of success are higher, but the price is generally high.

A summary of the features, advantages, and disadvantages of the main types of tendering are presented in Figure 3 above.

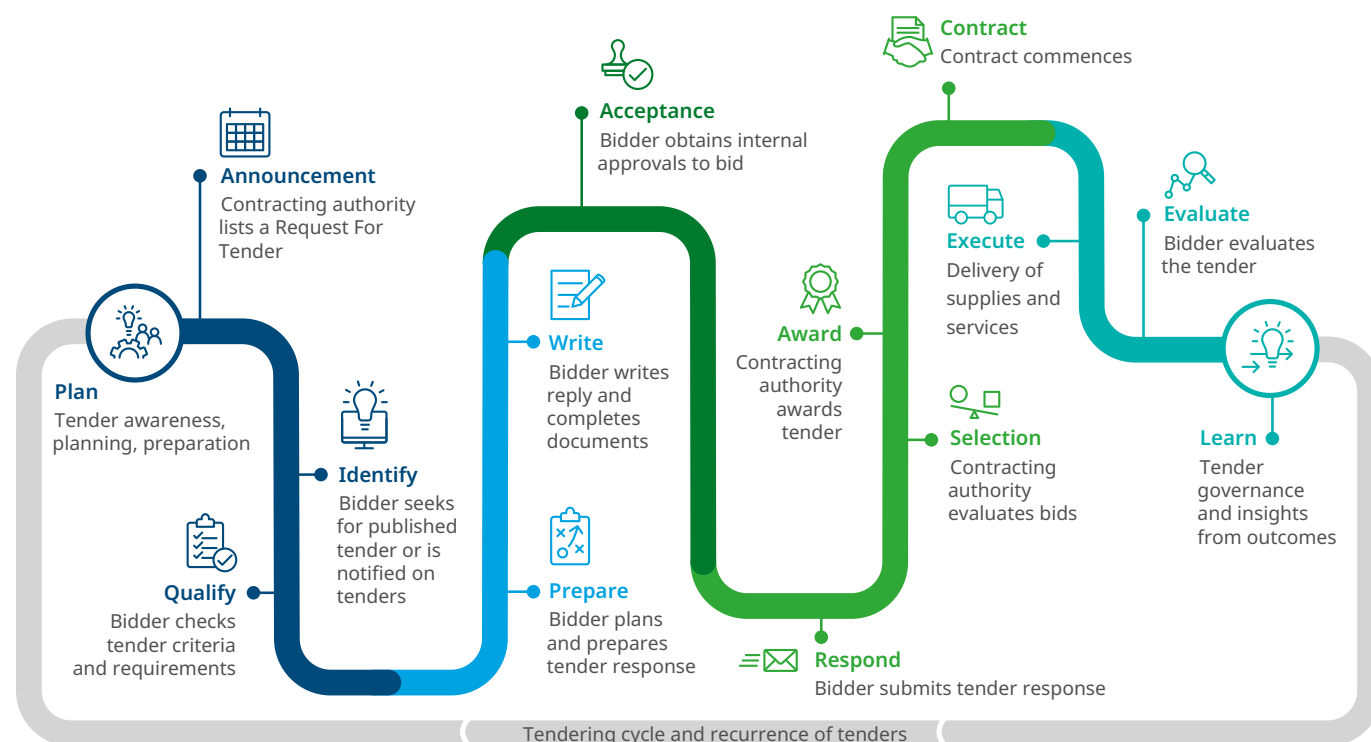
STEPS IN TENDERING CYCLE

Due to the characteristics of tendering as a standardized processes with controllability, the process is often considered difficult and complex. At various stages, it involves the contracting authority and the bidders to varying degrees, and the complexity of the process depends on the type of tendering. Due to the repetitive

nature of purchasing in the health care system, the complete process should be considered as a cycle in which to some extent both parties repeat their actions and thus can better prepare themselves for subsequent tenders. The scheme of the tendering cycle from the bidder perspective is presented in Figure 4.

The first step from the tendering body perspective is that the organization identifies unmet needs and requirements. In the case of a hospital, this could be, for example, the purchase of drugs to treat patients for specific conditions. The tendering body then begins the early stages planning for the procurement process. This includes defining the objectives of the tender, outlining the specific requirements of the contract and consulting stakeholders as part of the process. This stage may also include setting the procurement budget. The organization then defines the tender procedure and, in accordance with its rules, announces the tender or contacts the selected bidders. After announcing a tender, the organizer waits for incoming bids, answers bidders’ questions and, after the deadline for the submission of bids has passed, evaluates the bids in accordance with the

Figure 4: Steps in tendering cycle



Source: IQVIA expertise

tender criteria to determine the optimal selection of an awardee. After the contract with the supplier is signed, the tender is awarded. This is the end of the tendering process, and the supplier shall proceed with the order, and move to the execution phase and delivery.

For a bidder, on the other hand, the tendering process may start with obtaining information about a new tender, but a key step for the manufacturer or supplier, in advance of any tender process, is tender awareness, planning and preparation. This includes activities such as understanding the landscape, the competitors, the non-price criteria, identifying key stakeholders and Critical Success Factors as well as tender shaping activities, define tender segmentation, prioritization, and strategies. Considering the complexity of the process and the number of tasks faced by the bidder, manufacturers should be proactive, not reactive.

REGULATIONS ON EUROPEAN TENDERING

For public buyers and purchase values over a certain threshold (€140,000 in 2022 for most types of services and supplies purchased by central government authorities), the tendering process is then defined

by European Union (EU) regulations and directives.¹ Recent directives call for tenders to be based more on the “Most Economically Advantageous Tender” (MEAT) criteria. The MEAT criteria may include a best price to quality ratio, which enables the contracting authority (tenderer) to take the following factors beyond price into account: qualitative (e.g., quality and effectiveness of treatment), technical, ease of use and functional characteristics of the product (e.g., method and convenience of drug administration); accessibility; social, environmental (e.g., environmental impact, carbon footprint), and innovative characteristics; total life-cycle benefit; trading and delivery conditions; and after-sales service.

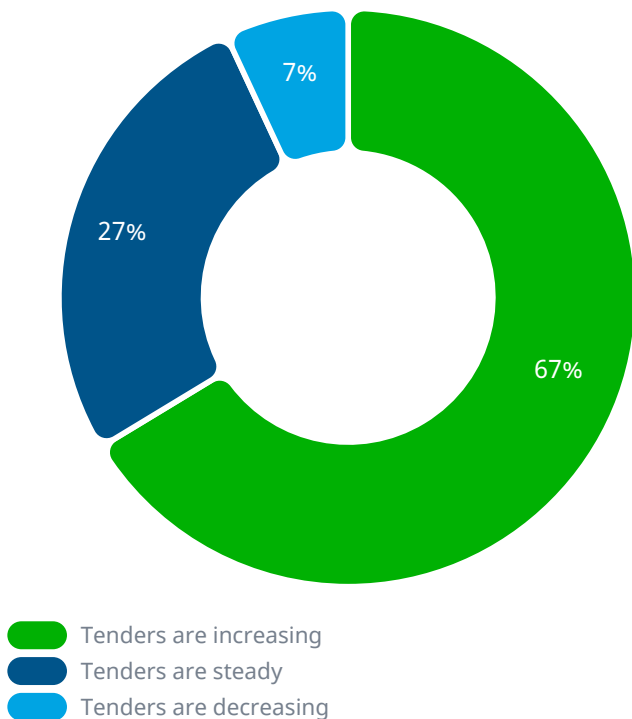
Below the public procurement thresholds in Europe, specific national requirements and exemptions may apply, but the general principles of public procurement (equal treatment, transparency, free competition, etc.) are still applicable. As national healthcare systems vary widely across the European Union, the procurement of drugs may also vary significantly in the legal space of each country.

Why do tenders matter?

THE NUMBER OF TENDERS IS INCREASING

Every year, over 250,000 public authorities in the EU spend around 14% of GDP (around €2 trillion per year) on the purchase of services, works and supplies. In many sectors such as energy, transport, waste management, social protection and the provision of health or education services, public authorities are the principal buyers. In healthcare, tendering is increasingly important because it not only helps to keep existing suppliers in mind in respect of their terms of service, prices offered and product quality, but means that suppliers submit proposals based on the specific requirements of the tendering body rather than on their own terms. Contracting bodies use tenders to obtain the best possible purchase price, while eliminating corruption and favoritism. These benefits have led the health care sector to rely increasingly on tenders.

Figure 5: Perspectives on the number of tenders



Source: IQVIA Tender Benchmark survey results 2019 - Report 1: The Tender Organization; more than 30 respondents; functions covering all regions; small to large sized companies, across Pharma and MedTech. The increase in the number of tenders indicated by the representatives of pharmaceutical companies interviewed by IQVIA is also confirmed by IQVIA data for several countries cited in the Case Studies chapter.

As payers across Europe struggle in recent years to balance constrained healthcare budgets and increasing demand, the role of tendering has increased. As a result, an increasing proportion of public and private purchases of drugs are subject to a tendering procedure. This trend is confirmed by data and studies conducted by IQVIA in which 67% of respondents indicated an increasing number of published tenders, 27% pointed a stable number of tenders and only 7% of respondents noticed a decreasing trend in the number of tenders.

TENDERING OCCURS IN THE MAJOR GROWTH SEGMENTS

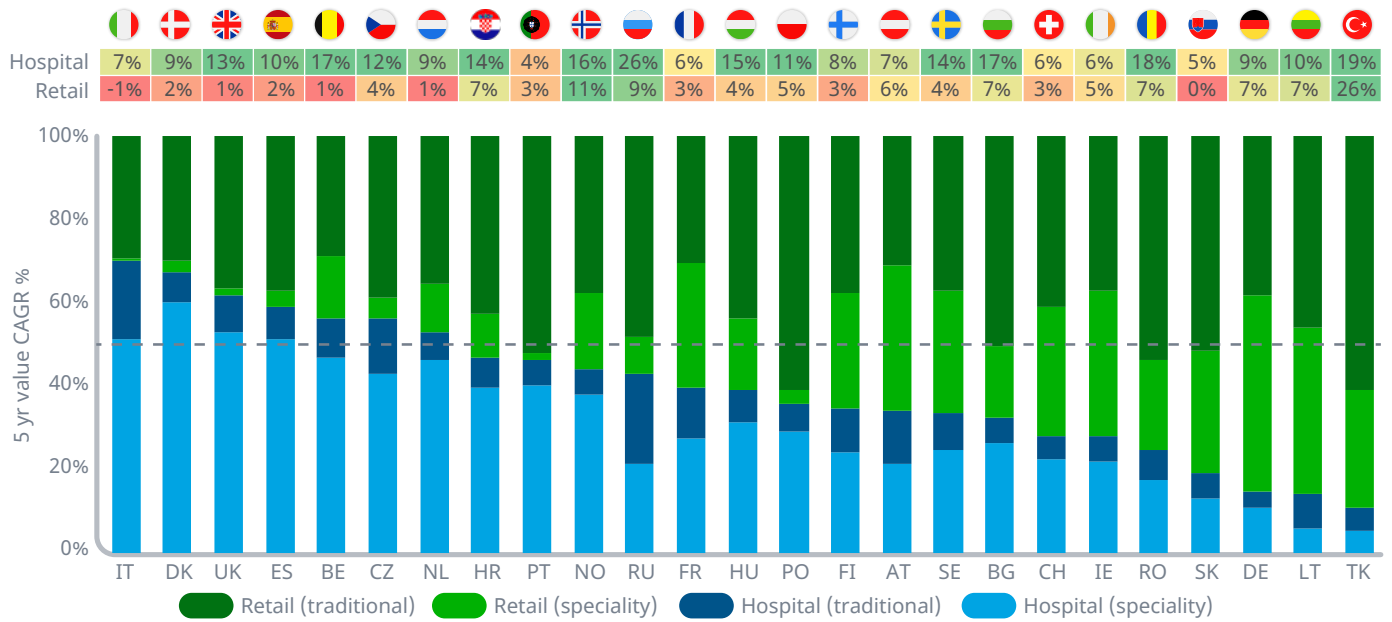
Global spending on health more than doubled in real terms over the past two decades, reaching US\$ 8.5 trillion in 2019, or 9.8% of global GDP. But it was unequally distributed, with high income countries accounting for approximately 80%.² With such rapid growth in health care spending, rising expectations from the health care system and constant pressure to optimize spending, public authorities can use tenders in a more strategic manner, to obtain better value for each euro of public money spent and to contribute to a more innovative, sustainable, inclusive, and competitive economy.

In both Western and Eastern European countries, tenders are considered a cost-effective strategy for purchasing drugs, which, in conditions of permanent inadequate financing of the health care system, increases their importance and role. The extent to which

67% of those surveyed by IQVIA indicated that the number of published tenders is increasing.

Figure 6: Hospital and retail market structure and value dynamics

FY 2021 value market share vs. 5 year value growth (2016-2021)



Source: IQVIA MIDAS, Q4 MAT 2021, by value.

health care systems in individual European countries use tendering largely depends on the structure of these markets. Tendering procedures are widely used in hospital market, which account for close to 50% of European market in value. Depending on the country, tenders account for 80 to 100 per cent of drug purchases made by hospitals. With a few exceptions, tendering is much less used in the retail market (see also the chapter “Today’s tendering landscape”).

Due to the pressure on health care systems caused by an aging population and the challenges posed by chronic diseases, governments and healthcare payers are looking to tenders as a long-term strategy to curb cost of drugs where possible. This is visible both in the number, value, and complexity of tenders conducted.

Recent developments in this field include expansion of tendering to biosimilars and vaccines, which in the latter case became particularly important during the pandemic. In addition, tenders are increasingly being issued by therapy area rather than molecule and criteria other than price are appearing among the selection measures for tenders, including Environmental, Social, and Governance (ESG) related

factors. Furthermore, with environment change high on the agenda in Europe and the need for reforming the supply chain, we expect substantial investment in green-projects, initiatives for carbon reduction and carbon capture, and social initiatives.

Depending on the country, tenders account for 80% to 100% of drug purchases made by hospitals.

COMPANY SUCCESS HINGES ON EFFECTIVE TENDERING APPROACHES

On the surface, tendering looks quite simple: high transparency of the process, price as the only (or most important) decision criterion, no (or limited) engagement with buyers, and highly structured process. However tender processes vary across markets and pharmaceutical companies must deal with multiple stakeholder involvement and limited access to them. There is also significant game-theory at play, with the actions of a company having significant impact on others within the market and their own success.

Therefore, the differences between countries force companies to adapt their activities to local specificity. Simultaneously, group purchasing organizations are becoming more frequent, this increases the purchasing power of buyers, putting the pressure on suppliers.

But despite these challenges, tenders also offer some opportunities like value-based procurement evaluation (if other criteria are considered) or lot exclusivity that can give companies a competitive advantage.

The significance of tenders goes far beyond sales of medicines to impact manufacturers or suppliers' market share and overall revenue. Inefficient tender management processes and a lack of insight into key metrics, such as win-loss ratios and resulting sales, can force a company into an unprofitable agreement or put it out of business for 24 or up to 36 months depending on tender duration practiced in the country concerned.

In a recent survey we carried out for the purpose of this study, more than half of the pharma companies surveyed said that over 80 per cent of their business comes from tendering.

Today's tendering landscape

TYPES OF HOSPITAL TENDERING

Differences in the organization of health care systems in European countries affect which entity organizes tenders in each country. In most countries, tenders are organized at the local level, i.e., by individual hospitals, and mostly concerns the purchase of drugs for the basic needs of hospitals, excluding vaccines and drugs used in centrally coordinated drug programs. In most European countries, private hospitals are excluded from tendering purchases and make purchases directly from wholesalers and manufacturers without tenders.

Central Europe is a region where there are both local and central tenders organized by government institutions such as the Ministry of Health or the National Health Fund. In some countries, such as Sweden and Finland, tenders are organized by regions that bring together groups of hospitals operating in those regions.

TENDERS ON THE RETAIL MARKET

Although in Europe tendering is most common in the hospital market, there is a group of countries where tendering mainly concerns retail or where tenders in this area represent a significant part of the market. In Denmark, tenders in the retail area take place on a

bi-weekly basis for generic drugs and the entire process is organized and managed by Amgro, a company owned by Denmark's five regions.

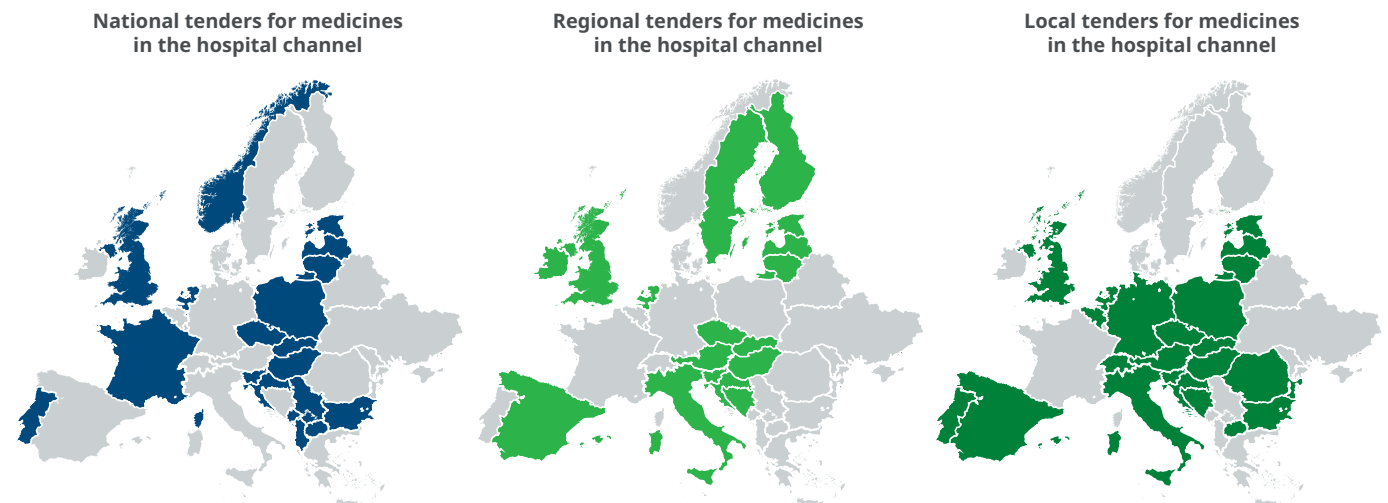
Germany is another pure retail tender market, where tenders are carried out by public and private health insurance companies (see also section 'Germany: leveraging competition in the retail market').

Figure 8: Countries where tenders dominate in the retail market



Source: IQVIA expertise and data

Figure 7: Types of hospital tendering



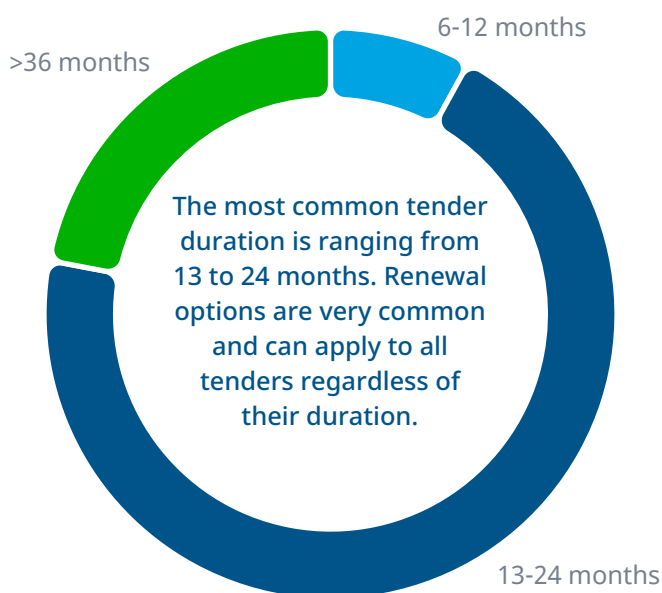
Source: IQVIA expertise and data

TENDER DURATION

The length of tenders depends on local market specifics, but the most common tender length in Europe is 13–24 months. These values have not particularly changed from the result of the survey quoted below, which IQVIA conducted in 2019. A relatively short tender period (up to 12 months) is only used by some countries, e.g., Denmark, Russia, or Ukraine. In contrast, long tender periods (36–48 months) are relatively rare and never as the only tender cycle in a country. Shorter tenders allow for multiple manufacturers to play a role in the market, while long tenders effectively ‘lock-out’ competition in a market for long periods. This has an impact on the long-term competitiveness of the market and can disincentivize competition while providing short-term gains for the payer.

Scandinavian countries use bidding plans that are published in advance for the following year, after gathering demand from individual hospitals. Such a process makes it easier for manufacturers to prepare for tenders and assess demand for particular therapies.

Figure 9: Average tender duration (2019)



Source: IQVIA Tender Benchmark survey results 2019 - Report 2: Current tender environment and awarding criteria.

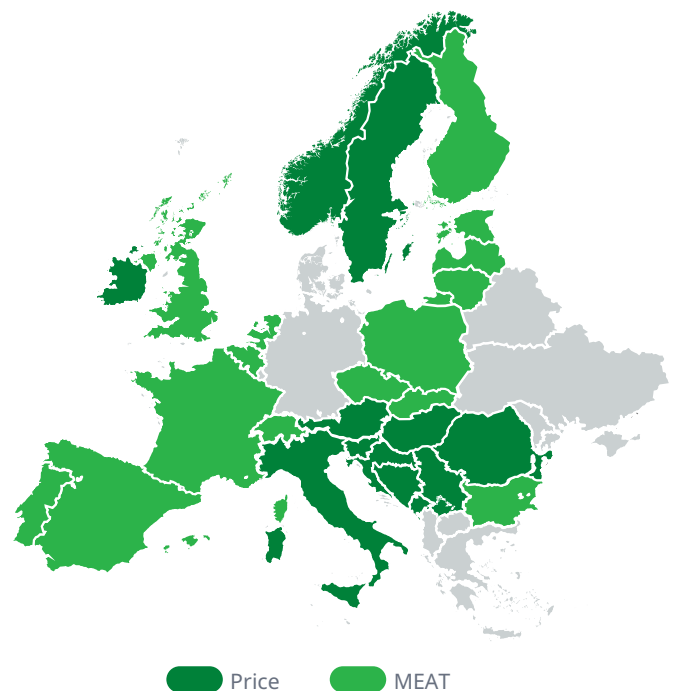
WIN/AWARD CRITERIA

Price only

Traditionally, when launching a tender to award a contract, there are a series of criteria that are considered, mainly economic and quality-related: the supplier that undertakes to deliver drugs in the time and form required at the cheapest price wins the contract. In most European countries, price is the only or one of the dominant criteria for tender selection (see figure below). The main reason for this is the orientation of purchasers towards minimizing the expenditure associated with the purchase of drugs.

This approach minimizes the cost of the purchase itself, but does not necessarily mean that the overall cost of using the drugs will be lower, as it does not take into account additional elements such as the effectiveness of a given therapy, the cost of storing the drugs, environmental impact, training, post-sale service and other costs, or supply volume risks.

Figure 10: Is price the only criteria in tenders?



Source: IQVIA expertise and data.



Example 1: Czech Republic

The basic selection criterion for the tender is the price combined with additional technical parameters. Approximately, 25 per cent of tenders are structured as “lowest bid”. Moreover, since 2013, public bodies directly subordinated to the Ministry of Health are obliged to use “lowest bid” tenders where possible and even when it is impossible and additional criteria are used, the weight of price criteria must be at least 70 per cent.



Example 2: Poland

Polish law requires that the price constitutes an award criterion with at least 50% of the weighted value of all award criteria. The “lowest bid” award scheme is used in approx. 85 % of the cases. However, hospitals also use other awarding criteria such as delivery term, additional services (workshops or trainings).

Most economically advantageous tenders

In 2014, the European Union’s Public Procurement Directives were updated to allow for greater use of quality criteria in tendering. Until then, the heavy reliance on price as the dominant award criterion has had the unfortunate effect of often limiting innovation and encouraging short-term thinking, neither of which is conducive to the best solutions to present-day problems. The European Union Directive 2014/24 defined new award criteria (Article 67) and buyers are now obliged to use the Most Economically Advantageous Tender (MEAT).

In this case, other criteria such as drug quality standards or the ability to deliver the required quantity of drugs at the expected times may serve as conditions (i.e., prerequisites) for access to tenders or alternatively, tender selection criteria may include quality, availability, or supply reliability. In this case, the award criteria shall be weighted according to their relevance in the selection of the tender. In the MEAT approach, in addition to cost, more supplier selection criteria are considered and may include:

- Quality (e.g., in manufacturing and approval process) and product outcomes for the target population documented by evidence (data)
- Price or cost using a cost-effectiveness approach (lifecycle costs)

- Technical aspects (e.g., storage conditions for drugs)
- Aesthetic and functional characteristics (e.g., ease of use and form of administration) considering patient preferences
- Accessibility
- Innovative characteristics
- After-sales service and technical assistance (e.g., training and support provided by the supplier)
- Delivery conditions such as date, process, and period

Each of the tender criteria used are assigned a relative weighting, which must be specified in the tender documents. Alternatively, they may be listed in order from most important to least important. Tenders based on MEAT criteria are evaluated according to the weighting of each criterion and a total score is then calculated to determine the winning bid. According to the regulations, the contract notice must clearly indicate to bidders that the MEAT criteria will be used to evaluate their bid. These criteria may not subsequently be amended. In most MEAT-based tenders, however, price remains the criterion with the highest weighting.

A specific example of MEAT criteria are localization criteria favoring those pharmaceutical manufacturers that produce medicines in a particular country or region. Localization of the pharmaceutical sector encompasses the local production and concentration of various aspects of the pharmaceutical value chain in a specific region. Local production leads to self-sufficiency, fulfilling domestic needs and empowering national healthcare systems—key pillars of a sustainable economy.³ The introduction of such criteria, combined with recurring supply chain problems, could be a reason to halt or even reverse the apparent decades-long trend of shifting API (Active Pharmaceutical Ingredient) production from Europe to Asia.

Tender purchase preferences for suppliers with local production exist already, for example, in Russia or the Middle East (Algeria, Saudi Arabia, Egypt, Jordan), and more countries in Europe are considering their introduction.

Environmental, Social, and Governance criteria

When tenders are awarded based on the MEAT procedure, the award criteria used in the evaluation may include Environmental, Social, and Governance (ESG) Criteria, if there is a genuine link with the subject matter of the contract, and they are economically advantageous in the opinion of the contracting authority. ESG criteria have become increasingly important in recent years and are strongly supported by the Green Public Procurement (GPP) Directive, which encourages European Union member states to make use of their economic power to purchase goods, services and works with the minimal environmental impact possible thereby contributing to the Sustainable Development Goals.

ESG factors: Environmental

Environmental criteria include the cost of energy suppliers take in and the waste they generate, the resources it needs, and the consequences for living beings as a result. Not least, 'Environmental' encompasses carbon emissions (e.g., through the purchase of products and services with a lower CO2 footprint throughout their life cycle) and climate change (e.g., efforts to combat global warming).

ESG factors: Social

Social criteria in tendering address the relationships suppliers have and the reputation it fosters with people and institutions in the communities where they do business. 'Social' therefore may include human rights, labor standards in the supply chain, diversity, inclusion, and more routine issues such as adherence to workplace health and safety.

ESG factors: Governance

Governance is the internal system of practices, controls, and procedures adopted by suppliers to govern themselves, make effective decisions, comply with the law, and meet the needs of external stakeholders.

IQVIA conducted a survey of pharmaceutical companies in 2016, and again in 2019, which surveyed more than 30 Life Sciences companies, capturing the state of tendering in the industry. In 2016, ESG was yet to be created in the form that it is now. There were rarely mentions of criteria beyond price, reliability

of supply, and the company capabilities as the major decision-making criteria. Viewing the market in 2022, in the wake of the COVID-19 pandemic and Russo-Ukraine conflict, future priorities have changed but the underlying trends remains present. Companies will require a compelling value proposition for their ESG credentials, which is something that is currently experiencing 'green-washing' and is relatively weak when viewed critically. The importance of this within tendering criteria will grow, although the speed at which this becomes important will be impacted by the cost-cutting focus by payers in the upcoming inflationary period. Tendering authorities need to develop a fair and transparent way to compare companies.

The new mixture of pricing and ESG criteria that is now more visible in the European tender environment for drugs and medical devices is not only occurring in the biggest pharmaceutical markets like France, Germany, Italy Spain, and the United Kingdom. More examples are coming from the Nordic countries (e.g., joint tender procurement initiative involving Denmark, Iceland, and Norway) that tenders which include environmental and sustainability criteria is fast increasing also. This is exemplified by the work of Karolinska University Hospital in Sweden⁴, which applies a long-term approach regarding environment and sustainability issues, both within the hospital's services, purchases and in cooperation with other parties. The hospital's environmental goals focus on reducing its environmental impact from pharmaceuticals, chemicals, and goods, as well as hospital's greenhouse gas emissions.

The changing environment may give an advantage to pharmaceutical manufacturers in Europe and North America, at the expense of China and India where ESG standards may take longer to adjust. This could be a factor prompting drug manufacturers to move production of active ingredients back to Europe in the long-term. The increased importance of ESG criteria may also be important for smaller pharmaceutical manufacturers, who will be able to adapt more quickly to the new requirements, increase their compliance with ESG criteria and ultimately increase their competitiveness.

Country case studies

The definition and approaches to tenders by country offer valuable insights into how countries approach tenders. No fixed model is used across Europe, which means that tendering strategy for manufacturers should reflect the different models, and expertise in each market is important for new companies launching, as well as supporting bespoke improvements to systems. Two countries have been chosen to illustrate the differences that European markets have taken to manage procurement, as well as resolve issues within their market.

Case study: Italy – multi-layered tendering



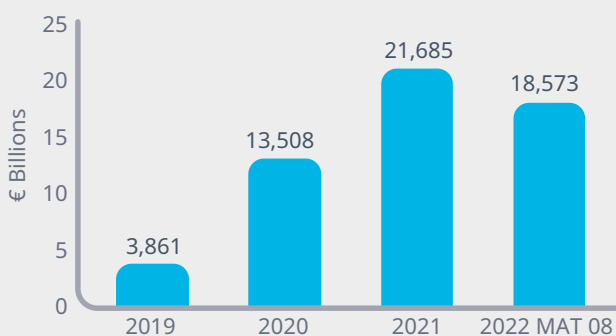
Italy is a major pharmaceutical market that also has high prescription drug usage. It could be argued that a combination of the aging population in Italy, and poor economic performance have created a need to purchase medicines through the most effective method available to handle the growing demand. To curb the cost, they use a combination of approaches such as clawbacks, price caps, and a separate budget for innovative medicines (the ‘Innovative Drug Fund’), and also tenders a very high proportion of its total medicines spending.

Italian tenders have some unique features. The tenders are carried out mainly on a regional basis (by regional purchasing agencies known as Centrali Regionali di Acquisto), hospitals, or by groups of hospitals within the same region. However, in certain cases (e.g., off-patent biological medicines) tenders are organized by multiple regions. This is different to most other markets which mostly use tendering at one level (e.g., only by hospitals, or only by regional structures).

Success in this market is challenging, with price as the major decision-making factor, and many companies being forced to use opportunistic approaches to work out which level, which time, and which products are worth competing for in Italy. Critics of this system in 2018⁵ suggested that a fall in the number of offers submitted for tendering contracts during recent years, as well as the cancellation, postponement, and failure to fulfil some contracts highlighted the failings of this approach.

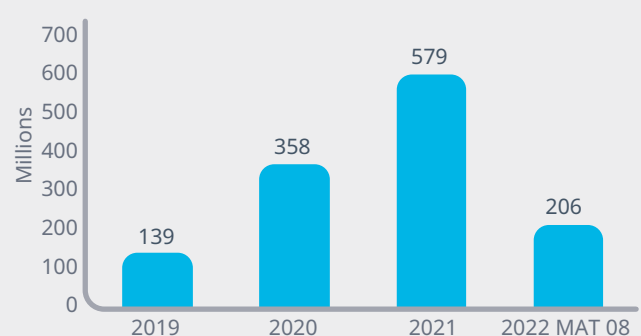
Supporting this, IQVIA data show a steady increase in the number and value of drugs tendered, and a reduction in the number of bidders. Last year, the value of awarded tenders reached €21.7 billion. In 2021 in Italy, 86 buyers concluded nearly 1000 tenders awarding more than 450 bidders. Fluctuations in the number of tenders are due to a change in the way some regions publish their tenders.

Value of awarded tenders



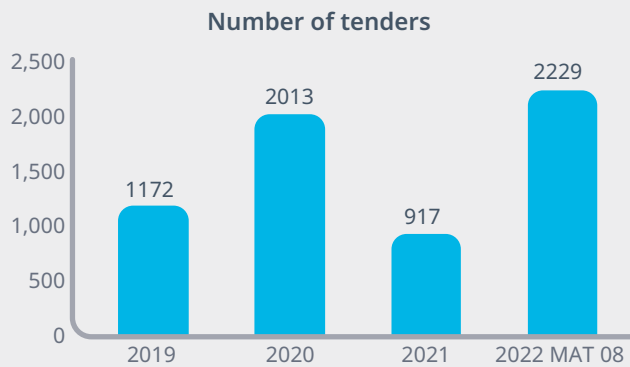
Source: IQVIA data.

Number of drug packages awarded through tenders

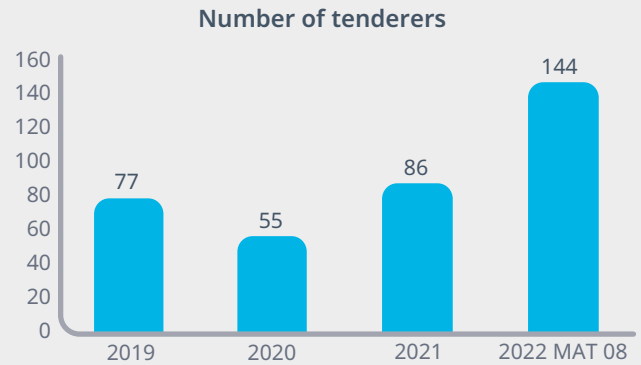


Source: IQVIA data.

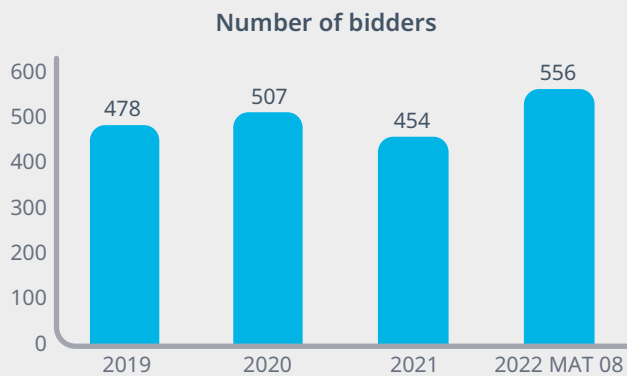
Case study: Italy – multi-layered tendering *continued*



Source: IQVIA data.



Source: IQVIA data.



Source: IQVIA data.

In Italy, tenders only concern hospitals, but it is worth noting that hospitals account for as much as 70 per cent of the value of the pharmaceutical market (the highest in Europe). Therefore, the effectiveness of tenders organized at different levels and the level of discounts obtained (up to 80–90 per cent) is of great importance for the costs of the entire health care system.

Case study: Germany – Adjusting tender requirements to reduce shortages



Germany has a specific and different system of tendering from other countries called ‘Open-House’ which is a contract between health insurance companies and suppliers wishing to deliver the requested drug. Conditions and prices (discounts) are already pre-defined and identical to all bidders who can join the open-house contract at any time during the contract validity period, however the end of the contract is the same for all participants. Open-House contracts refer to the “*Non-exclusive drug discount agreements according to § 130a Abs. 8 SGB V of German law*” and no minimum purchase volume or the purchase quantity is guaranteed and depends on the market needs (physicians, pharmacies, etc.). Bid prices are not publicly available and data points do not allow for their computation. The lowest price is the only criterion considered to select awardees.

Since 2007, health insurance funds have used tenders and supply contracts to lever down pharmaceutical purchase prices in Germany; primarily, though not exclusively, for generics, now also for biosimilars. These have generated substantial savings – voluntary discount agreements are reported by Federal Association of the Pharmaceutical Industry (*Bundesverband der Pharmazeutischen Industrie - BPI*) to have generated €5 billion in savings for statutory health insurance funds in 2020, after consistently generating over €4 billion in annual savings since their introduction in 2007, according to data provided by the largest Statutory Health Insurance (SHI) fund AOK (*Allgemeine Ortskrankensversicherung*). IQVIA data show that more than half of all drugs in the SHI market are the subject of discount contracts, which number close to 28,000, and which involve deals concluded by around 200 pharmaceutical companies with more than 100 health insurance companies.

Biosimilars were first included in a tender for tumor necrosis factor (TNF)-alpha inhibitors issued in September 2015, and a biosimilar infliximab product was among the winners. By 2018, nearly all biosimilars were subject to a discount contract. While discount contracts generate substantial savings for sick funds, their impact on the supply of some drugs has been the subject of growing concern. This has prompted the introduction of new regulations, outlined in the 2017 Act to Strengthen SHI Pharmaceutical Supply, and the pursuit by sick funds of more nuanced approaches to contracting. Under new rules:

- Contracts must contain a clause guaranteeing adequate, uninterrupted supply of the drugs involved
- Since March 2018, the delivery of drugs at agreed prices commences no earlier than six months after the signature of tender documents, allowing manufacturers to build up stocks
- Manufacturers must inform providers of potential shortages as soon as possible, while the federal authorities may request sales and prescription volume data from manufacturers to prevent shortages
- Exclusive discount contracts for vaccines are banned, with sick funds obliged to sign contracts with at least two companies to supply each region. The issue of exclusive discount contracts for other drugs was not included and this continues to be criticized by the industry

The 2017 rule changes also banned individual sick funds from tendering for cytostatic drugs with pharmacies – but allowed them to negotiate discount contracts for cytostatics directly with manufacturers. Sick funds have also begun to adopt more nuanced approaches to tendering in a bid to tackle supply shortages, including:

Case study: Germany: Adjusting tender requirements to reduce shortages *continued*

- ‘Open-house’ tenders: Enabling all companies to meet required conditions to supply products under a contract. Once the payer has accepted a price, the products involved are granted rebate status, which means doctors may prescribe them without any problems. The ‘open-house’ approach is favored particularly for tenders issued immediately after the patent on an original brand has expired.
- ‘Mixed’ tenders: Under this approach, half of the molecules involved may be subject to exclusive tender agreements, while the remaining half is split, with a quarter issued as ‘open-house’ contracts and the remaining 25% awarded jointly to two or three suppliers.

Combining tender models (exclusive, open-house and three partner) is on the increase, with some of the country’s biggest sick funds tendering for the supply of certain molecules through the three-partner model. The AOK fund, which generates around 40% of all tender business, has adopted a three-partner model for molecules where it has previously experienced supply problems.

The use of alternative models does not appear to have had a significant impact on prices. Supply shortages remain an issue, however, since individual winning bidders do not know in advance what share of the overall tender business they will be granted. Shares are determined entirely by market demand and are not specified by the sick funds. Despite some shortcomings of the new models, the health insurer-managed retail tender system in Germany can be considered effective from the cost saving perspective but it remains to be seen whether the approaches to manage the security of supply can handle the shocks to the supply chain that have been seen during COVID-19, the war in Ukraine, and the impact of inflation which results in smaller products no longer being commercially viable.

Conclusion

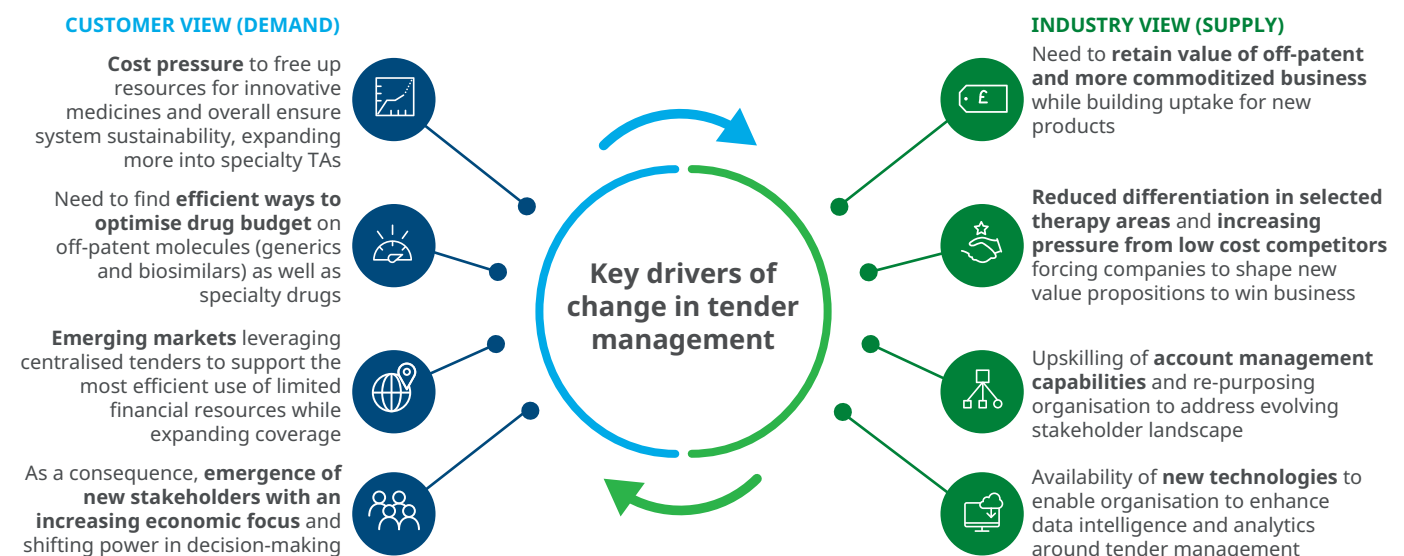
Tenders follow a strict and well-defined process but are rarely the same, nor are they simple. Tendering for medicines becomes an increasingly important part of the healthcare ecosystem, and is responsible for the purchasing of a cohort of medicines that are critical to long-term savings for payers (biosimilars), to patient outcomes (hospital tendered specialty medicines), and to public health (vaccine tenders). This study has highlighted the breadth of approaches, sustainable and unsustainable practices that are used across Europe, and some of the unintended consequences of a poorly set-up system.

As tendering becomes more sophisticated, price transparency slowly but steadily increases, and demand for integrated solutions is driving changes in product offers, requiring new sales tactics from suppliers. Value-based drug procurement is becoming a reality today, and it is proving to be a key driver to enabling outcome-based value for healthcare systems and patients. It is facilitated by the latest European Union directive on public procurement (2014/24), with decisions assessed from two perspectives: total cost of ownership and price-quality ratio. This novel approach to tendering will force changes on the part of both tendering bodies and bidders.

Tendering bodies will need to develop and standardize processes for vetting and evaluating bidders against MEAT criteria. This will sometimes require adapting local regulations to the guidelines in this area recommended by the European Union. During the transition period, as MEAT criteria are introduced into tendering procedures and pharmaceutical companies and suppliers adapt to them, there may be disruption to the supply chain and availability of drugs. It will therefore be important for the tendering bodies to assess the readiness of bidders to meet some of the MEAT criteria.

On the side of those bidding for European tenders, there will be a need to invest in neutralizing their environmental impact and improving their 'social' and 'governance' performance. Manufacturers and suppliers should therefore have much longer-term planning. Bidders will need to engage early in the tender process, act at the right level and quickly; and offer a value proposition 'beyond price'. Efficiency in the conduct of tender processes will be key not only to winning the tender, but also to meeting the basic requirements of the tender. The new elements for evaluation of tenders will also create opportunities for smaller pharmaceutical companies and suppliers to adapt more quickly to the new requirements. For them, this could be a ticket to contracts previously reserved (due to previous requirements) for the largest suppliers.

Figure 11: Key drivers of change in tender management



Source: IQVIA expertise and data

With an increasing number of tenders, the ability to prepare for a tender will become more important and be crucial to success. It will require an improved data infrastructure, AI-enabled technology, daily monitoring of opportunities, tender-specific processes and commercial strategy. But while preparation is important, agility in execution should not be deprioritized. To successfully compete in the tender and contracting market in 2022 and beyond, life science companies need a strong and robust tender organization with a global-to-local tender strategy,

supported by clear processes and organizational structures. Most importantly, predicting the bid-success of your competitors, and the importance of the upcoming tender to an organization sets the 'competitors' apart from the 'leaders' in the market. While companies struggle to grasp this predictive element of tender strategy, there remains vast opportunity. IQVIA will cover this topic in a second whitepaper on the subject of tenders due for publication in 2023.

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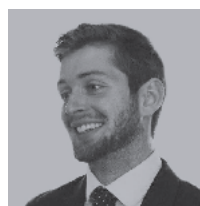
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