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Public Procurement of Healthcare in Europe: The Case of Medical Devices

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This paper analyzes the public procurement of orthopaedic implants and related medical devices in Europe. We analyze the legal framework laid down by the EU Procurement Directives, especially with regard to awarding procedures and contractual forms. We then use data covering the universe of EU public tenders for the period 2009-2014 to describe the key empirical features of the market with regard to awarding procedures and contractual forms. We discuss implications for quality, competition, corruption and product innovation in light of both our data and the new Directive 2014/24/EU. [JEL Classification: K23; L51; L90].

Keywords: healthcare; auctions; regulation.

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1. - Introduction¹

The healthcare sector is an area of growing interest for economists. Together with its increasing share in the budgetary outlays of developed countries, the main reason is the growing reliance on economic principles to design new healthcare markets. In the US, for instance, the ongoing shift from the traditional fee-for-service model to subsidized private provision of Medicare (the \$500 billion a year program offering healthcare benefits to the elderly) is radically changing how the government spends money in healthcare.

In Europe, this trend is evidenced by the increased reliance of awarding procedures to secure the supply of both drugs and medical devices. This process was fostered both by regulatory changes, namely the adoption of Directive 2004/18/EC, as well as by the growing concerns about financial stability of the public sector that is often the main buyer in the drug and medical device markets. This also follows a general trend in public procurement to move toward more transparent procedures and promote competition between suppliers. Although this transformation will likely deeply impact producers' incentives and, ultimately, consumers' welfare, very little is known about the functioning of the procurement system in these sectors across the different European countries.

This paper is a first attempt to offer a descriptive analysis of the EU-wide procurement system in the healthcare sector. Given the complexity of the task, our analysis is narrowed down to a specific aspect of the procurement system, *i.e.* the awarding procedures used to select suppliers, and to a specific market, *i.e.* the market for orthopaedic implants and medical devices intended to treat fractures or orthopaedic degenerative conditions.

Understanding the awarding procedures used is an essential first step to study the efficiency of the public procurement system relative to the risks it faces in this important market. Indeed, medical devices represent one of the main components of the healthcare sector. In Europe, the total turnover for medical technology amounts to more than 70 billion euro per year. Although in both Europe and the US, the public procurement of medical devices is increasingly relying on auction mechanisms, this is an area in which quality of the products matters enormously and an improper auction design could be extremely harmful.

The study by Merlob *et al.* (2012) has shown that the auction for durable medical equipment, that was recently introduced for the purchase of these goods in the US

¹ The opinions expressed in this research work remain, in any case, the sole responsibility of the authors and do not necessarily reflect those of Boston University or the Bank of Italy.

Medicare system, is a very poorly designed mechanism. Their lab experiments isolate various design flaws in the median-bid auction adopted by Medicare and show that it is unable to generate competitive prices and an efficient allocation of contracts.

In Europe, although most of the healthcare sector is organized in country-specific ways, the procurement of medical devices is in part regulated through the harmonized system laid down by the EU procurement directives. Therefore, our analysis will start with an overview of the awarding methods allowed under these directives. Here, we will offer our proposed characterization of the various mechanisms laid down by the directives into three types of awarding *formats*² – First Price (FP) auctions, Scoring Rule (SR) auctions and Negotiations (N) – and three main types of contractual arrangements – Contracts (C), Framework Agreements (FA) and Dynamic Purchase System (DPS).

We will then quantitatively assess the relevance of these formats and contractual arrangements in the market for orthopaedic implants and medical devices using data on all the tenders for such products present in the European Tenders Electronic Daily (TED) database for the period between 2009 and the first half of 2014. We will highlight differences across countries as well as document features relative to both the demand and supply side.

The time frame of the analysis was chosen to be after the Directive 2004/18/EC was adopted by all states, but before the new Directive 2014/24/EU was implemented. This new Directive contains various innovations relative to the previous one in terms of awarding formats and we will conclude this essay with a discussion of what such innovations might imply for the European procurement system.

2. - Auction Procedures, Award Criteria and Types of Contract in the European Legal System

Typically, whenever a medical device is used to perform medical procedures financed from the public budget, the purchase of such device must comply with national regulations and EU procurement Directives³. For the types of products

² Which in the European system combine two elements: an award procedure and an award criterion.

³ More specifically, an EU Directive is a form of legislation that is “directed” at the Member States. It sets out the objective or policy which needs to be attained. The Member States must then pass the relevant domestic legislation to give effect to the terms of the Directive within a time frame set in the Directive, usually two years. Directives are used to set minimum EU standards to be applied at national level, but also leave Member States free to apply more stringent national measures, provided these do not conflict with free movement and free market rules.

that we analyze, the EU procurement Directives apply for awarding of contracts exceeding about EUR 200,000. For the time period on which this paper focuses (2009-2014), the relevant Directive is Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts. In April 2014, such Directive was repealed by the new Directive 2014/24/UE on public procurement, which Member States are required to implement at national level by April 2016.

The remaining part of this section describes the award criteria, procedures and types of contractual agreements laid down in the Directive 2004/18/EC.

2.1 *Procedures and Award Criteria*

The Directive 2004/18/EC provides four main types of procedures to select private contractors (open, restricted, negotiated procedures and competitive dialogue) e two award criteria (the “lowest price” criterion or “economically most advantageous offer” criterion).

a) Open and restricted procedures

Open procedures and restricted procedures are “ordinary” procedures for the assignment of procurement contracts⁴. Both are marked by little discretionary power for administrations in the choice of contractors and presume that the administration itself is capable of defining, accurately and from the beginning, the subject of the contract and the relevant technical specifications, so that bidders may immediately submit definite, non-renegotiable offers (at least as far as the essential aspects of the contract are concerned)⁵.

In the *open procedure* the administration publishes a contract notice containing, among other things, an accurate description of the subject of the contract. The call for tender precedes the presentation of the offers by all interested parties, whose fulfillment of the requisites is verified when the bids received are assessed. The *restricted procedure* (and the so-called accelerated restricted procedure, allowed where urgency renders impracticable the ordinary time limits)⁶ provides for an

⁴ See art. 28 of the Directive.

⁵ See DECAROLIS F. - GIORGIANTONIO C. - GIOVANNIELLO V. (2010, 2011).

⁶ In the case of restricted procedures, the minimum time limit for the receipt of tenders is 40 days from the date on which the invitation is sent; in the case of accelerated restricted procedures, the minimum time limit for the receipt of tenders is 10 days from the date of the invitation to tender. See art. 38, paragraphs 3(b) and 8(b), of the Directive.

initial phase consisting of a prequalification to ascertain requisites and identify the enterprises to invite on the basis of predetermined objectives and non-discriminatory criteria⁷ and a subsequent phase, where the administration invites bids from only the subjects thus identified. In short, in open procedures the administration must specify the full characteristics of the service both in the contract notice and in the relevant auction documentation, while the restricted one this exposition can be effected beforehand in the invitation letters.

The second key rule concerning contract awards is the specification of the criterion for determining the winner. Both procedures can use either the “lowest price” criterion or “economically most advantageous offer” criterion. By the former, the enterprise offering the lowest price is awarded the contract, provided that this price is judged to be “reliable” by the PA, pursuant to the regulations governing abnormal tenders⁸; by the latter, not only price but a range of other parameters, linked to the subject-matter of the public contract in question and specified in the contract notice are assessed⁹.

b) Negotiated procedures

Negotiated procedures, marked by significant discretionary powers for the administration, are those where the PAs consult their chosen economic operators

⁷ In this phase, selective aspects – such as financial soundness or technical capacity – may be assessed.

⁸ If tenders appear to be abnormally low in relation to the goods, the contracting authority, before it may reject those tenders, requests in writing details of the constituent elements of the tender which it considers relevant. Those details may relate for example to: *i*) the technical solutions chosen and/or any exceptionally favourable conditions available to the tenderer for the supply of the goods; *ii*) the originality of the supplies proposed by the tenderer; *iii*) compliance with the provisions relating to employment protection and working conditions in force at the place where the supply is to be performed. The contracting authority verifies those constituent elements by consulting the tenderer, taking account of the evidence supplied. See art. 55, paragraphs 1 and 2, of the Directive.

⁹ For example, quality, technical merit, aesthetic and functional characteristics, environmental characteristics, running costs, cost-effectiveness, after-sales service and technical assistance, delivery date and delivery period or period of completion (see art. 53, paragraph 1(a), of the Directive). The contracting authority specifies in the contract notice or in the contract documents the relative weighting which it gives to each of the criteria chosen to determine the most economically advantageous tender. Those weightings can be expressed by providing for a range with an appropriate maximum spread. Where, in the opinion of the contracting authority, weighting is not possible for demonstrable reasons, the contracting authority indicates in the contract notice or contract documents the criteria in descending order of importance (see art. 53, paragraph 2, of the Directive).

and negotiate the conditions of the contract with one or more of them. Insofar as these procedures represent a derogation to the general ban on renegotiating offers, they are basically exceptional, being admissible only when specific conditions apply (chiefly those related to urgency or lack of appropriate offers or applicants)¹⁰.

Depending on type of information requirements, hence the greater or lesser discretionary powers of the PA, we may distinguish between two main types of negotiated procedures:

- i) negotiated procedure with the publication of a contract notice* (and the so-called accelerated negotiated procedure with the publication of a contract notice, allowed where urgency renders impracticable the ordinary time limits)¹¹, where the administrations publish a notice and, respecting the principle of equal treatment, negotiate offers with the bidders;
- ii) negotiated procedure without the publication of a contract notice*, where administrations identify the operators with which to initiate negotiations independently on the basis of market surveys¹².

The negotiations must in any case observe the principles of non-discrimination and equal treatment and both the most economically advantageous offer and the lowest price criteria are applicable.

c) Competitive dialogue

Competitive dialogue, one of the most significant innovations of the European Directive 2009/18/EC, is a procedure in which any economic operator may request to participate and whereby the contracting authority conducts a dialogue with the candidates admitted to that procedure, with the aim of developing one or more suitable alternatives capable of meeting its requirements, and on the basis

¹⁰ See articles 30 (negotiated procedure with the publication of a contract notice) and 31 (negotiated procedure without the publication of a contract notice) of the Directive.

¹¹ In the case of negotiated procedures, the minimum time limit for receipt of requests to participate is 37 days from the date on which the contract notice is sent; in the case of accelerated negotiated procedures with the publication of a contract notice, the minimum time limit for the receipt of requests to participate is 15 days from the date on which the contract notice was sent, or 10 days if the notice was sent by electronic means. See art. 38, paragraphs 3(a) and 8(a), of the Directive.

¹² Given the absence of the publication of a contract notice, the possibilities to apply this procedure are particularly limited: see art. 31 of the Directive.

of which the candidates chosen are invited to tender¹³. It was introduced in order to reconcile a greater flexibility in the assignment of complex works with compliance with EU principles on competition, transparency and equality of treatment¹⁴.

Competitive dialogue is limited to “particularly complex contracts” (for which open or restricted procedures are not practicable), defined as those for which the administration is *objectively* unable to define *ex ante* the technical means needed to satisfy its needs or the juridical and financial structure of the project¹⁵. The only applicable award criterion is the economically most advantageous offer¹⁶.

TABLE 1

EU AUCTION FORMATS

<i>Award procedures</i>	Open Procedure + Restricted Procedure + Accelerated Restricted		Accelerated Negotiated + Award of a contract without prior tender publication + Competitive Dialog + Negotiated + Negotiated without a call for competition
<i>Award Criterion</i>	Lowest Price	Most Economically Advantageous Tender (MEAT)	Lowest Price or MEAT (but only MEAT for Competitive Dialog)
<i>Format</i>	FP	SR	N

¹³ See art. 1, paragraph 11(c), of the Directive. According to the article 29 of the Directive, contracting authorities open with the candidates a dialogue the aim of which is to identify and define the means best suited to satisfying their needs. They discuss all aspects of the contract with the chosen candidates during this dialogue. During the dialogue, contracting authorities ensure equality of treatment among all tenderers. In particular, they do not provide information in a discriminatory manner which may give some tenderers an advantage over others. Contracting authorities provide for the procedure to take place in successive stages in order to reduce the number of solutions to be discussed during the dialogue stage by applying the award criteria in the contract notice or the descriptive document. The contracting authority continues such dialogue until it can identify the solution or solutions, if necessary after comparing them, which are capable of meeting its needs. Having declared that the dialogue is concluded and having so informed the participants, contracting authorities ask them to submit their final tenders on the basis of the solution or solutions presented and specified during the dialogue. These tenders contain all the elements required and necessary for the performance of the project. Contracting authorities assess the tenders received on the basis of the award criteria laid down in the contract notice or the descriptive document and choose the most economically advantageous tender.

¹⁴ See GIORGIANTONIO C. and GIOVANNIELLO V. (2009).

¹⁵ See art. 1, paragraph 11, of the Directive.

¹⁶ See art. 29, paragraph 1, of the Directive. Moreover, the Directive clearly provides that, in order to take account of the different circumstances obtaining in Member States, they should be allowed to choose whether contracting authorities may use the competitive dialogue procedure, as defined and regulated at European level. See consideration 16 of the Directive.

2.2 *Types of Contract*

The auction procedures and award criteria described before can be used to stipulate different types of contract between contracting authorities and economic operators. The ordinary one is a *public supply contract* (C), a public contract¹⁷ having as their object the purchase, lease, rental or hire purchase, with or without option to buy, of products¹⁸. In this case, the contract disciplines a current contractual relation between one or more contracting authorities and one or more economic operators.

The others, framework agreement and dynamic purchasing system, discipline the terms or the way in which future public supply contracts will be stipulated¹⁹. More specifically, a *framework agreement* (FA) is an agreement between one or more contracting authorities and one or more economic operators, the purpose of which is to establish the terms governing contracts to be awarded during a given period, in particular with regard to price and, where appropriate, the quantity envisaged²⁰. Contracts based on a framework agreement are awarded in accordance with different procedures depending on the number of involved operators²¹. Those procedures are applied only between the contracting authorities and the economic

¹⁷ Public contracts are contracts for pecuniary interest concluded in writing between one or more economic operators and one or more contracting authorities and having as their object the execution of works, the supply of products or the provision of services within the meaning of the Directive (see art. 1, paragraph 2(a)).

¹⁸ A public contract having as its object the supply of products and which also covers, as an incidental matter, siting and installation operations shall be considered to be a public supply contract. See art. 1, paragraph 2(c), of the Directive.

¹⁹ The Directive clearly provides that, in order to take account of the different circumstances obtaining in Member States, they should be allowed to choose whether contracting authorities may use framework agreements and dynamic purchasing systems, as defined and regulated at European level. See consideration 16 of the Directive.

²⁰ See art. 1, paragraph 5, of the Directive. According to the art. 32, paragraph 2, of the Directive, for the purpose of concluding a framework agreement, contracting authorities follow the rules of procedure referred to in the Directive for all phases up to the award of contracts based on that framework agreement. The parties to the framework agreement are chosen by applying either the lowest price criterion or economically most advantageous offer criterion.

²¹ Where a framework agreement is concluded with a single economic operator, contracts based on that agreement shall be awarded within the limits of the terms laid down in the framework agreement. For the award of those contracts, contracting authorities may consult the operator party to the framework agreement in writing, requesting it to supplement its tender as necessary. Where a framework agreement is concluded with several economic operators, the latter must be at least three in number, insofar as there is a sufficient number of economic operators

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operators originally party to the framework agreement²². The term of a framework agreement may not exceed four years, save in exceptional cases duly justified, in particular by the subject of the framework agreement.

A *dynamic purchasing system* (DPS) is a completely electronic process for making commonly used purchases, the characteristics of which, as generally available on the market, meet the requirements of the contracting authority, which is limited in duration and open throughout its validity to any economic operator which satisfies the selection criteria and has submitted an indicative tender that complies with the specification²³. In order to set up a dynamic purchasing system, contracting authorities shall follow the rules of the open procedure in all its phases up to the award of the contracts to be concluded under this system²⁴. Such system may not last for more than four years, except in duly justified exceptional cases.

3. - Data and Market

The dataset that we use is composed of all the tenders for medical devices appearing in the European TED between 2009 and the first half of 2014. This is the database version of the ‘Supplement to the Official Journal of the European Union’ dedicated to European public procurement. We integrated these TED data with

to satisfy the selection criteria and/or of admissible tenders which meet the award criteria. Contracts based on framework agreements concluded with several economic operators may be awarded either: *i*) by application of the terms laid down in the framework agreement without reopening competition, or *ii*) where not all the terms are laid down in the framework agreement, when the parties are again in competition on the basis of the same and, if necessary, more precisely formulated terms, and, where appropriate, other terms referred to in the specifications of the framework agreement, in accordance with the following procedure: *a*) for every contract to be awarded, contracting authorities shall consult in writing the economic operators capable of performing the contract; *b*) contracting authorities shall fix a time limit which is sufficiently long to allow tenders for each specific contract to be submitted, taking into account factors such as the complexity of the subject-matter of the contract and the time needed to send in tenders; *c*) tenders shall be submitted in writing, and their content shall remain confidential until the stipulated time limit for reply has expired; *d*) contracting authorities shall award each contract to the tenderer who has submitted the best tender on the basis of the award criteria set out in the specifications of the framework agreement. See art. 32, paragraph 3 and 4, of the Directive.

²² When awarding contracts based on a framework agreement, the parties may under no circumstances make substantial amendments to the terms laid down in that framework agreement. See art. 32, paragraph 2, of the Directive.

²³ See art. 1, paragraph 6, of the Directive.

²⁴ See art. 33, paragraph 2, of the Directive.

detailed information from the tender calls on the device procured. With these data, we perform a descriptive analysis of procurement practices in the EU. The data allow us to cleanly identify the type of awarding format used as well as the contractual type. Moreover, the data contains other useful information about the product, the auctioneer, the winner(s) and various other features of the awarding stage.

To narrow down the analysis to a healthcare market that is both economically relevant, but also sufficiently homogeneous to make feasible jointly analyzing the tenders involved, we selected tenders defined by objects identified by three sets of common procurement vocabulary (CPV) codes: *i*) Disposable non-chemical, non-biological consumables (CPV=33141xxx); *ii*) Orthopaedic artificial parts of the body (CPV=33183xxx); *iii*) Non-orthopaedic artificial parts of the body (CPVPC=33184xxx). After excluding a small number of tenders with unusually high awarding prices exceeding 10 million EUR, the resulting dataset that we work with has 34,164 tenders summing up to a total awarded value of nearly 33 billion EUR. In the next section, we will split our sample according to various elements of the data to offer a broad overview of public procurement patterns in the EU.

However, before moving to this descriptive analysis, it is useful to discuss whether these data are able to offer a complete figure of the market for surgical and medical devices in the EU. For the type of products that we study, the transmission of the tender information to the TED involves every tender whose value exceeds about 200,000 EUR (the threshold slightly changes over time). Due to the pervasive presence of public financing for the medical procedures where the devices are used, both private and public hospitals will typically be subject to public regulations, including the publicity on the TED. This suggests that, in principle, our data should cover nearly the universe of transactions. Nevertheless, in addition to the unobservable tenders below 200,000 EUR, there are a few other reasons why our data is unlikely to cover the universe of the transactions.

First, there can be failures to properly report to the TED. This can take the form of full non-compliance so that no element of the tender is communicated to the TED or incomplete communications. An instance of the latter case regards the set of CPV indicated in the tender. Given the very large number of tenders present on the TED, filtering by CPV is unavoidable if one intends to analyze a well-defined market. However, our exploration of the database revealed that it is sometimes the case that tenders for the type of products we are interested in were only recorded with the higher level CPV (33100000 - Medical equipments). In part this might be due to the fact that tenders are often divided into multiple lots which may be defined broadly, including multiple categories of devices. Indeed,

suppliers typically bid for a subset of the lots and this is why our analysis is at the level of awardings and not of tenders. We have considered the possibility of integrating our data with additional tenders reporting in their object description keywords like: joint reconstructive implants (hip, knee, elbow and shoulder implants), bone cement, bone cement accessories, pulsed lavage, spine devices or trauma devices. However, we ultimately did not use these additional data and kept in the database only tender with the three sets of CPV indicated above. We leave for future work better addressing this issue.

The second and more substantive reason why our data is incomplete is that EU countries are heterogeneous in the way their healthcare systems are organized and this translates in a high fragmentation of the procurement system and regulations. The harmonization process promoted by the 2004 directives is not completed during our period of analysis. Moreover, this interacts with the regulations regarding the authorizations for the sale of medical devices. The EU regulations have in part harmonized this aspect as well. Indeed, the European regulatory system mandates a *conformity assessment* procedure whereby the manufacturer, or an authorized body, certifies that the product complies with some essential requirements, which differ depending on the risk class of the device. Devices that pass this *conformity assessment* can be CE-marked and can circulate freely in the European Union. Nevertheless, our understanding of the practices in this market suggest that individual countries can put additional restrictions. For instance, in Scandinavian countries it appears customary to place track record requirements on the product that limit the possibility of entry for new devices. More generally, the presence of public reimbursement systems that vary from country to country together with the fact that procurement is often decentralized at the hospital level, implies high degrees of heterogeneity in the extent to which public tender are used and communicated to the TED. Indeed, our understanding of the market is that off-tender purchases, often involving bilateral negotiations, are still relevant in many countries and that this is especially the case when the needs involve very innovative implants or other special implants.

Finally, it is important to point out that, even when we observe an awarding in the data, this does not necessarily imply that a transaction took place. For framework agreements this is obvious as the nature of the contract is that the supplier agrees to supply its devices at certain conditions, but only during the life of the agreement demand by hospitals and other entities allowed to participate in the agreement will materialize. However, in our data we found that even for conventional contracts it is sometimes the case that the outcome of tenders is the se-

lection of a few *shortlisted* suppliers. The devices will then be subsequently purchased from one or more of the suppliers in the shortlist. Although we have tried to address this aspect, at this ongoing stage of our analysis we are still unable to fully characterize this phenomenon and, hence, our assessment of the value of the tenders awarded is likely to be inflated.

4. - Descriptive Analysis

We use the TED data, under the caveats discussed in the previous section, to analyze the public procurement of medical devices under various dimensions.

First of all, building from the discussion in section 2, we report in Table 2 our data separately for the three awarding formats (FP, SR and N) and the three contractual types (C, DPS, FA). This table offers a first look at the relevance of the various procurement mechanisms by describing the number (top row of each cell) and value (bottom row of each cell) of tenders they were used to procure. From this table we readily see that FP and SR are the most relevant formats, while contracts and framework agreements are the most relevant contractual types. Based on this finding, the rest of the paper will ignore in the empirical analysis Negotiations (N) and Dynamic Purchase System (DPS) awarding, pooling them together with the non-specified cases into a residual category that we refer to as "Other". As regards the comparison between Contract (C) and Framework Agreements (FA), we note that 65% of all the awarding involve C, but when we look at their value, this is only 50.2% of the total awarded value in the sample. The contrary is true for FA that represent 11.2% of the awardings, but 20.1% in terms of awarded value. These numbers, however, need to be interpreted carefully as the FA awarded value might be larger than the final value that gets purchased by the time the agreement is over. Unfortunately, our data do not allow to observe this ex post realization as well as any other ex post phenomenon like price renegotiations. Finally, the fact that a comparison between FP and SR also indicates a reversal between the number and the value of the contracts like that recorded for C and FA is in part related to the larger share of FA relative to C that get awarded via SR. In part, however, it is also due to the fact that even among C, it is the most complex and expensive ones that are typically awarded via SR.

TABLE 2

AUCTION FORMATS AND CONTRACT TYPES					
	FP	N	SR	Not Specified	Total
Contract	49.2% [29.0%]	0.2% [0.1%]	13.7% [18.7%]	2.0% [2.4%]	65.2% [50.2%]
Dynamic Purchase System	0.0% [0.0%]	0.0% [0.0%]	0.0% [0.0%]	0.0% [0.0%]	0.1% [0.1%]
Framework	5.6% [7.6%]	0.4% [0.1%]	4.1% [10.1%]	1.1% [2.3%]	11.2% [20.1%]
Not Specified	4.9% [3.3%]	0.8% [0.1%]	13.2% [18.8%]	4.7% [5.7%]	23.6% [27.9%]
Total	59.7% [39.3%]	1.4% [0.3%]	31.1% [47.6%]	7.8% [10.4%]	34,164 awardings 32,663 million EUR

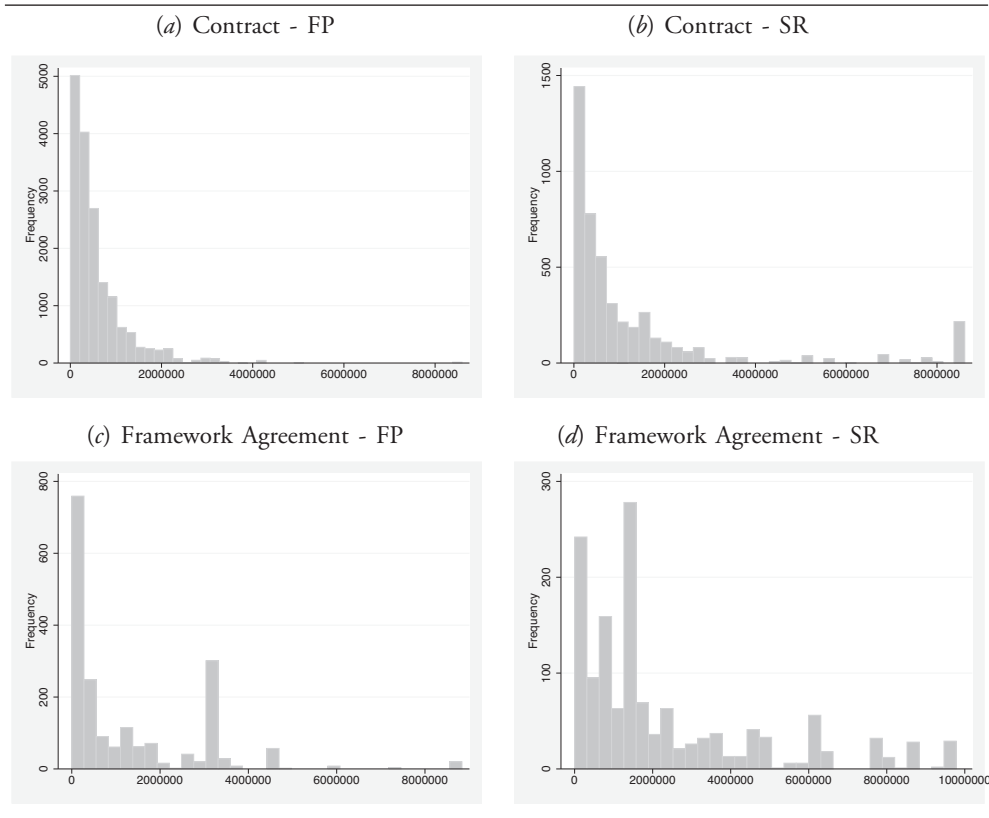
To better understand the nature of the procurement system, the remaining part of this section splits the sample according to features of the object procured and characteristics of the demand and supply. Given the difficulties in assessing the value awarded, we will focus on the number of awardings.

4.1 *Object Characteristics*

A first characterizing element of a tender is the awarded amount. Graph 1 reports the histogram of the variable recording the awarded amount, separately for each of the four awarding systems considered: (C-FP), (C-SR), (FA-FP) and (FA-SR). The Graph confirms that contracts awarded via FP are both particularly numerous and characterized by relatively low awarding prices. The opposite is true for framework agreements awarded via SR. In this latter case, it is also evident a certain lumpiness of the variable in various points of its distribution. Regardless of whether the contractual type is C or FA, the tenders awarded via SR tend to be of higher value.

GRAPH 1

TENDERS BY AWARDED AMOUNT



A second dimension along which the tenders differ is related to the type of product procured. The products that we analyze can be divided into the three macro groups that we described before in terms of CPVs: *i*) Disposable non-chemical, non-biological consumables; *ii*) Orthopaedic artificial parts of the body and *iii*) Non-orthopaedic artificial parts of the body. All of our tenders cover at least one of these three macro products, and possibly more of them simultaneously. In this latter case, we will say that the product type is “mixed”. Table 3 illustrates how the data are split by product type and awarding method. Mixed and orthopaedic are the most frequent object types. The incidence of the different awarding systems across products does not reveal any special association between such systems and the different products.

TABLE 3

	TENDERS BY PRODUCT TYPE					Total
	Contract		Framework		Other	
	FP	SR	FP	SR		
Disposable non-chemical, non-biological consumables	7.1%	2.9%	0.9%	0.5%	5.4%	16.8%
Orthopaedic artificial parts of the body	18.4%	4.5%	2.7%	1.1%	7.2%	34.0%
Non-orthopaedic artificial parts of the body	5.8%	1.2%	0.2%	0.6%	3.8%	11.6%
Mixed	17.9%	5.1%	1.8%	1.9%	10.9%	37.6%
Total	49.2%	13.7%	5.6%	4.1%	27.3%	34,164 awardings

4.2 Demand Characteristics

A key dimension along which to analyze the data is that regarding the country where the procurement takes place. In this regard, Table 4 offers valuable insights on the content of the TED database: more than half of the awarding (56.2% of the cases) are originated in a single country: Poland. The other most relevant countries are France, which accounts for 17.4% of the awardings, followed by Spain, Italy and Romania, all accounting for about 5% of all the awardings. Given the size differences among countries, the data in Table 4 are suggestive that while certain countries source a large share of the implants purchased via public tenders (communicated to the TED) (this is for instance the case of the Baltic States), others rarely rely on tenders (indeed, no tenders at all are communicated from Austria or Ireland).

Furthermore, the data reveal interesting heterogeneity in terms of the awarding systems used in the different countries. For instance, while in Romania the main system is framework agreements awarded via FP and while awarding framework agreements via FP is also common in Slovenia, in all other countries where FA are used, the most common format employed to award them is SR. This is for instance the case in Belgium, Denmark, France, Italy and the UK. SR are also extensively used to award C in Italy and France, but there are also countries where contracts are awarded via FP. This is the case of Belgium, Lithuania, Poland, Slovenia and Slovakia.

TABLE 4

TENDERS BY COUNTRY

	Contract		Framework		Not Specified	Total
	FP	SR	FP	SR		
BG	0.5%	0.1%	0.0%	0.2%	1.7%	2.4%
CY	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
CZ	0.0%	0.1%	0.0%	0.2%	0.2%	0.4%
DE	0.0%	0.0%	0.0%	0.0%	0.1%	0.1%
DK	0.0%	0.0%	0.0%	0.4%	0.3%	0.7%
EE	0.0%	0.0%	0.0%	0.0%	0.0%	0.1%
ES	0.0%	0.8%	0.0%	0.6%	3.6%	5.1%
FI	0.0%	0.0%	0.0%	0.0%	0.2%	0.3%
FR	0.0%	2.3%	0.2%	2.2%	12.6%	17.4%
GR	0.0%	0.0%	0.0%	0.0%	0.1%	0.1%
HU	0.1%	0.1%	0.0%	0.0%	0.8%	0.9%
IE	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
IT	0.2%	1.6%	0.0%	0.1%	2.7%	4.6%
LT	1.5%	0.0%	0.0%	0.0%	1.3%	2.8%
LV	0.1%	0.1%	0.0%	0.0%	0.1%	0.2%
MT	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
NL	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
NO	0.0%	0.0%	0.0%	0.1%	0.0%	0.1%
PL	46.0%	8.4%	0.2%	0.0%	1.6%	56.2%
PT	0.1%	0.1%	0.0%	0.0%	0.2%	0.4%
RO	0.1%	0.0%	4.6%	0.0%	0.4%	5.1%
SE	0.0%	0.0%	0.0%	0.0%	0.2%	0.2%
SI	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SK	0.3%	0.0%	0.1%	0.1%	0.5%	1.1%
SL	0.3%	0.0%	0.3%	0.0%	0.2%	0.8%
UK	0.0%	0.0%	0.0%	0.2%	0.5%	0.8%
Total	49.2%	13.7%	5.6%	4.1%	27.3%	34,164 awardings

These differences from country to country are certainly related to their national healthcare systems. In this respect, it is interesting to try to split the data by the type of body making the award. This would be especially useful to evaluate the question of whether certain countries are more likely to try to achieve cost savings by consolidating buyer power within Group Purchasing Organisations (“GPOs”). Table 5 reports our first look at this phenomenon using the categorization of purchasing authorities present in the TED data: *i)* central government; *ii)* local government; *iii)* public body and *iv)* other. The latter comprises many types of bodies, including international organizations and public utility companies. Although somewhat interesting, as it reveals asymmetries in the use of C and FA between central and local governments, this division is not sufficiently detailed to address the question of GPOs. Although the data contains the name of the authority, the lack of standardization in the way the authority name is recorded in the TED data makes the task of using the authority name an issue that we leave for future research.

TABLE 5

	TENDERS BY TYPE OF PROCURER					Total
	Contract		Framework		Not Specified	
	FP	SR	FP	SR		
Central Government	0.4%	0.0%	2.4%	0.1%	1.6%	4.7%
Local Authority	0.3%	1.5%	0.0%	0.9%	4.3%	7.1%
Public Body	37.0%	8.4%	1.4%	1.7%	9.3%	57.8%
Other	11.6%	3.7%	1.7%	1.3%	12.1%	30.4%
Total	49.2%	13.7%	5.6%	4.1%	27.3%	34,164 awardings

4.3 Supply Characteristics

The last dimension that we consider concerns supply characteristics. In particular, although we cannot perfectly quantify the market shares of each supplier, our data are sufficiently detailed to obtain a partial answer. Table 6 reports our data split according to the identity of the winner: there we look at the 8 largest firms in terms of number of awardings received and we pool together all remaining firms. Furthermore, to account for the fact that sometimes firms win a contract having formed a temporary joint venture with other firms, we include a row

for “partnership top 8”, that identifies tenders won by temporary joint ventures involving more than one of the 8 largest firms.

TABLE 6

	TENDERS BY AWARDEE'S IDENTITY					Total
	Contract		Framework		Not Specified	
	FP	SR	FP	SR		
Aesculap	3.7%	1.0%	0.0%	0.0%	0.2%	5.0%
Biomet	4.8%	0.7%	0.1%	0.2%	0.9%	6.6%
Depuy	5.1%	1.9%	0.1%	0.2%	1.8%	9.0%
Medtronic	2.0%	0.5%	0.0%	0.1%	0.5%	3.0%
Smith&Nephew	1.5%	0.4%	0.0%	0.2%	0.7%	2.7%
Stryker	5.3%	1.0%	0.3%	0.3%	1.9%	8.7%
Synthes	4.3%	0.9%	0.1%	0.3%	1.6%	7.2%
Zimmer	0.0%	0.3%	0.0%	0.2%	1.0%	1.5%
Partnership Top 8	0.0%	0.0%	0.0%	0.2%	0.2%	0.3%
Others	22.6%	7.1%	5.1%	2.6%	18.6%	56.0%
Total	49.2%	13.7%	5.6%	4.1%	27.3%	34,164 awardings

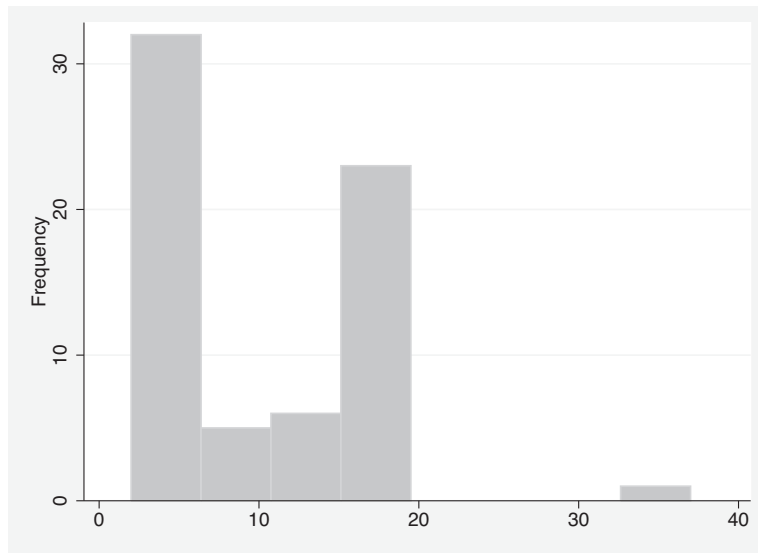
The Table reveals that the residual category, “Others”, has the largest number of awardings (56%). This is in part due to the presence of local/national firms. In many, but not all EU, many local competitors are present: Metrimed and Sanametal are only active in Hungary; Biotech is active in Hungary and Croatia; Dedienne is active in France and Spain; Summit is only active in Germany; Stanmore Implants Worldwide Ltd is only active in the UK; Beznoska is only active in the Czech Republic; Aston, ATF, Biotecni, C2F, Euros, Evolutis are only active in France.

As for the top the top 8 firms, they seem all able to win both in FP and SR auctions and in both C and FA. Furthermore, at first glance their market shares do not seem to reveal a strong market concentration. Nevertheless, this is possibly due to our grouping of many different devices together, while they possibly belong to separate markets from the perspective of a competitive assessment.

Finally, it is interesting to consider the cases of awards to multiple firms. Such cases are concentrated almost exclusively in (FA-SR). Although, like for other awarding formats, the vast majority of cases entails a single winner (1,216 cases), for this format we observe 67 cases where multiple firms win. For these cases, Graph 2 reports the distribution of the number of winners.

GRAPH 2

TENDERS BY NUMBER OF SUPPLIERS (IF >1)
 Framework Agreement - SR (1,216 awardings with N. Suppliers=1)



5. - Economic and Regulatory Considerations

In this section, we develop four sets of considerations motivated both by the evidence presented in the previous section and by the recent regulatory innovations introduced by the new Directive 2014/24/EU of the European Parliament and the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC. For the considerations already mentioned in the previous paragraphs, the transposition of the new Directive by Member States will be crucial to evaluate the relevance and the effectiveness of the regulatory innovations.

5.1 Suppliers' Competition

Fostering competition among suppliers is a main goal of the procurement system. In this respect, the use of harmonized tendering procedures in terms of both awarding mechanisms and contractual types should be an effective mechanism to allow suppliers to compete in multiple geographic markets. Therefore, the persistent heterogeneity across countries revealed by the evidence in Table 4 suggests

that there are still significant barriers to competition across countries and that, from the perspective of a competition analysis, the markets are separated at national level. In this respect, some changes could be introduced by the transposition of the new Directive. In fact, it establishes new rules on cross-border joint procurement in order to facilitate cooperation between contracting authorities and enhancing the benefits of the internal market by creating cross-border business opportunities for suppliers and service providers²⁵.

Competition benefits procurers because it implies that, unless a firm offers a sufficiently good price (or price and quality) bid, the procurer can switch to a rival firm. The use of public tenders makes switching a credible threat since the procurer commits to adhere to the awarding mechanism indicated in the tender notice and select whoever will offer the best bid. Nevertheless, for the types of products that we are studying, switching from one supplier to a different one is known to be potentially problematic. In particular, each medical device typically requires some product-specific training (for both doctors and nurses) and, indeed, higher post-op complications after switching products are generally attributed to insufficient product-specific training.

This implies that a more nuanced view of the benefits of competition should be applied to this sector. In particular, we see a rationale in this sector for trying to limit participation to more established products for which doctor and nurses are more likely to be sufficiently experienced. This is indeed a common solution often followed in Scandinavian countries, where bidders interested in participating in a public tender must have solid track records to pass eligibility criteria. This, however, could limit entry of new players and the adoption of innovations. Thus, as an alternative, one could envision the possibility of having suppliers bid in SR auctions, where some of the criteria weighted are related to the type of product-specific training that the bidder is willing to offer in case it wins the tender.

An additional concern in terms of suppliers' competition worth mentioning is that, although the market does not seem particularly concentrated, this situation might be rapidly changing. There seems to be an ongoing tendency toward greater producers concentration achieved via mergers and acquisitions. The most recent

²⁵ The principles laid down by the Directive determine the conditions for cross-border utilisation of central purchasing bodies and designate the applicable public procurement legislation, including the applicable legislation on remedies. In addition, contracting authorities from different Member States should be able to set up joint entities established under national or Union law. See consideration 73 and art. 39 of the new Directive.

case is the acquisition of Biomet by Zimmer. These are two of the top 8 producers listed in Table 6 and the creation of a combined entity, announced in the summer 2014, has recently received the clearance of the antitrust authorities in both Europe and the US. As it is well known, a merger may significantly reduce competition in a market by removing competitive constraints on one or more sellers, who, hence, gain increased market power. The direct effect of the merger between Biomet and Zimmer is the loss of competition between them: if, before the merger, Biomet might have been careful to increase its prices to avoid customers switching to Zimmer's products, this is no more a concern after the merger since all products belong to the same firm. The reduction in the competitive constraints can thus lead to significant price increases. It is therefore important to monitor how the market will evolve as a consequence of this and other mergers that recently happened or that are still ongoing.

Finally, a last point concerning competition that deserves attention is the presence of joint bidding. The presence of a few instances in the data of tenders won by temporary partnerships of firms reveals that joint bidding is allowed in at least a subset of the tenders analyzed. The implications of this practice are not yet well understood (Albano, Spagnolo and Zanza, 2009), but its potential anti-competitive effects are evident as the possibility of joint bidding limits firms' needs to compete.

From this point of view, the new Directive does not seem to offer sufficient attention to prevent risks of collusion between firms. The problem is tackled only through a broad range of measures to facilitate the involvement of SMEs in the public procurement market, including the extension of the scope of the obligation to consider the appropriateness of dividing contracts into smaller lots, by requiring contracting authorities to provide a justification for a decision not to divide contracts into lots or by rendering a division into lots obligatory under certain conditions²⁶. Such approach does not seem to adequately consider that one of the potentially negative effects of the division of the contract into lots (if improperly carried out) is exactly the facilitation of collusion between firms (Sánchez-Graells, 2015; Dimitri, Piga and Spagnolo, 2006).

5.2 *Quality Concerns and the Role of SR*

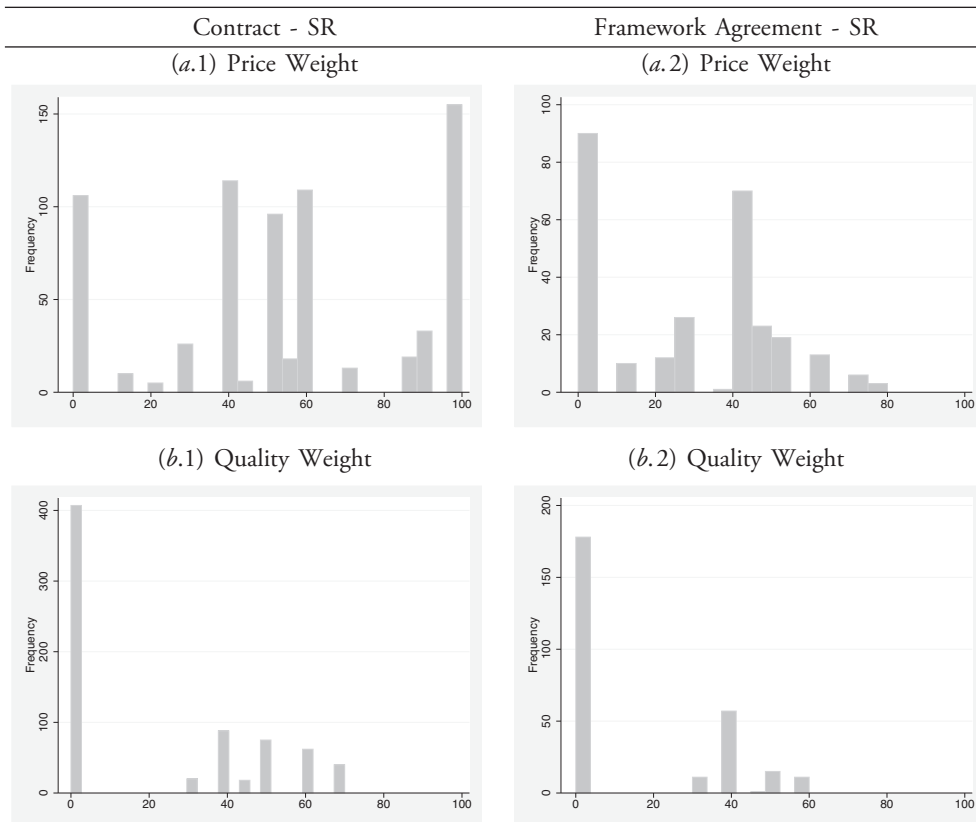
A main concern with the use of competitive tenders is the risk that fostering competition could produce a reduction of prices accompanied, however, by significant quality worsening, see Decarolis (2014). To limit this risk, SR where quality elements

²⁶ See consideration 78 and art. 46 of the new Directive.

can be explicitly included in the awarding criteria can play an important role. One valuable aspect of the TED data is that for the majority of SR auctions it is possible to observe what weights were assigned to price, quality measures and other measures. Graph 3 reports the distributions of such weights, separately for contracts and framework agreements. Although in many cases quality has a high weight, in the majority of cases it does not. In such cases, criteria we classified as “other” are the ones that matter the most, along with price. Since among them a prominent role is played by features like conditions of the delivery, from this first look at the data it seems that even within the current SR price considerations play a key role²⁷.

GRAPH 3

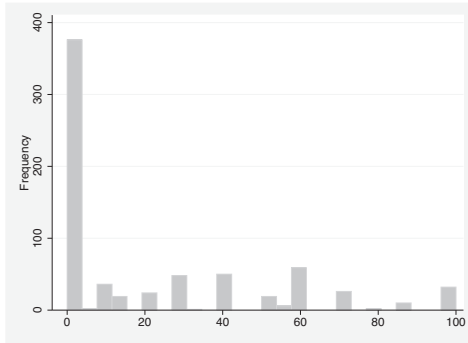
WEIGHTS USED IN SR AWARDINGS



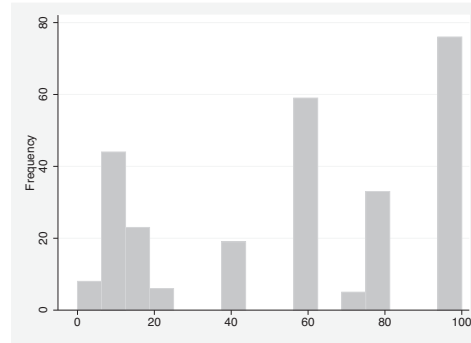
./.

²⁷ This assessment, however, is likely too preliminary and it would be useful to assess the quality of the winning products by comparing them using an objective metric, like life-expectancy metrics that the prosthesis manufacturers have to submit when launching their device in the EU.

(c.1) Other Criterias Weight



(c.2) Other Criterias Weight



This situation seems destined to change given the approval of Directive 2014/18/UE. In order to encourage a greater quality orientation of public procurement, the new Directive emphasizes SR auctions and, more generally, the use of “most economically advantageous tender” criterion, which becomes the main (and potentially the only)²⁸ award criterion. In order to avoid confusion with the award criterion that is currently known as the most economically advantageous tender in Directive 2004/18/EC, a different terminology is used to cover that concept, the “best price-quality ratio”²⁹. The new dispositions seem to give more importance to quality elements in order to reduce the role of price. In particular, according to the new Directive, the cost element may also take the form of a fixed price or cost on the basis of which economic operators will compete on quality criteria only³⁰.

Another significant innovation is the introduction of the concept of “cost” in alternative to the simple concept of “price”. The price is the amount which contracting authorities have to pay to the economic operator to obtain a specific supply³¹. It does not represent the only relevant economic element to award public contracts. In fact, in order to assess the “best price-quality ratio”, contracting au-

²⁸ According to the art. 67, paragraph 2, of the new Directive, Member States may provide that contracting authorities may not use price only or cost only as the sole award criterion or restrict their use to certain categories of contracting authorities or certain types of contracts.

²⁹ Consequently, it should be interpreted in accordance with the case-law relating to those Directives, except where there is a clearly materially different solution in this Directive. See consideration 89 of the new Directive.

³⁰ See art. 67, paragraph 2, of the new Directive.

³¹ Or service or work.

thorities have to evaluate the entire cost – different from price alone – that the community will sustain selecting a particular offer rather than another, according to a cost-effectiveness approach such as life-cycle costing³². In particular, in the case of surgical and medical devices, aspects of after-sale service (e.g. the extent of advisory and replacement services) or environmental aspects (e.g. the cost imputed to environmental externalities) are particularly relevant.

Moreover, the new directive extends the qualitative criteria linked to the subject-matter of the contract that contracting authorities can use to assess the “best price-quality ratio”. In addition to those already mentioned in Directive 2004/18/EC³³, factors involved in *i*) the specific process of production, provision or trading of works, supplies or services or *ii*) a specific process for another stage of their life cycle are considered to be linked to the subject-matter of the public contract³⁴, even where such factors do not form part of their material substance.

Finally, it is worth mentioning that the chosen award criteria do not confer an unrestricted freedom of choice on the contracting authority and they have to ensure the possibility of effective and fair competition and be accompanied by arrangements that allow the information provided by the tenderers to be effectively verified.

5.3 *Corruption Risk and Discretionality: Framework Agreements and Negotiations*

In addition to SR, the significant role of FA, also implies a potentially large scope for discretionality in this market. Compared to standard auctions, FA - also called indefinite-delivery/indefinite-quantity (IDIQ) contracts - allow the procurer more flexibility to decide the exact timing, quantity and mix of final prod-

³² See article 68 of the new Directive. Depending on the service or product concerned, such factors could, for instance, include conditions of delivery and payment, aspects of after-sale service (e.g. the extent of advisory and replacement services) or environmental or social aspects (e.g. whether books were stamped on recycled paper or paper from sustainable timber, the cost imputed to environmental externalities or whether the social integration of disadvantaged persons or members of vulnerable groups amongst the persons assigned to performing the contract has been furthered).

³³ In particular, *a*) quality, including technical merit, aesthetic and functional characteristics, accessibility, design for all users, social, environmental and innovative characteristics and trading and its conditions; *b*) organisation, qualification and experience of staff assigned to performing the contract, where the quality of the staff assigned can have a significant impact on the level of performance of the contract; or *c*) after-sales service and technical assistance, delivery conditions such as delivery date, delivery process and delivery period or period of completion. See art. 67, paragraph 2, of the new Directive.

³⁴ Where they relate to the works, supplies or services to be provided under that contract in any respect and at any stage of their life cycle. See art. 67, paragraph 3, of the new Directive.

ucts to purchase.³⁵ This type of procurement method is still little studied in the auction literature, but is generating growing interest (Albano and Sparro, 2008; Gur *et. al.*, 2014). Given the major importance of procuring high quality devices, discretion is useful if used correctly, for instance to advantage contractors with a reliable track record. Nevertheless, major concerns have recently emerged concerning abuses of this discretion by corrupted public officials. The World Health Organization (WHO) estimates that worldwide 10-25% of public procurement spending in medical devices and pharmaceuticals is lost to corrupt practices. In Europe, an extensive study commissioned by the EU Commission “Study on Corruption in the Healthcare Sector” (HOME/2011/ISEC/PR/047-A2) has indicated specifically the procurement of medical devices as one of the areas of the healthcare system most vulnerable to corruption phenomena and identified various corruption scandals involving medical device procurement.³⁶

The new Directive tries to find a better equilibrium between discretion and transparency, in order to limit corruption risks and, at the same time, to assure adequate flexibility in the selection of private contractors.

For instance, the new Directive introduces specific measures related to FAs. First of all, it clarifies some uncertain aspects, in particular that FAs do not have to be used by contracting authorities which are not identified in them³⁷. Likewise, a framework agreement does not have to be open to entry of new economic operators once it has been concluded³⁸. On the other hand, contracting authorities

³⁵ Directive 2004/18/EU states: FA is «an agreement between one or more contracting authorities and one or more economic operators, the purpose of which is to establish the terms governing contracts to be awarded during a given period, in particular with regard to price and, where appropriate, the quantity envisaged».

³⁶ See also the study by the EU Anti-Fraud Office: *Identifying and reducing corruption in public procurement in the EU*.

³⁷ See art. 33, paragraph 2, of the new Directive. For that purpose, the contracting authorities that are parties to a specific framework agreement from the outset should be clearly indicated, either by name or by other means, such as a reference to a given category of contracting authorities within a clearly delimited geographical area, so that the contracting authorities concerned can be easily and unequivocally identified: see consideration 60 of the new Directive.

³⁸ See art. 33, paragraph 2, of the new Directive. This implies for instance that where a central purchasing body uses an overall register of the contracting authorities or categories thereof, such as the local authorities in a given geographical area, that are entitled to have recourse to framework agreements it concludes, that central purchasing body should do so in a way that makes it possible to verify not only the identity of the contracting authority concerned but also the date from which it acquires the right to have recourse to the framework agreement concluded by the central purchasing body as that date determines which specific framework agreements that contracting authority should be allowed to use: see consideration 60 of the new Directive.

are given additional flexibility when procuring under FA, which is concluded with more than one economic operator and which sets out all the terms. In such cases, contracting authorities should be allowed to obtain specific supplies³⁹, that are covered by the FA, either by requiring them from one of the economic operators, determined in accordance with objective criteria and on the terms already set out, or by awarding a specific contract for the supplies⁴⁰ concerned following a mini-competition among the economic operators parties to the FA⁴¹. To ensure transparency and equal treatment, contracting authorities have to indicate in the procurement documents for the FA the objective criteria that will govern the choice between those two methods of performing the FA⁴².

In addition, the new Directive enhances the role of negotiations for the cases where contracting authorities are unable to define the means of satisfying their needs or of assessing what the market can offer in terms of technical, financial or legal solutions, or where an open or restricted procedure resulted only in irregular or unacceptable tenders⁴³, but differs depending on the type of negotiated procedure. More specifically, the only enhanced negotiated procedure⁴⁴ is the so-called competitive procedure with negotiation, introduced in the place of negotiated procedure with the publication of a contract notice⁴⁵, in which any economic operator may submit a request to participate in response to a call for competition⁴⁶. However, the new Directive explicitly provides that the competitive procedure with negotiation has to be accompanied by adequate safeguards ensuring observance of the principles of equal treatment and transparency⁴⁷.

³⁹ Or services or works.

⁴⁰ Or services or works.

⁴¹ See art. 33, paragraph 4, lett. *a)* and *b)*, of the new Directive.

⁴² Such criteria could for instance relate to the quantity, value or characteristics of the works, supplies or services concerned, including the need for a higher degree of service or an increased security level, or to developments in price levels compared to a predetermined price index.

⁴³ See considerations 42-44 of the new Directive.

⁴⁴ Together with the competitive dialogue.

⁴⁵ The two procedures are very similar, but in the new procedure seems more flexible in the negotiation of the tenders.

⁴⁶ See article 29 of the new Directive.

⁴⁷ In particular, contracting authorities indicate beforehand the minimum requirements which characterise the nature of the procurement and which cannot be changed in the negotiations. Award criteria and their weighting should remain stable throughout the entire procedure and should not be subject to negotiations, in order to guarantee equal treatment of all economic operators. The Directive clarifies that the minimum requirements to be set by the contracting

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On the contrary, in view of the detrimental effects on competition (in particular, risks of corruption), the new Directive limits the scope of negotiated procedures without prior publication of a contract notice. They have to be used only in very exceptional circumstances. This exception has to be limited to cases where publication is either not possible, for reasons of extreme urgency brought about by events unforeseeable for and not attributable to the contracting authority, or where it is clear from the outset that publication would not trigger more competition or better procurement outcomes, not least because there is objectively only one economic operator that can perform the contract⁴⁸.

More generally, the new Directive tries to promote the transparency of the EU public procurement processes through the use of electronic means of information and communication. They should become the standard means of communication and information exchange in procurement procedures⁴⁹. For that purpose, transmission of notices in electronic form, electronic availability of the procurement documents and – after a transition period of 30 months – fully electronic communication, meaning communication by electronic means at all stages of the procedure, including the transmission of requests for participation and, in particular, the transmission of the tenders (electronic submission) have to be made mandatory⁵⁰. Member States and contracting authorities remain free to go further if they so wish⁵¹.

5.4 Procurement of Healthcare Innovations

Research and innovation, including eco-innovation and social innovation, are among the main drivers of future growth and have been put at the centre of the Europe 2020 strategy for smart, sustainable and inclusive growth. Public author-

authority are those conditions and characteristics (particularly physical, functional and legal) that any tender should meet or possess in order to allow the contracting authority to award the contract in accordance with the chosen award criteria. In order to ensure transparency and traceability of the process, all stages have to be duly documented. Furthermore, all tenders throughout the procedure have to be submitted in writing. See consideration 45 and art. 29 of the new Directive.

⁴⁸ Exclusivity can also arise from other reasons, but only situations of objective exclusivity can justify the use of the negotiated procedure without publication, where the situation of exclusivity has not been created by the contracting authority itself with a view to the future procurement procedure. See consideration 50 and art. 32 of the new Directive.

⁴⁹ As they greatly enhance the possibilities of economic operators to participate in procurement procedures across the internal market. See consideration 52 of the new Directive.

⁵⁰ See artt. 48-55 of the new Directive.

⁵¹ See consideration 52 of the new Directive.

ities should make the best strategic use of public procurement to spur innovation.

The rapid lifecycles and continuous improvement which characterise the medical technology industry present a particular challenge in procurement. The desired outcome of the process is to achieve the optimal compromise between quality and price, but that is difficult to achieve without an accurate appraisal of the value of innovation. Recent studies show that one of the main barriers to innovation in medical devices is represented by procurement systems that do not focus on procuring innovation⁵². If procurement rules do not properly recognise and reward innovation, then there will be fewer incentives to innovate⁵³.

In this respect, the new Directive could introduce some changes. First of all, the introduction of a cost-effectiveness approach such as life-cycle costing in order to assess the “best price-quality ratio” (see paragraph 5.2) should lead contracting authorities to take into account elements beyond the sole acquisition cost, such as process innovations and the long-term clinical and economic benefits.

In addition, for the cases in which a need for the development of an innovative product⁵⁴ and the subsequent purchase of the resulting supplies⁵⁵ cannot be met by solutions already available on the market, the new Directive provides a specific procurement procedure (so-called innovation partnership) in respect of contracts falling within the scope of this Directive⁵⁶. This specific procedure allows contracting authorities to establish a long-term innovation partnership for the development and subsequent purchase of a new, innovative product⁵⁷ provided that such innovative product⁵⁸ can be delivered to agreed performance levels and costs,

⁵² See WHO (2013); EUCOMED (2014), which highlights that UK and Sweden have developed new approaches around this objective.

⁵³ Future investment in new technology will be endangered and patient access to the best solutions will be restricted.

⁵⁴ Or service or innovative works.

⁵⁵ Or services or works.

⁵⁶ It should be recalled that a series of procurement models have been outlined in the Commission Communication of 14 December 2007 entitled “Pre-commercial Procurement: Driving innovation to ensure sustainable high quality public services in Europe”, which deals with the procurement of those R&D services not falling within the scope of this Directive. Those models would continue to be available, but this Directive should also contribute to facilitating public procurement of innovation and help Member States in achieving the Innovation Union targets.

⁵⁷ Or service or works.

⁵⁸ Or service or works.

without the need for a separate procurement procedure for the purchase⁵⁹. Whether in respect of very large projects or smaller innovative projects, the innovation partnership should be structured in such a way that it can provide the necessary “market-pull”, incentivising the development of an innovative solution without foreclosing the market⁶⁰.

⁵⁹ The innovation partnership is based on the procedural rules that apply to the competitive procedure with negotiation and contracts are awarded on the sole basis of the best price-quality ratio, which is most suitable for comparing tenders for innovative solutions.

⁶⁰ Contracting authorities do not have to use innovation partnerships in such a way as to prevent, restrict or distort competition. In certain cases, setting up innovation partnerships with several partners could contribute to avoiding such effects.

BIBLIOGRAPHY

- ALBANO G.L. - SPAGNOLO G. - ZANZA M., «Regulating Joint Bidding in Public Procurement», *Journal of Competition Law and Economics*, vol. 5, issue 2, 2009, pp. 335-360.
- ALBANO G.L. - SPARRO M., «A Simple Model of Framework Agreements: Competition and Efficiency», *Journal of Public Procurement*, vol. 8, 2008, pp. 356-378.
- DECAROLIS F., «Awarding Price, Contract Performance and Bids Screening: Evidence from Procurement Auctions», *American Economic Journal: Applied Economics*, vol. 6, issue 1, 2014, pp. 108-132.
- DECAROLIS F. – GIORGIANTONIO C. - GIOVANNIELLO V., «The Awarding of Public Works in Italy: An Analysis of the Mechanisms for the Selection of Private Contractors», Bank of Italy, *Occasional Paper*, vol. 83, 2010.
- , -, -, «L'affidamento dei lavori pubblici in Italia: un'analisi dei meccanismi di selezione del contraente privato», in *Mercato concorrenza regole*, anno XIII, n. 2, 2011, pp. 235-272.
- DIMITRI N. - PIGA G. - SPAGNOLO G., *Handbook of Procurement*, Cambridge University Press, 2006.
- EUCOMED, «Key Principles of Smart Procurement for Medical Devices», *Reflection Paper*, vol. 20, October, 2014.
- GIORGIANTONIO C. - GIOVANNIELLO V., «Infrastructure and Project Financing in Italy: The (Possible) Role of The Regulation», Bank of Italy, *Occasional Paper*, vol. 56, 2009.
- GUR Y. - LU L. - WEINTRAUB G.Y., *Framework Agreements in Procurement: An Auction Model and Design Recommendations*, mimeo, 2013.
- SANCHEZ-GRAELLS A., *Public Procurement and the EU Competition Rules*, Bloomsbury Publishing, 2015.
- MERLOB B. - PLOTT C. - ZHANG Y., «The CMS Auction: Experimental Studies of a Median-Bid Procurement Auction with Nonbinding Bids», *Quarterly Journal of Economics*, vol. 127, issue 2, 2015, pp. 793-827.
- WORLD HEALTH ORGANITAZION (WHO), «Compendium of Innovative Health for Low Resource Settings», http://www.who.int/medical_devices/innovation/compendium/en/, 2013.