# Value-Oriented Public Procurement in Healthcare

*Zagreb, April 2023*

AmCham

American Chamber of Commerce in Croatia Američka gospodarska komora u Hrvatskoj

# Table of Contents

# Current State of Public Procurement in Healthcare in the Republic of Croatia

Public procurement accounts for approximately 14% of EU GDP[1], and average government healthcare spending in the EU in 2020 exceeded 8% of the GDP, i.e., more than 1 trillion euros.

Nearly a fifth of government healthcare spending in the EU (about €200 billion) pertains to spending on medicines, medical devices and equipment[2].

AmCham Croatia has prepared a document providing specific recommendations regarding the public procurement of medicines, medical devices and equipment. The aim of the document is to ensure that future Croatian healthcare procurement practices, including unified public procurement, allow the introduction of innovations and directing the procurement towards providing maximum value for money. That would improve clinical outcomes and the economic efficiency of the healthcare system to benefit the economy and society as a whole.

Unified procurement is deemed an efficient instrument to achieve more cost-effective public expenditures within the system of public procurement. It is coordinated procurement where two or more public contracting authorities transfer their authority to a central public procurement body which in turn conducts a single procedure for all the contracting authorities through common preparation of technical specifications for the procurement.

The Central State Office for Public Procurement[3] outlined the advantages of unified procurement as follows:

- Standardization of goods and services through the creation of unified technical specifications and alignment of subjects procurement
- Process optimization
- Reduction of public procurement costs (preparation and performance of one procedure instead of preparation of individual procedures, publication of one call for proposals...), and
- Reliance of smaller public contracting authorities on specialist knowledge and competencies of other contracting authorities.

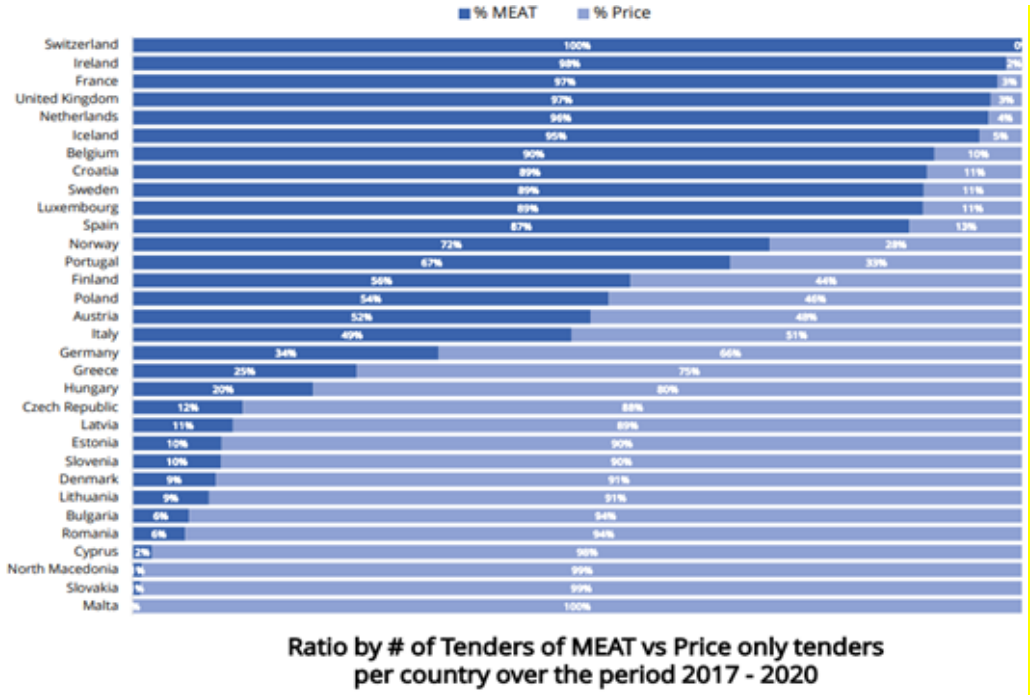
[1] European Commission, available at *https://single-market-scoreboard.ec.europa.eu/business-framework-conditions/public-procurement_en*, accessed on March 27, 2023
[2] *https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20220311-1*, accessed on February 17, 2023
[3] Central State Office for Public Procurement, available at https://sredisnjanabava.gov.hr/rezultati-objedinjene-nabave/52, accessed on October 27, 2022

The decision of the Ministry of Health of November 5, 2021[4] requires the performance of a third round of common public procurement in healthcare. It encompasses 45[5] procurement categories and is to be implemented by the Ministry, three Institutes, and ten clinical hospital centers/clinical hospitals/clinics.

This common procurement is planned to achieve financial savings of HRK 400 million by 2024 and introduce uniformity of items in use, equalize prices, and increase efficiency by harnessing the effect of economies of scale.

AmCham Croatia estimates that this common procurement encompasses more than 60% of the total market of medicines and medicinal products and nearly 90% of the total market of medicines and medicinal products related to hospitals.

A European study of the application of the MEAT criterion in public procurement procedures for several categories of medicines in Croatia indicates a high level of MEAT tenders which would place the Croatian public procurement sector significantly above many West European countries like Germany, Denmark, Italy, and Norway.[6]




*Source: "Key insights of the Tender Market for the Pharmaceutical Industry in Europe", Cube RM, Sep, 30 2021, p. 23;

[4] Ministry of Health, available at https://zdravlje.gov.hr/UserDocsImages//2022%20Objave//1.%20Odluka%20o%20zajedni%C4%8Dkoj%20provedbi%20odre%C4%91enih%20postupaka%20nabave.pdf, accessed on October 27, 2022

[5] Ministry of Health, available at https://zdravlje.gov.hr/UserDocsImages//2022%20Javna%20nabava//2.%20Izmjena%20i%20dopuna%20Odluke%20o%20zajedni%C4%8Dkoj%20provedbi.pdf, accessed on October 27, 2022

[6] Source: "Key insights of the Tender Market for the Pharmaceutical Industry in Europe", Cube RM, Sep, 30 2021, p. 36;

| | OffPatent | Oncology | Biosimilars | Diabetes |
|---|---|---|---|---|
| Austria | 0% | 100% | | |
| Belgium | 90% | 80% | 88% | 69% |
| Bulgaria | 0% | 4% | 3% | 0% |
| Croatia | 100% | 94% | 87% | 100% |
| Cyprus | 0% | 0% | 0% | |
| Czech Republic | 24% | 15% | 11% | 29% |
| Denmark | 3% | 2% | 2% | 29% |
| Estonia | 0% | 7% | 0% | 0% |
| Finland | | | | |
| France | 100% | 99% | 100% | 97% |
| Germany | 31% | 23% | 23% | 31% |
| Greece | 25% | 37% | | |
| Hungary | 12% | 4% | 6% | 13% |
| Ireland | | 88% | 100% | |
| Italy | 8% | 36% | 3% | 30% |
| Latvia | 16% | 0% | | 20% |
| Lithuania | 0% | 10% | 7% | 0% |
| Luxembourg | 100% | 67% | 100% | |
| Malta | 0% | 0% | 0% | 0% |
| Netherlands | | 100% | | |
| North Macedonia | 3% | 3% | 3% | 3% |
| Norway | | 33% | 0% | 100% |
| Poland | 39% | 34% | 31% | 44% |
| Portugal | 44% | 71% | 50% | 100% |
| Romania | 1% | 5% | 3% | 2% |
| Slovakia | 0% | 0% | 0% | 0% |
| Slovenia | 0% | 0% | 0% | |
| Spain | 87% | 93% | 95% | 100% |
| Sweden | 100% | 94% | 86% | 100% |
| United Kingdom | 100% | 100% | 100% | 100% |

On the other hand, according to European Commission assessments published within the "single-market-scoreboard," the state of public procurement in the Republic of Croatia is assessed as average.[7]

The experience of AmCham members confirms that, in practice, MEAT is only nominally applicable as a tender selection criterion. In most public procurement procedures, Croatian contracting authorities continue to use the price as the prevailing criterion in the ratio of the price and the non-price criterion (mostly 90% price to 10% non-price criteria). The members additionally point out that the most frequently used non-price criterion in procurement procedures is the period of delivery[8], while criteria directly related to the quality of clinical performance, treatment outcomes, and medical service cost efficiency are exceptionally rarely used.

It is, therefore, necessary to use great caution in interpreting international statistics and rankings. Considering the possibility that the same argument is also applicable in other countries in this and similar published analyses (complicating comparisons between countries), it remains to conclude that procurement in Croatian healthcare is predominantly oriented on evaluating the price criterion.

An additional challenge in the procurement of medicines and vaccines in the Republic of Croatia is the fact that such procedures almost always end in the selection of a single tenderer. Patients, therefore, have limited access to medicines and vaccines and/or continued treatment using the same product if there is a shortage of the

[7] European Commission, available at https://single-market-scoreboard.ec.europa.eu/countries/croatia_en, accessed on October 27, 2022

[8] At the same time, the period of delivery is not a justified criterion in individual procedures (for example, it makes no sense to attach any value to it if the opening of consignment storage is required and/or it is questionable if it is sensible to evaluate it in circumstances of daily deliveries by wholesale medicine suppliers and most wholesale medical device suppliers).

product selected through the public procurement procedure (e.g., due to delays, product quality issues, product recalls, or shortage of raw materials). Such public procurement procedures restrict the capacity of healthcare institutions to avoid or ameliorate increasingly frequent shortages of medicines and vaccines and increase procurement costs.

Public procurement procedures where only a single supplier is selected for a group of subjects of procurement have an adverse impact on market competition. Namely, it is not uncommon for companies not selected as the supplier to reduce the scope and intensity of market dedication/commitment. It is a logical consequence of the fact that they cannot cover their expenses (e.g., costs of maintenance of marketing authorizations and maintenance of company production lines for the product) with market revenue. Reduced intensity of business is regularly accompanied by reductions in the number of jobs and consequent adverse fiscal and social effects.

Current reforms in healthcare herald the placement of greater emphasis on value-based healthcare. Such healthcare entails improvements to treatment outcomes with equal or reduced costs of the provision of healthcare services. Despite that, procurement procedures are still often structured in a manner insufficiently appreciative of technological solutions having a positive impact on treatment outcomes (e.g., lower incidence of complications, shorter hospital stays, a lower rate of review, improved quality of life).

Such technological solutions bring documented additional value to physicians, patients, and others involved in treatment. Such additional value is the result of investments in research and development as well as investments in the production of high-quality, solid, and indisputable evidence on the impact of advanced solutions on the quality of clinical outcomes. That additional value should be appropriately evaluated using the MEAT criterion in public procurement procedures by increasing the proportion of high-quality non-price criteria in relation to the price criterion.

AmCham member companies have noted that public procurement planning is often neglected and inefficient. This primarily pertains to determining the estimated procurement value but also determining the required quantities. For example, estimated procurement value in a new procurement procedure is almost regularly based on prices achieved in the preceding procedure making the introduction of new, innovative technological solutions difficult. In the present-day situation of disrupted supply chains and inflationary pressures generating increased production costs, such practice is not currently appropriate and may lead to failures in the performance of procedures due to the inability of tenderers to prepare their tenders within the required parameters. If contracting authorities insist on estimating the procurement value according to the prices achieved in the previous procurement procedures, it is necessary to take into account inflationary trends and determine the estimated procurement value reflecting the current price growth rate.

# Recommendations

AmCham Croatia proposes a more frequent and more comprehensive application of the following principles in public procurement in healthcare:

## *Higher quality planning of public procurement procedures*

High quality and timely strategic planning of public procurement procedures ensure implementation of the principle of "best value for money".

We deem the following key steps particularly important in the preparation of tender documentation:

- **Diligent and exhaustive market analysis** – with a particular emphasis on the number and type of supplier, technological solutions, and the average market price (valuated in light of the current availability of the subject of procurement and inflationary trends).

  If market research is poorly performed, it may lead to deficiencies in technical specifications, ambiguously defined tender documentation requirements, poorly estimated procurement value, and ambiguously defined contract performance conditions. All of the above leads to frequent amendments to the documentation and an increased number of complaints, ultimately affecting the total time required to complete the procurement procedure and conclude a contract.

- **Adequate planning of needs** – it is necessary to ensure that needs follow the planned levels of activity of the contracting authority. In the need planning stage, it is vital to realistically present the needs (e.g., not specify the quantity of 100 in the tender documentation when 15 items were procured under the preceding contract and the contracting authority has not expanded its capacity to perform its basic activities). That allows the tenderers to properly form their tenders with prices optimized for the needs of the contracting authority. In the contract performance stage, it is particularly important to comply with the provisions of the Public Procurement Act on permitted amendments to the contract (for example, the provision on the maximum permitted increase of the contract value) and the realistic presentation of needs.

- **Realistic determination of the estimated procurement value** which allows tenders to be received from the largest possible number of suppliers taking into account:
  - The degree of additional value of the subject of procurement
  - The change in procurement prices/supplier prices
  - The stability of supply chains
  - The availability of raw materials and/or production capacity
  - The inflation rate
  - The bank interest rate
  - The payment period exceeding legal time limits

- **Preparation of clear, unambiguous, and precise tender documentation**

  - Use of the term "equivalent"

It is necessary to systematically explain in greater detail the meaning of the term "equivalent" – is it comparability/similarity of physical characteristics of the subject of procurement (length, width, weight, color) or comparability/similarity in achieving a specific clinical effect or comparability/similarity in achieving a specific clinical outcome.

  - Variability of prices in circumstances of unusual inflationary trends

In contracts/framework agreements concluded for a period longer than 12 months, it is necessary to foresee in the tender documentation the adjustment of the contract price in compliance with the change in the Consumer Price Index (CPI). We propose that it is provided that, in cases where the CPI exceeds the rate of 3% in the previous 12-month period (according to the Croatian Bureau of Statistics report), the supplier/provider is authorized to correct the prices by up to 80% of the determined inflation rate.

Example:

Start of a contract/framework agreement: 01/01/2021

End of the contract/framework agreement: 01/01/2024

Contract price of a product at the time of conclusion of the contract = €10

| **Period (year n)** | **Inflation (year n-1)** | **Amount of increase (80% of the indexed price)** | **Price (year n)** |
|---|---|---|---|
| 1–12/2022 | 2.5% | 0 (below the 3% threshold) | €10 |
| 1–12/2023 | 10.9% | 8.72% | €10.87 |

The above approach is applied in framework agreements concluded by the Ljubljana University Medical Centre with suppliers of goods and services.

## *Higher-quality of use of the most economically advantageous tender criterion*

### A. Relation of price and non-price criteria

Contracting authorities have the option of using a wide spectrum of non-price criteria adaptable to their needs (quality, technical value, aesthetic and functional properties, organization, qualifications and experience of staff performing a particular contract,

aftersales services and technical assistance, delivery conditions, etc.). Additional work is required to ensure the implementation of such criteria that generate actual value for money instead of insisting on the application of inappropriate criteria (such as the period of delivery) which do not generate additional value in healthcare.

Specifically, it is necessary to ensure an optimal ratio of the price and non-price criteria rewarding valuable innovations and taking into consideration the specific characteristics of the subject of procurement and the degree of risk posed by a specific product to a patient. Products carrying greater risks for patients (especially medical devices implanted in the human body or used invasively) require a greater proportion of the non-price, qualitative criterion in relation to the price criterion.

We think that public contracting authorities should orient the selection criteria used in public procurement procedures in healthcare towards obtaining maximum value (measured by the quality of clinical outcomes) for the funds spent. In that respect, it is particularly important to measure the expended funds over the entire service life of a product[9], not considering just the cost of the initial procurement. That allows long-term fiscal sustainability of the healthcare system and prevents short-term planning which would lead to a significant financial burden over a longer period). The funds spent in the public procurement procedure must be justified by the achieved value of clinical outcomes.

We suggest orienting the selection of the non-price criteria towards:

- Determining and demonstrating the relationship between the technical characteristics/technological solutions and the desired clinical effect
- Determining and demonstrating the relationship between the clinical effect and the desired clinical outcome
- Evaluating the available evidence (Evidence-Based Medicine system, EBM) on the degree of the effect on the quality of clinical evidence
- Determining the effect of the quality of clinical outcomes on the overall cost-effectiveness in healthcare (both at the level of the healthcare service provider and at the level of the payer of the healthcare service provided within the framework of public healthcare)
- Recognition of the specificities of procurement of various types of medical devices considering class/degree of risks to patients
- Recognition of the specificities of procurement of various types of medical devices considering the medical device type (in vivo capital equipment, in vitro diagnostics, consumables, implantation materials, connecting materials, closing, cutting and coagulation materials, plaster cast, gloves, drains)
- Recognition of the compatibility of use with the existing/installed infrastructure/technological platform/software support (some consumable but invasive medical devices are only compatible with apparatus made by one manufacturer)

[9] The total cost of the product includes the cost of procurement, costs of use, costs of maintenance, and costs of disposal at the end of its function.

- Recognition of the specificities of procurement of various types and characteristics of medicines and vaccines (e.g., number and type of vaccine serotypes)

Examples of good practices are set out in Annex 1.

### *Centralized determination of relative weights for individual types of subjects of procurement*

Healthcare institutions and public healthcare institutions conduct a large number of various subjects of procurement ranging from procurement of non-medical products (food, paper, toilet paper...), through construction works, various services (translations) to procurement of medicines, vaccines, and medical devices. Every subject of procurement has its specificities; therefore, the selection criteria should be specific for each subject of procurement and related to it.

We deem that the head of the central authority of the state administration should use the option afforded by Article 284(8) of the 2016 Public Procurement Act and determine the relative weights for individual types of subjects of procurement for public contracting authorities within their field of competence. In the process, it would be necessary to take into consideration various criteria, e.g., risks for patients, complexity of application, degree of impact on clinical outcomes, technical value, aesthetic and functional properties, level of aftersales service and technical assistance, maintenance support – response, duration of maintenance/repairs, provision of substitute devices while the apparatus is undergoing maintenance/repair, etc.).

The proposal for determining the relative weightings for certain types of healthcare procurement items is listed in Annex 3.

### *Introduction of public procurement with multiple selected tenderers*

Selection of a single selected tenderer for an extended period of time increases the risk that one or multiple tenderers/suppliers which were not selected decide to cease the investments required to maintain production and supply in the country and subsequently leave the Croatian market for an extended time. Considering the significant exposure of the healthcare system to risks in cases of reliance on a single tenderer (e.g., insolvency, bankruptcy, or shortages in production of that tenderer), it is proposed to introduce public procurement with multiple selected tenderers.

Articles 148(1) and 153(6) of the 2016 Public Procurement Act allow the conclusion of framework agreements with several economic operators, and individual contracts may be awarded in the course of performance of the framework agreement on the basis of mini-competitions among the parties to the framework agreement when the actual need for procurement of the subject of procurement arises. This form of procurement is also encouraged by the Ministry of Economy and Sustainable

Development in its guidelines for the encouragement of participation of SMEs in public procurement.[10]

In such procurement procedures, a greater part of the procured quantity (e.g., 60%) should be awarded to the tenderer which submitted the best tender, while a smaller portion of the procured quantity should be awarded to the tenderer submitting the second and third-best tenders.

Such a method of awarding contracts would not only ensure certain sales for the second and third tenderers covering their fixed costs and maintaining the presence of a medicine, vaccine, or medical device on the market but also provide a very effective means of mitigation of the risks associated with potential shortages suffered by the first-ranked tenderer.

One example of this type of good practice is public procurement involving multiple selected tenderers conducted by NHS England, where the tenderers are guaranteed different quantities depending on their tenders, i.e., the tenderer who submitted the most advantageous tender receives the greatest share to ensure competitiveness and sustainability of the medicines market with multiple suppliers remaining active in the market.[11]

Another example of this type of good practice is the previously mentioned suture thread public procurement procedure in Italy conducted by CONSIP.

The proposal for awarding a framework agreement by distributing the volume of the contract is listed in Annex 4.

### *Consistent performance of contracts/framework agreements*

Tender documentation normally provides only a framework specification of the quantity of the subject of procurement, while the actual procured quantity may be lower or higher than foreseen, but the minimum quantity the contracting authority undertakes to order and pay for is not specified.

We propose that the following be specified in the tender documentation:

- Obligation to order at least 70% of the contractual quantity. An example of good practice is the unified public procurement of orthopedic implants in Lithuania[12], where the contracting authority undertakes to request delivery of 70% of the contractual quantity (the equivalent of 2600 complete joint constructs), and the

[10]Ministry of Economy and Sustainable Development available at *http://www.javnanabava.hr/userdocsimages/Smjernice%20MSP.pdf*, accessed on February 17, 2023

[11]EFPIA, available at https://www.vbb.com/media/Insights_Articles/efpia_white_paper_public_procurement.pdf, accessed on February 17, 2023

[12] *https://katalogas.cpo.lt/pirkimai/cartid,230020/* (documentation including a sample contract in English available on request), accessed on February 17, 2023

supplier is authorized to deliver and invoice at least 70% of the contractual quantity by the end of the term of the contract.

- Restrict the value of stock kept in consignment storage to no more than 1/10 of the annual contractual quantity (if the tenderer is requested to provide consignment storage at the premises of the contracting authority).

- Obligation to sign a consignment contract clearly defining the mutual obligations of the consignee (institution) and the consignor (supplier).

- If the contract prescribes the provision of equipment for use, it is necessary to accurately define the obligations of the seller and the buyer and specify the quantity of the subject of procurement the buyer undertakes to order within a specific term of the contract/framework agreement.

- Consistent performance of the contract/framework agreement entails full compliance with the contractual time limits for payments.

## *Annex 1 –Proposals with examples of good practice in Croatia and the European Union*

### 1. Proposals for determining the MEAT criterion depending on the degree of risk posed by the subject of procurement to patients

We are outlining proposed approaches depending on the degree of risk posed by the subject of procurement to patients:

- **Procurement of standard wound dressing**

The specific case concerns a product carrying a low risk to patients[13].)

Price criterion – 80% / Non-price criteria – 20%

Proposed non-price criteria:

- Degree of complexity of application by medical staff
- Degree of patient satisfaction
- Degree of environmental impact

- **Procurement of artificial joint**

The specific case concerns a product carrying a high risk to patients[14].

Price criterion – 50% / Non-price criteria – 50%

Proposed non-price criteria:

- % of functionality 10 years after implantation as documented by data drawn from the register of implants
- Rate of review 5 years after implantation as documented by data drawn from the register of implants
- Reliability and accuracy of application of instruments for implantation – refer to the section on testing by healthcare professionals found in the annex
- Degree of invasiveness at the time of implantation
- Quality of clinical outcomes – painfulness of movements
- Quality of clinical outcomes – range of movements
- Availability of aftersales support by the supplier

[13] The product is used non-invasively, in contact with the patient over a relatively short period (hours/days). Non-performance/failure of function does not affect the quality of treatment outcomes significantly, and it does not entail significant additional efforts by medical staff and, therefore, no significant additional costs for the healthcare system/payer of the medical service.

[14] The product is used invasively/it is implanted in the body, it remains in contact with the patient over an extended period (more than 10 years). Non-performance/failure of function significantly affects the quality of treatment outcomes, and it entails significant additional efforts by medical staff and, therefore, also significant additional costs for the healthcare system/payer of the medical service.

**Examples of good practice in Croatia:**

- Procurement of artificial joints

| Public contracting authority | Subject of procurement | EOJN number | % share of price criterion | % share of non-price criterion | % share of clinical efficiency |
|---|---|---|---|---|---|
| Osijek Clinical Hospital Center[15] | Orthopedic implantation materials and consumables | 2021/S 0F2-0001333 | 65% | 35% | 30% |
| "Dr. Ivo Pedišić" General Hospital, Sisak[16] | Orthopedic and traumatology consumables | 2020/S 0F2-0013326 | 60% | 40% | 30% |

## 2. Proposals for the performance of assessment of samples by end users

### 2.1. Sample quality assessment tests

| Test type | Characteristics of the tested product |
|---|---|
| Tests for the assessment of the quality of thread: | 1. Appearance of sutures, uniformity and area size, handling and conductivity<br>2. Out of package memory<br>3. Ease of knotting, placing of knots, strength of knots<br>4. Ease of passage through tissue |
| Needle quality assessment tests: | 1. Appropriate needle and thread caliber, strength of needle-to-thread connection<br>2. Stability on needle holders<br>3. Constant penetration force passing through tissue even after multiple passages<br>4. Resistance to deformations and failure |
| Packaging quality assessment tests: | 1. Ease of opening of packaging (wrapping) and pulling out of the thread<br>Ligatures: simplicity, ease, and speed of extraction of the thread<br>Threads with needles:<br>- Needle accessibility<br>- Protection of the point of the needle |

[15] TED, available at https://ted.europa.eu/udl?uri=TED:NOTICE:21718-2021:TEXT:EN:HTML&src=0, accessed on February 17, 2023
[16] TED, available at https://ted.europa.eu/udl?uri=TED:NOTICE:161199-2020:TEXT:EN:HTML&src=0, accessed on February 17, 2023

| | |
|---|---|
| | - Safety and speed (minimum number of movements) for correct positioning of the needle on a holder<br>Simplicity and speed of extraction of the thread |
| **Other items needed for sample testing** | |
| Tools to be used: | • Magnifying glass<br>• Scanner (electronic magnifier)<br>• Tissue simulator<br>• Basic suture simulation pad<br>• Semi-hard support (or support simulating soft tissue / fibrosis)<br>• Rigid support (simulating hard tissue such as skin) |
| Detailed testing protocol | • Thread quality<br>• Needle quality<br>• Packaging quality |
| Clinical evidence for assessment of anti-bacterial threads: | • Quantitatively (number of papers)<br>• Qualitatively (level of evidence) |

**Examples of good practice from the EU**

- An example of good practice is the unified procurement of suture thread in Italy performed by the central authority for public procurement CONSIP in compliance with the described criteria.[17]

  That procedure also included an end user (healthcare professional) in the evaluation of the offered subject of procurement, the testing of samples of the offered subject of procurement by the end user (healthcare professional) in accordance with a clear and detailed testing procedure specifying in detail who is performing the tests, which characteristics are being tested, which tools/devices are used in the tests, the method of recording of the test results, the method of scoring of the test results).

[17] TED, available at https://ted.europa.eu/udl?uri=TED:NOTICE:296676-2017:TEXT:HR:HTML&src=0, accessed on February 17, 2023

## 2.2. Proposed method of evaluation of suture thread properties and a description of their relationship with clinical effects/advantages for the end user (healthcare professional)

| | Properties | Relevant component of the suture thread | Desirable characteristic | Foreseen advantages for the end user |
|---|---|---|---|---|
| 1 | package memory retention | thread | the lower the better | faster, more comfortable placing of sutures |
| 2 | incising | thread | the lower the better | fewer hand injuries, fewer glove replacements, faster placing of sutures |
| 3 | flexibility | thread | the higher the better | faster, more comfortable placing of sutures |
| 4 | pulling through | thread | the easier the better | faster, more comfortable placing of sutures |
| 5 | tensioning/ placing of a knot | thread | the easier the better | faster, more comfortable placing of sutures |
| 6 | ease of passing | needle | the higher the better | faster, more comfortable, and more precise placing of sutures |
| 7 | resistance to bending | needle | the higher the better | faster, more comfortable, and more precise placing of sutures |
| 8 | anti-bacterial properties | thread* | the higher the level of evidence the better | reduction of infections on the place of surgery |

Anti-bacterial property of the suture thread is not the subject of the sample testing, however, scientific evidence pertaining to that thread is assessed according to the CEBM scale[18], Oxford:

| Description | Awarded points | Test performance method |
|---|---|---|
| **Anti-bacterial action** | | The level of quality of scientific evidence related to anti-bacterial action is assessed by referring to the CEBM scale of assessment of scientific evidence |
| level 3a, 3b, 4 and 5 scientific evidence | 1 | |
| level 2a, 2b, and 2c scientific evidence | 3 | |
| level 1a, 1b, and 1c scientific evidence | 10 | |

[18] Centre for Evidence-Based Medicine, available at https://www.cebm.net/2009/06/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/, accessed on March 27, 2023

The above scale distinguishes 10 levels of quality of evidence:

| | |
|---|---|
| 1a: | Systematic reviews (with homogeneity) of randomized controlled trials |
| 1b: | Individual randomized controlled trials (with narrow confidence interval) |
| 1c: | All or none randomized controlled trials |
| 2a: | Systematic reviews (with homogeneity) of cohort studies |
| 2b: | Individual cohort study or low quality randomized controlled trials (e.g., <80% follow-up) |
| 2c: | "Outcomes" Research; ecological studies |
| 3a: | Systematic review (with homogeneity) of case-control studies |
| 3b: | Individual case-control study |
| 4: | Case-series (and poor quality cohort and case-control studies) |
| 5: | Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles" |

### 2.3. Proposal of assignment of points in the process of sample testing and/or assessment of enclosed scientific evidence

Assigned points represent the average calculated as the sum of points assigned to the sample by each person performing the test divided by the number of such persons.

| Example: | | | | | |
|---|---|---|---|---|---|
| LOT sample #1, product #2, tenderer#3 | | | | | |
| **Tenderer** | **Tenderer code** | **Tester 1 points** | **Tester 2 points** | **Tester 3 points** | **Average points** |
| Fortune Ltd. | ABC123 | 3 | 3 | 5 | 3.67 |

Proposal for scoring of testing of e.g., resistance of the suture thread needle to bending

| **Description** | **Awarded points** | **Test performance method** |
|---|---|---|
| **Resistance to bending** | | The suture thread is extracted from the original packaging using a surgical instrument and then it is positioned and inserted (in the manner corresponding to actual cases) through the model of animal tissue suitable for the type of needle/suture thread. |
| The needle bends when foreseen regular/usual load is applied | 1 | |
| The needle bends when loads greater than the foreseen load are applied | 5 | |
| The needle does not bend when loads greater than the foreseen load are applied | 10 | |

## 2.4. Examples of good practice of evaluating clinical evidence of clinical efficiency of a medical device/impact on the quality of clinical outcomes:

### 2.4.1. Procurement of orthopedic implants by the NHS in Scotland, United Kingdom

Price criterion: 50%
Non-price criterion: 50%

List of criteria and shares in the total number of points:

**Tender selection criterion**

| Description of criteria | Scoring |
|---|---|
| Quality — clinical references | 10 |
| Servicing, aftersales support | 15 |
| Training/education of end users | 10 |
| Management of consignment stock | 10 |
| Costs and management of the set of instruments | 5 |
| Price | 50 |

### 2.4.2. Procurement of vaccines in accordance with the vaccination program in effect in Croatia (CIPH)

Non-price criteria should be defined by experts on the basis of epidemiological data in Croatia related to the characteristics of vaccines.

- Number of serotypes
- Types of serotypes
- Ease of application
- Ease of storage (cold chain)

3. **Proposed determination of relative weights for individual types of subjects of procurement in healthcare:**

| Type of subject of procurement | Relative weight of the tender selection criterion | |
|---|---|---|
| **Non-medical** | **Price** | **Non-price** |
| Food | *80%* | *20%* |
| Sources of energy | *90%* | *10%* |
| Furniture | *90%* | *10%* |
| IT equipment | *80%* | *20%* |
| **Medical** | | |
| Medicine, generic | *80%* | *20%* |
| Medicine, innovative | *65%* | *35%* |
| Medical device, class 1 | *80%* | *20%* |
| Medical device, class 2 | *70%* | *30%* |
| Medical device, class 3 (implant) | *50%* | *50%* |
| Medical apparatus/equipment | *70%* | *30%* |
| In vitro medical device | *80%* | *20%* |

4. **Proposed award of framework agreement with multiple selected tenderers by distributing the scope of the contract:**

| |
|---|
| **Price criterion** 65% |
| **Non-price criterion** 35% |

| | Points for the offered price | Ranking according to the price criterion | Points for the non-price criterion | Ranking according to the non-price criterion | Total number of points | Overall ranking | Awarded volume of the contract |
|---|---|---|---|---|---|---|---|
| **Supplier 1** | 50 | 2 | 35 | 1 | 85 | 1 | 60% |
| **Supplier 2** | 40 | 3 | 32 | 2 | 72 | 3 | 15% |
| **Supplier 3** | 65 | 1 | 10 | 5 | 75 | 2 | 25% |
| **Supplier 4** | 35 | 4 | 30 | 4 | 65 | 4 | 0% |
| **Supplier 5** | 20 | 5 | 33 | 3 | 53 | 5 | 0% |

For additional information, please contact:
American Chamber of Commerce in Croatia
Andrea Doko Jelušić,
Executive Director T: 01 4836 777
E: andrea.doko@amcham.hr