euriphi

European wide Innovation Procurement in Health and Care

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825922-EURIPHI

European cross-border innovation procurement in health and social care

Legal guidance

In collaboration with Euriphi partner

CMS Law.Tax

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Introduction

From our procurement lawyers' experience, procurement entities active into healthcare consider it to be a challenge to apply public procurement procedures to healthcare purchases (medical devices, drugs, support services and innovative solutions and technology). These purchases are indeed often highly sensitive, with even lifesaving aspects, they are crucial for the physician's and hospital employees' activities and are in general very innovative and evolving goods.

Health and social care actors emphasize the necessity to put the focus on "value" for these products and to make long term assessments of their integration into the care suppliers' organization. "Value based procurement processes", including innovation, partnership aspects and collaboration between the industry and the healthcare sector as well as global and integrated solutions are preconized in the health and social care sector. These elements are taken into account in the present document to provide some guidelines and suggestions on how to apply "value based" and innovative procurement processes onto European innovative health and social care purchases.

When it comes to global solutions, European health and social care institutions can envisage collaborative approaches for their procurement processes. This document includes legal guidance on cross-border procurement and proposes three collaborative procurement Models that can be used in the framework of cross-border value based innovation procurement.

1 Guidelines on the organization of a "Value based" PPI or PCP procedure for health and social care purchases

To structure a healthcare public procurement process, thorough preparation on the part of a care supplier's procurement team, physicians and hospital staff and, as the case may be, legal team, will be crucial. During this preparation phase, the project team will have to answer to different questions related to the different stages of the award and implementation of the contract (see below, section 1.1).

To elaborate more on these aspects, a preliminary market consultation phase can be conducted with the potential tenderers. This will allow the procurement team of the health and social care institution to realize what the industry can offer in terms of innovative solutions (see section 1.2).

The preparatory work should include identifying the most relevant and appropriate award procedure for the specific healthcare purchase to be made. The present document provides some guidance on the available award procedures and the respective advantages and constraints of these procedures in the framework of health and social care innovative purchases (see section 1.3).

Further guidance is provided in section 1.4 of this document on the choice of the selection and award criteria.

1.1 Preparation of a value-based procurement process

When envisaging a purchase based on the long term value of an innovative solution (whether it is a technology, a device, services or a global solution), the contracting authority should take into consideration different crucial elements, relevant at different stages of the award procedure or contract implementation. The present document aims to provide some guidance related to these various topics.

Some of these preparatory questions are summarized below. These questions can be used during the preparatory phases of any innovative procurement project to structure the work and the discussions.

Structuring the healthcare procurement project – key questions

Key questions

i. What do we want to "buy"?

ii. How do we want to buy and how do we want to structure the procurement procedure?

iii. What are the goals/objectives we can achieve with the purchase?

iv. How do we want to award?

v. How do we want to work with the suppliers?

i. What do we want to buy?

- Does it exist on the market?

- Do we want to buy a product (machine?)?
    - Just the product or also consumables, maintenance, educational services?
- Do we want to buy a concept/solution?
    - services only for example: set up of a process or
    - combination supplies/services)?
- Do we need an R&D phase that would lead to a tool/device or tool?

→ *Need for the legal team to understand the technical background of what we are going to buy*

→ *This will determine the procedure to be chosen, the criteria that can be chosen, the structure of the procurement process*

ii. How do we want to buy and how do we want to structure the procurement procedure?

- Centrally or per institution/country?
- Will we contract with several economic operators or just one?
- Which procedure will we use?
    - Open or restricted procedure ?
    - Competitive procedure with negociation ?
    - Competitive dialogue?
    - Innovative partnership?
    - Negotiated procedure without call for competition ?

→ *For complex contracts: Procurers/legal advisers deliverable: need to frame/map the procedures (and the PCP concept) and describe the pro & cons of each procedure + highlight the suggested procedure*

→ *This exercise has been done in section 1.3 of the present document in the framework of health and social care purchases.*

- Is it appropriate to divide the contract in lots and/or to award a framework agreement (with or without mini competitions)?
- It is appropriate to collaborate with other procurement organizations, possibly of other countries.

iii. What are the goals/objectives we can achieve with the purchase ?

- What is the expected outcome for the hospital, care givers or patients?
    - Focus on performances/results and openness for any solution?
    - Focus on direct price/direct or indirect cost?
    - Focus on prevention and reduction of costs on a broader perspective and more long-term scale (ex. Avoidance of complications, exacerbation, length of stay; time spent by care providers)?
    - Focus on direct quality of the care delivery inherent to the technology/the services (ex. user friendliness of the device, less risks of infection etc.)?

iv. How do we want to award?

- Which ***selection*** criteria will we use?
    - Which technical capacity criteria and minimal requirements?
    - Which economic capacity criteria and minimal requirements?
    - Do we go for a restriction phase in the framework of the qualitative selection?
- Which ***award*** criteria will we use?
    - Best price-cost/quality ratio --> using Value Based procurement framework
    - Cost is broader than price and could integrate costs of the institutions, care provision, social-economic costs
    - → need to choose the appropriate criteria
- Which award method will we opt for?
    - Classic method of awarding points and weight per criterion?
    - Willingness to pay method?
- Are we capable to assess verify what we are asking for?

v. How do we want to work with suppliers?

- During the contract implementation phase, there are a number of issues to consider in relation to the nature of the relationship[/partnership with the relevant suppliers[1]:
    - Establishing a "Value-Based Agreement": Value-based contracting is a contractual model to align the economic interests of the procurer and supplier to the impact a medical technology or solution delivers in practice, based on criteria selected within the Value-based Procurement framework. Value-based contracting enables risk sharing when the expected outcomes or benefits, or the cost impact, are less clear or lack detailed evidence at the time of contract negotiations. Value-Based Contracting is broader than outcomes-based contracting as it focuses on value, which includes (i) outcomes, (ii) other benefits for stakeholders and (iii) total cost of care impact[2].
    - When drafting the contractual requirements, it is important for the contracting authority to project itself in the real implementation of the contract and draft clauses that "work" (about delivery modalities, sanctions, monitoring of results, etc.);
        - → *often, contracting authorities draft abstract clauses or are copying clauses from other contracts which leads to contractual provisions that do not fit with the reality of the future implementation of the contract*
    - Anticipate potential problems (out of stock, delays etc.); organise "plan B" for them (if appropriate);
    - If appropriate, set realistic (outcome-based) KPIs and SLA's (use KPI's and SLA's that you can actually verify/assess);
    - Anticipate the termination of the contract (possible termination if a new product/generics enters on the market? Compensation? etc.);
    - Request stakeholders, nurses, clinicians to provide feedback on what went well/ what went wrong and take this into account for the next procurement.
    - How do we plan, prepare and conduct the contract Monitoring phase?

vi. Summary: success factors for a value-based procurement

- In summary, the following elements are important when it comes to procuring "value" in the healthcare sector:
    - Thinking broader;
    - Thinking future;
    - Preparing the procurement process with the relevant stakeholders (clinicians, nurses, management, economic operators);
    - When writing tender documents, clearly contemplating the operation of the contract in order to draft contractual provisions that will "work";
    - Asking for answers one can compare/assess/verify/enforce during the procurement process AND the implementation of the contract.

[1] For some Value Based Contracting examples and types [*like 1. Evidence-based care discounts, 2. Product or service guarantee, 3. Risk share by product, 4. Risk share by alternative payment model and 5. Fully integrated care provision including risk and contracting vs. payer*], see "Overview Value-Based Contracting" presentation, WP2, September 2019.
[2] See "Overview Value-Based Contracting" presentation, WP2, September 2019.

1.2 Being aware of innovation through preliminary market consultation

In order to identify and assess needs and to have an insight into the budget and affordability of the purchase, the preliminary market consultation is an important phase in the preparation of a procurement procedure. It allows contracting authorities to identify what they want to procure. This is one of the most important tasks, given that once a public contract is awarded, it can only be modified to a limited extent (and under specific conditions). Anticipation and having a good knowledge on the opportunities on the market is therefore crucial. Being aware of the existing possibilities also allows contracting authorities to innovate. In order to innovate, one should indeed know what's already available on the market and how these solutions can be improved.

The benefits of a good understanding of the market include:

- Stimulating competition which can reduce the dependency on a small number of suppliers;
- Providing procuring organizations with information and insights which can be used to develop an informed and forward-looking procurement strategy. It can also reduce the tendency to rely on incumbents and help "level the playing field", as well as avoid requirements and specifications being based on or strongly influenced by the products and services provided by incumbents, thus mitigating any incumbency advantage;
- Managing market expectations – by engaging with a supplier base, and setting out procurement pipelines and the capabilities needed to deliver them, suppliers can be prepared for upcoming tenders, and officials can be better assured that those companies asked to provide products and services can meet the stated needs;
- Strengthening the relationship between industry and procuring authorities and providing the opportunity for smaller or new market players who may be responsible for placing new technology on the market to compete;
- Providing an opportunity for the health authority to sense-check its requirements, the feasibility of the requirements, the timescales in which they can be achieved and the capacity of the market to deliver. Procuring authorities can also use this opportunity to consult on whether splitting a contract into smaller contracts or lots to stimulate greater competition and the involvement of SMEs would be appropriate;
- Allowing the market to raise questions or challenge procurement approaches, thus minimising the risk of any legal challenges once the tender has commenced;
- Avoiding the need for long and complex procurement procedures which may be chosen where procurement or clinical teams are unsure as to the products available on the market;
- Allowing the formulation of appropriate, realistic and tailored requirements;
- Identifying and evaluating risks early and designing risk management strategies.

The way the subject matter of the contract is described is one of the key-factors for successful procurement. This is certainly true for innovation procurement. The *Guidance on Innovation Procurement*[3] explains how the description of the subject-matter can have an important impact. It makes a difference between so-called descriptive requirements and functional requirements and underlines that the functional requirements are far more innovation friendly, as they allow tenderers to meet the requirements in various ways. This is of course only one aspect that demonstrates the importance of the preliminary market consultation.

[3] https://ec.europa.eu/transparency/regdoc/rep/3/2018/EN/C-2018-3051-F1-EN-MAIN-PART-1.PDF

The conduct of the preliminary market consultation

The public procurement directive 2014/24 clarifies that before launching a procurement procedure, contracting authorities may conduct market consultations with a view to preparing the procurement and informing economic operators of their procurement plans and requirements[4]. Generally speaking, market consultations are crucial and very beneficial for the preparation of the procurement process. However, a contracting authority should conduct these market consultations carefully and bear in mind that the procurement process deriving from them should still be impartial and non-biased by these market consultations. Often indeed, economic operators participating in these market consultations will try to influence the technical specifications, award criteria or priorities in their favor. The contracting authority should bear in mind that it is important to consult a sufficiently broad panel of firms when holding preparatory meetings. Moreover, a contracting authority must ensure these meetings do not include pre negotiations and do not restrict competition and therefore still allow for other economic operators to participate in the subsequent procurement process.

We also note that under German law a primary market consultation is not allowed if it has the sole purpose of a cost or price determination. This could be criticized in our view, as the primary market consultation can also be a useful tool to estimate the value of the contract (which will allow the contracting authority to determine the applicable rules).

Note that the provisions of the directive include a specific time indication: the preliminary market consultation must take place before "launching a procurement procedure". This is prior to the publication of the contract notice or in case this is not mandatory, before inviting the tenderers to submit a tender. The Italian Council of State clarified that this phase is a pre-tender phase allowing a contracting authority to start an informal dialogue with economic operators.[5]

According to the EU provisions, contracting authorities may for example seek or accept advice from independent experts or authorities or from market participants. That advice may be used in the planning and conduct of the procurement procedure, provided that such advice does not have the effect of distorting competition and does not result in a violation of the principles of non-discrimination and transparency. According to the Legal Affairs Division of the French Ministries of Economy and Finance, the contracting authority can take the following actions:

- Conducting a survey in the relevant economic sector;

- Organizing or participating in trade fairs in order to make the contracting authorities' needs known to economic operators or to identify new needs, particularly in the innovation sector;

- Meeting several economic operators before launching the procurement procedure, in order to obtain information on the relevant market, the operators in the sector and the available services or products, etc. This information gathering may include sending questionnaires to several suppliers or service providers.

[4] See article 40 of the Directive 2014/24 on "preliminary market consultations": "*Before launching a procurement procedure, contracting authorities may conduct market consultations with a view to preparing the procurement and informing economic operators of their procurement plans and requirements.*
For this purpose, contracting authorities may for example seek or accept advice from independent experts or authorities or from market participants. That advice may be used in the planning and conduct of the procurement procedure, provided that such advice does not have the effect of distorting competition and does not result in a violation of the principles of non-discrimination and transparency".

5 Italian Council of State, judgement of 23 September 2019.

Prior involvement of candidates or tenderers

Whilst pre-tender engagement is usually beneficial for both contracting authorities and economic operators, economic operators need to be careful that the pre-tender engagement is not conducted in such a way that it could lead to their exclusion in the subsequent procurement. The prior involvement of candidates or tenderers[6] can indeed under certain conditions lead to their exclusion[7].

Candidates and/or tenderers should avoid receiving any information that could constitute an advantage during the future procurement procedure, or seeks to influence the tender specifications in a way that would be discriminatory towards other potential tenderers. Moreover, the contracting authority should ensure that it shares the information exchanged during the preliminary discussions with all tenderers to ensure that all tenderers are in the same position when preparing their tenders.

In the event of such prior involvement, the contracting authority must take appropriate measures to ensure that competition is not distorted by the participation of that candidate or tenderer. Such measures shall include:

- the communication to the other candidates and tenderers of relevant information exchanged in the context of or resulting from the involvement of the candidate or tenderer in the preparation of the procurement procedure
- the fixing of adequate time limits for the submission of tenders;
- special attention to the fact that the specifications should not have been influenced or biased during the preliminary market consultations for example in a way that would be discriminatory towards certain tenderers.

The candidate or tenderer concerned shall only be excluded from the procedure when there are no other means to ensure compliance with the duty to observe the principle of equal treatment.[8]

Prior to any such exclusion, candidates or tenderers shall be given the opportunity to prove that their involvement in preparing the procurement procedure is not capable of distorting competition.

6 The prior involvement must be understood extensively: it is sufficient that a candidate or tenderer or an undertaking related to a candidate or tenderer has advised the contracting authority, whether in the context of Article 40 ("preliminary market consultations") or not, or has otherwise been involved in the preparation of the procurement procedure.

[7] See article 41 of Directive 2014/24.

[8] We note that in Switzerland (which is not a member of the EU), a similar provision is laid down in the Swiss procurement law. However, undertakings that were priorly involved do not have to be excluded if their competitive advantage is compensated of if the exclusion would jeopardize effective competition. This last hypothesis is not foreseen under the European directives 2014/24 and 2014/25.

1.3 Guidance on the choice of award procedure for innovative health and social care purchases

Depending on the subject matter of the requirement envisaged, different innovative procurement procedures can be contemplated. PCP (which does not fall under the scope of the public procurement directives) or a classic PPI procurement procedure would be relevant, depending on the subject matter of the procurements.

The aim of the present section 1.3 is to provide to the stakeholders of an innovative procurement with an overview of the procedures that could be used for value based healthcare purchases. We highlight their constraints, their advantages and disadvantages for health and social care purchases.

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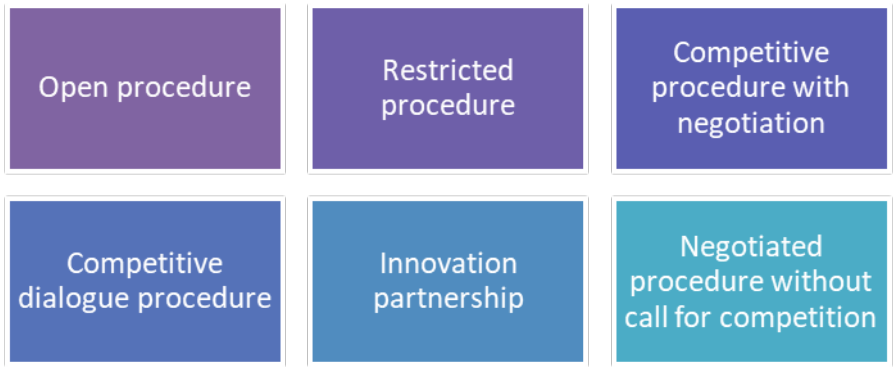
The Directives provide for six main contract award procedures:



All of the above procedures are suitable to be used, with the exception of the negotiated procedure without a call for competition (otherwise known as a direct award, which can be used only in very exceptional circumstances and which is not discussed further in the present Guidelines). Framework agreements, which have a number of advantages in the framework of cross-border procurement (see *infra*, section 2.3.3), can be awarded using all these procedures (with the exception of the negotiated procedure without a call for competition).

Contracting authorities can choose freely between the open and restricted procedures. They are also free to select the innovation partnership procedure, although this is intended for very specific circumstances (discussed below).

In order to use the competitive procedure with negotiation or the competitive dialogue procedure, a contracting authority must justify its use on one of the following grounds:

- the needs of the authority cannot be met without adaptation of readily available solutions;
- the works, supplies, or services include design or innovative solutions;
- the contract cannot be awarded without prior negotiation because of specific circumstances related to the nature; the complexity or the legal and financial make-up or because of risks attached to them; or
- only irregular or unacceptable tenders have been submitted in response to an open or restricted procedure.

The key differences between these procedures, their constraints and their advantages and disadvantages for the Project are summarised in the following pages.

1.3.1 Open Procedure

Under this procedure all those candidates that respond to the Contract Notice (or PIN) are entitled to submit a tender for the contract.

There is no initial selection stage limiting the number of candidates to be invited to tender.

Despatch of OJEU Contract Notice

Time limit: Min 35 days
(reduced to 30 days where allowing for electronic submission)
(reduced to 15 days with PIN or in case of urgency)

Receipt of tenders

Elimination of unsuitable candidates not satisfying the minimum requirement of economic and financial standing and/or technical and/or professional ability, and/or mandatory and discretionary exclusion grounds

Evaluation of most economically advantageous tender and appointment of preferred tenderer; issue of standstill letters

Observe min 10/15 calendar day standstill period before concluding the contract

Issue OJEU Contract Award Notice

Advantages:

- The open procedure is quicker than the other award procedures as it is conducted in one phase.
- The tender will contain all information related to the selection phase (including the European Single Procurement Document (ESPD)), the compliance and the award phase and the tenders will be assessed in one go.
- It is probably the least complex procedure in the public procurement framework of award procedures.

Disadvantages:

- This procedure may be more onerous in terms of the number of tenders to be evaluated if a significant number of tenderers participate in the procedure.
- There can be no negotiations after the submission of the tenders. The tenders that are not compliant with the specifications will be declared "non compliant" and excluded.
- The contracting authority will have to describe precisely what it wants to buy and how.

Consequences for innovative health and social care purchases:

This procedure is appropriate where:

- the contracting authority knows that the number of tenders will not be too high (max. 5 or 6);
- the product to buy already exists, the contracting authority can describe precisely the solution/product it wants to buy and is able to draft comprehensive contractual documentation that does not need to be further negotiated (contract terms are clear and not complex).

1.3.2 Restricted Procedure

This procedure allows a contracting authority to limit the number of candidates to be invited to tender by using an initial selection stage to shortlist a limited number of tenderers.

The selection is performed by means of the European Single Procurement Document (ESPD), which candidates complete and submit.
The restricted procedure requires that a minimum of five qualifying candidates be Invited to Tender (ITT).

Despatch of OJEU Contract Notice (or PIN)

Time limit: Min 30 days
(reduced to 15 days in case of urgency)

Receipt of completed ESPDs

Evaluation of ESPDs and elimination of unsuitable candidates who do not satisfy the minimum requirement of economic and financial standing and/or technical and/or professional ability and/or mandatory and discretionary exclusion grounds

Scoring of ESPDs and pre-selection of a minimum of five qualifying tenderers and issuing of ITT (need to invite enough tenderers to ensure genuine competition)

Time limit: Min 30 days
(reduced to 25 days where allowing for electronic submission)
(reduced to 10 days with PIN or in case of urgency)

Evaluation of most economically advantageous tender and appointment of preferred tenderer; issue standstill letters

Observe min 10/15 calendar day standstill period before concluding the contract

Issue OJEU Contract Award Notice

Advantages:

- The restricted procedure is conducted in two phases: a selection phase and an award phase.
- The number of tenders will be restricted during the selection phase according to the rules as laid down in the specifications.
- In the restricted procedure the minimum number of candidates shall be five. Where the number of candidates meeting the selection criteria and the minimum levels of ability is below the minimum number, the contracting authority may continue the procedure by inviting the candidates with the required capabilities.

Disadvantages:

- This procedure takes more time and requires more involvement of the decision taking functions of the contracting authority (two official decisions to be taken).
- As is the case for the open procedure, there can be no negotiations after the submission of the tenders. The tenders that are not compliant with the specifications will be declared "non compliant" and excluded.
- The contracting authority will have to describe precisely what it wants to buy and how.

Consequences for innovative health and social care purchases:

This procedure is appropriate where:

- the Contracting authority knows that the number of tenders will be too high (more than 5 or 6);
- the product to buy already exists and the contracting authority can describe precisely the solution/product it wants to buy and is able to draft comprehensive contractual documentation that does not need to be further negotiated (contract terms are clear and not too complex).

1.3.3 Competitive Procedure with Negotiation (CPN)

This procedure allows a contracting authority (i) to limit the number of candidates to be invited to negotiate the terms of the contract using an initial selection stage to shortlist a limited number of tenderers; and(ii) to negotiate with the tenderers after the submission of their tenders.

The selection is performed by means of an ESPD. The CPN procedure requires that a minimum of three qualifying candidates be Invited to Negotiate (ITN). Contract negotiations are conducted following the submission of Initial Bids.

Despatch of OJEU Contract Notice (or PIN)

Time limit
Min 30 days(reduced to 15 days in case of urgency)

Receipt of completed ESPDs

Evaluation of ESPDs and elimination of unsuitable candidates who do not satisfy the minimum requirement of economic and financial standing and/or technical and/or professional ability and/or mandatory and discretionary exclusion grounds

Scoring of ESPDs and pre-selection of a minimum of three qualifying tenderers and issuing of ITN

▼

Time limit: Min 30 days
(reduced to 25 days where allowing for electronic submission)
(reduced to 10 days with PIN or in case of urgency)

▼

Submission of Initial Bids followed by contract negotiations – to be concluded in an open and transparent manner ensuring equal treatment of tenderers – may take place in successive stages in order to reduce the number of tenders

▼

Submission of Final Bids, evaluation of most economically advantageous tender and appointment of preferred tenderer; issue standstill letters

▼

Observe min 10/15 calendar day standstill period before concluding the contract

▼

Issue OJEU Contract Award Notice

Advantages:

- The CPN procedure is conducted in two phases: a selection phase and an award phase. The number of tenders will be restricted during the selection phase according to the rules as laid down in the specifications.
- In the CPN the minimum number of candidates shall be three.
- This procedure offers much more flexibility to the tenderers and the contracting authority: the contracting authority will be entitled to negotiate the tenders and, if necessary, under certain conditions, modify its own specifications.
- There is a possibility to amend non final tenders that would be not compliant.

Disadvantages:

- This procedure takes more time and requires more involvement of the decision taking functions of the contracting authority (two official decisions to be taken as well as a team required for negotiations).

Consequences for innovative health and social care purchases:

The conduct of a CPN is restricted to a limited number of grounds listed in the directive[9]. If a contracting authority decides to use the CPN procedure because it considers that the conditions of one of these grounds are met, it shall justify this formally in the relevant contract documentation. The grounds which are relevant to innovative health and social care purchases are likely to be the following:

- The needs of the contracting authority cannot be met without adaptation of readily available solutions:
  - ➔ Contracting authorities shall need to prove that the current solutions offered on the market are insufficient to meet their needs and must therefore be adapted.
- The intended purchases include design or innovative solutions:
  - ➔ This means that the product or solution to be purchased require an element of design or innovative solutions. Contrary to the abovementioned condition, there is no adaptable solution here, as the solution must be created.
- The contract cannot be awarded without prior negotiations because of specific circumstances related to the nature, the complexity or the legal and financial make- up or because of the risks attaching to them:
  - ➔ This ground was created for complex purchases such as sophisticated products, intellectual services, or major information and communications technology (ICT) projects.
- The technical specifications cannot be established with sufficient precision by the contracting authority:
  - ➔ This ground refers to situations in which contracting authorities are unable to establish the technical prescriptions that shall be contained in the procurement documents.

If the product or solution that will be purchased does not exist as such, requires innovative solutions or is purchased in the framework of a complex purchasing scheme, a CPN can be used by a contracting authorities. The procurement process will take more time than the procurement process in an open or restricted procedure but will allow more flexibility to adapt/improve the solutions to be purchased.

[9] Further conditions are mentioned in article 26 of Directive 2014/24.

1.3.4 Competitive Dialogue Procedure (CD)

This procedure allows a contracting authority to limit the number of candidates to be invited to conduct dialogue with the authority to establish a solution that would meet the authority's stated needs and requirements, and one on which it can invite suppliers to submit final tenders

The competitive dialogue procedure is designed to be used for the award of particularly complex contracts, where it is objectively impossible for the authority to define in advance the means of satisfying its needs or to specify the most appropriate solution. The competitive dialogue procedure is generally used for establishing long-term Public Private Partnerships (PPPs), for the purchase of solutions (including for example risk sharing schemes) or for other major infrastructure and IT contracts.

After a selection phase, the procuring authority will invite undertakings to participate in a dialogue with the aim of developing one or more solutions capable of meeting the authority's needs and requirements.

The main idea behind the competitive dialogue procedure is to enable the private sector to deliver more innovative and responsive solutions whilst optimising value for money for the public sector.

Despatch of OJEU Contract Notice

Time limit
Min 30 days

Receipt of completed ESPDs

Evaluation of ESPDs and elimination of unsuitable candidates who do not satisfy the minimum requirement of economic and financial standing and/or technical and/or professional ability and/or mandatory and discretionary exclusion grounds

Scoring of ESPDs/PQQs and pre-selection of a minimum of three qualifying tenderers and issuing of Invitation to Participate in Dialogue (ITPD).

▼

▼

Discussions conducted over successive stages to reduce the number of solutions; and to identify and define the solution(s)s best suited to meet the requirement.

▼

End of Dialogue Phase and Invitation to Submit Final Tenders (ISFT)

▼

Time limit
Not specified but must be reasonable

▼

Choice of most economically advantageous tender and appointment of preferred tenderer; negotiation; issue standstill letters

▼

Observe min 10/15 calendar day standstill period before concluding the contract

▼

Issue OJEU Contract Award Notice

Advantages:

- The number of participants to the dialogue can be restricted during the selection phase according to the rules as laid down in the specifications.
- The minimum number of candidates shall be three.
- This procedure offers more flexibility to the tenderers and the contracting authority: the contracting authority will be entitled to enter into dialogue with the participants to identify the solutions that would meet its needs. The contractual documents and specifications can be further elaborated after the closure of the dialogue phase.
- This procedure contains a long and more formal phase of "commercial dialogue" in which the contracting authority will be able to question the economic operators about the solutions they can bring into the process etc. before actual tenders are submitted.

Disadvantages:

- Competitive dialogue is usually perceived by public authorities as a complex procedure, with a negative impact on procurement cost and time. The process is seen as resource-intensive, expensive and lengthy and requires a well-equipped team of internal staff or external advisors. The dialogue stage indeed requires careful preparation in order to be effective and this may not be compatible with the tight schedules many contracting authorities are often working under.
- Competitive dialogue is, in some countries on Europe, a relatively new procedure for which no established practice is available. it can give rise to dealing with a number of unfamiliar issues such as: confidentiality, proprietary information, down-selecting bidders and, more generally, the mechanics of running several parallel negotiations with different bidders in a multi-stage procedure.
- This procedure also requires significant involvement from the bidders.

Consequences for innovative health and social care purchases:

As it is the case for the CPN, the conduct of a competitive dialogue is restricted to a limited number of grounds listed in the directive. We refer in this regard to the same four grounds that have been described above for the CPN. If a contracting authority decides to use the competitive dialogue procedure because it considers that the conditions of one of these grounds are met, it shall justify this formally in the relevant contract documentation.

If the contracting authority ignores what the market could offer in terms of solutions to its needs, if the product or solution that will be purchased does not exist as such, contains innovative solutions or is purchased in the framework of a complex purchasing scheme, a competitive dialogue can be envisaged by a contracting authority. The procurement process will take more time than the procurement process in an open or restricted procedure and will be even more intense than in a CPN. It will allow a great deal of flexibility to adapt/improve the solutions to be purchased and to further elaborate the specifications. It is, however, extremely time and resource consuming and can expensive both for bidders and the procuring authority.

1.3.5 Innovation Partnership Procedure

This procedure is intended for the situation where there is a need for the development of an innovative product or service or innovative works which are not already available on the market.

The innovation partnership procedure is intended to be used where there is a need to develop an innovative product or service or innovative works and the subsequent purchase of the resulting supplies, services or works cannot be met by solutions already available on the market.

It allows contracting authorities to establish a long-term innovation partnership for the development and subsequent purchase of a new, innovative product, service or works without the need for a separate procurement procedure once the product, service or work has been developed.

In order to know if such solutions exist and before launching the innovation partnership procedure, the contracting authority must conduct a sufficiently extensive market research.

The main feature of the innovative partnership is that the innovation occurs during the performance of the contract, whereas in most other procedures, the public authority already knows what type of solution it is buying and innovation occurs in the pre-contracting phase.

The procedure can be organised in successive phases following the sequence of steps in the research and innovation process, with intermediate targets to be attained by the partners.

- Based on the targets, the authority may decide after each phase to either terminate the partnership or reduce the number of partners, but only if the authority had indicated in the procurement documents these possibilities and the conditions for their use.

- The authority must always ensure that the structure of the partnership and, in particular, the duration and value of the different phases reflect (i) the degree of innovation of the proposed solution, and (ii) the sequence of the research and innovation activities required for the development of an innovative solution not yet available on the market.

Furthermore, the contracting authority is obliged, before entering the last ("buying") phase, to determine the solution (or solutions) that suit(s) its needs best based on non-discriminatory and objective criteria set out in the contracts.

Despatch of OJEU Contract Notice

Time limit: min 30 days

Receipt of completed ESPDs

Evaluation of ESPDs and elimination of unsuitable candidates who do not satisfy the minimum requirement of economic and financial standing and/or technical and/or professional ability and/or mandatory and discretionary exclusion criteria

Scoring of ESPDs and pre-selection of a minimum of three qualifying candidates and issuing of invitation to participate

Submission of tenders and negotiations

Choice of most economically advantageous tender and appointment of preferred tenderer; negotiation; issue standstill letters

Observe min 10/15 calendar day standstill period before concluding the contract

Issue OJEU Contract Award Notice

▼

Implementation: R&D (with potential reduction of the participants in function of pre-determined milestones)

▼

Implementation: development of the product/services/works and purchasing

Advantages:

- The number of participants to the procedure can be restricted during the selection phase according to the rules as laid down in the specifications.
- In the IP the minimum number of candidates shall be three.
- This procedure allows the contracting authority to negotiate with the economic operators during the award process.
- The innovative partnership allows the contracting authority to choose several economic operators to conduct the R&D phase. The number of the participants of this phase can then be further reduced pursuant to predetermined performance requirements and milestones to enter in a second implementation phase.
- An important advantage of the IP procedure is that the contracting authority has the possibility to purchase products/supplies developed during the R&D phase (which is not possible in the PCP).

Disadvantages:

- This procedure is applicable only if the implementation phase of the contract contains a proper research and development ("R&D") phase. This implies that the product/service/works that will be purchased still have to be developed.
- The restriction of the economic operators during the R&D phase can be complex and risky.
- The drafting of the specifications and the contractual clauses is complex as they concern a product that still has to be developed.
- Special attention will need to be given to the arrangements concerning IP rights and to potential State Aid questions.

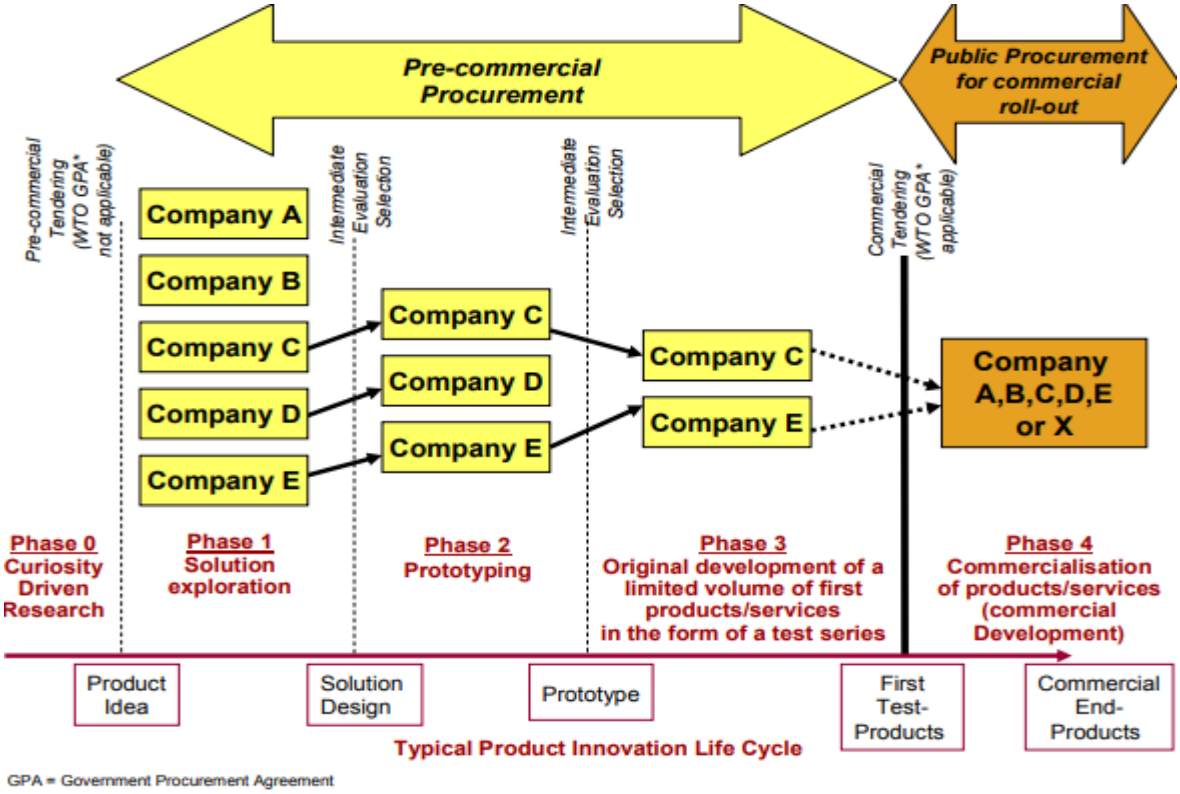
Consequences for innovative health and social care purchases:

The Innovative partnership will only be conducted if the purchase still requires an R&D phase to be performed, with the contracting authorities, under the contract. In practice, the application of such a process is relatively rare.

1.3.6 Pre-commercial procurement (PCP)

PCP is not a procurement award procedure. It does not fall under the scope of the Directives on public procurement. PCP concerns an R&D phase before the commercialisation of the relevant products. This concept allows contracting authorities to acquire R&D services to research, develop and test innovative products, services or works that are not already available on the market.

The aim of PCP is to enable all interested candidates, in a competitive environment, to submit alternative solutions to address a particular issue of public interest. The phases developed hereunder allow for a progressive selection of candidates of the best competing solutions. A first contract will be concluded for a limited duration and may include the development of prototypes or limited volumes of first products or services in the form of a test series and, in case of a purchase of commercial volumes of the innovative solution created, a second procurement procedure will have to be organised and a second contract will be concluded.



Source: http://ec.europa.eu/transparency/regdoc/rep/2/2007/EN/2-2007-1668-EN-1-0.Pdf

Solution exploration **(PCP):** evaluation of the technical, economic and organisational feasibility of each candidate's proposal

Prototyping **(PCP):** verification of the coherence between the features exhibited by the prototype and the requirements set forward by the public purchaser

First test products **(PCP):** verification and comparison of the performance of the different solutions in real life operational conditions of the targeted public service. At least two companies must remain at the outcome of this phase

Commercial end products **(PPI)** (*this phase is not included in the PCP process*): public procurement to be organised to purchase the end products/services

It is important to note that PCP does not fall under the scope of the EU public procurement Directive. Article 14 Directive 2014/24, entitled "Research and development services", indeed provides that:
"*This Directive shall only apply to public service contracts for research and development services which are covered by CPV codes 73000000-2 to 73120000-9, 73300000-5, 73420000-2 and 73430000-5 provided that both of the following conditions are fulfilled*[10]*:*
(a) the benefits accrue exclusively to the contracting authority for its use in the conduct of its own affairs, and
(b) the service provided is wholly remunerated by the contracting authority".

Three conditions must therefore be met to fall outside the scope of the Directive and for the PCP process to be applicable:

- The scope of the requirements must be for R&D services (other than the ones covered by the CPV codes mentioned in Article 14).
- The public purchaser must share the risks and benefits with economic operators in developing solutions that are better than what the market offers and can therefore not reserve the R&D results exclusively to its own use. Recital 35 of the Directive insists on the fact that fictitious sharing of the results of the R&D should not prevent the application of the Directive.
- The services provided must be co-financed. Again, recital 35 insists on the fact that purely symbolic participation from a third party in the remuneration of the service provider should not prevent the application of the Directive.

The main differences between a PCP procedure and a procurement procedure (for example, an innovative partnership) are the following:

Advantages:

- A PCP procedure does not fall under the scope of the Directives. It will not be submitted to the time constraints and specific rules applicable to procurement procedure.
- The process will therefore be much more flexible (but still submitted to the principles of competition, transparency, equal treatment).

Disadvantages:

- A PCP procedure applies only for R&D **services** (not for the purchasing of products or works).
- A PCP procedure does not entitle a contracting authority to purchase the end-services (or products that would have been conceived at the end of the R&D services phase) that are ready for commercialisation. It will be obliged to organise a new procurement procedure for this purchase. This is the main pitfall of the PCP procedure as it raises a lot of questions regarding the trade secrets and IP of the company that participated in the PCP phase, or regarding the advantages that would benefit to this company in comparison to other economic operators that would participate in the procurement phase.

Consequences for innovative health and social care purchases:
A PCP will only be appropriate if the procurement need requires R&D services to be performed and if the two conditions above are met. A contracting authority should also be aware that a second procurement process will have to be conducted at a later stage, after the R&D services phase if the purchase of a product or solution, conceived during the R&D phase, is taken forward.

[10] See Annex II A of Directive 2004/18, modified by Annex of VI Directive 2014/24.

1.4 Guidance on the choice of selection and award criteria

Once the award procedure has been chosen, special attention will need to be given to (i) the selection criteria and (ii) the award criteria. These two categories of criteria shall need to be clearly distinguished as it is forbidden to use selection criteria as award criteria and vice versa[11].

Before defining the selection and award criteria, the contracting authority should define the technical specifications[12] of the solutions it want to purchase, as the selection and award criteria should be linked to the object of the contract (see below).

1.4.1 The selection criteria

The selection criteria relate to the first phase of the evaluation. They aim to assess the capacity of the economic operator (or the capacity it has at its disposal). The Directives set out an exhaustive list of the types of information that authorities can request from candidates at the selection stage. The prescribed types of information fall within three broad categories:

- personal standing (with mandatory and discretionary exclusion grounds);
- economic and financial standing; and
- technical and/or professional ability.

The contracting authority shall list the relevant selection criteria and the minimal requirements related to each criterion, to be met by the candidates.

1.4.2 The award criteria

1.4.2.1 Principles and constraints applicable when determining value-based award criteria

The award criteria relate to the solution/product/services to be offered in the framework of the implementation of the contract.

In identifying the award criteria, one could examine which criteria of the Value Based Procedure Framework could be suitable for the proposed purchase (see below, section 1.4.2.2). However, when selecting award criteria, the contracting authority shall need to pay attention to the requirements under the Directive that have to be fulfilled by the award criteria:

- **The criteria shall be linked to the subject-matter** of the contract to be awarded; those criteria should thus **allow for a comparative assessment of the level of performance offered by each tender in the light of the subject-matter of the contract**, as defined in the technical specifications. In other

[11] Some exception apply.

[12] 'technical specification' means one of the following:
(a) in the case of public works contracts the totality of the technical prescriptions contained in particular in the procurement documents, defining the characteristics required of a material, product or supply, so that it fulfils the use for which it is intended by the contracting authority; those characteristics include levels of environmental and climate performance, design for all requirements (including accessibility for disabled persons) and conformity assessment, performance, safety or dimensions, including the procedures concerning quality assurance, terminology, symbols, testing and test methods, packaging, marking and labelling, user instructions and production processes and methods at any stage of the life cycle of the works; those characteristics also include rules relating to design and costing, the test, inspection and acceptance conditions for works and methods or techniques of construction and all other technical conditions which the contracting authority is in a position to prescribe, under general or specific regulations, in relation to the finished works and to the materials or parts which they involve;
(b) in the case of public supply or service contracts a specification in a document defining the required characteristics of a product or a service, such as quality levels, environmental and climate performance levels, design for all requirements (including accessibility for disabled persons) and conformity assessment, performance, use of the product, safety or dimensions, including requirements relevant to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking and labelling, user instructions, production processes and methods at any stage of the life cycle of the supply or service and conformity assessment procedures;

words, the criteria have to be related the nature of the products and services to be performed under the contract.

Examples –
- additional services:

- If subject-matter = devices: critera relating to trainings about the purchased devices are in principle allowed (not general trainings about the pathology)
- If the subject matter is broader: trainings can have a broader scope

- environmental criterion: shall need to relate specifically to the device (not the supplier in general)
- subjective criteria?: are allowed if linked to the subject matter of the contract and assessed objectively (eg. smell of the hand gel: OK? Yes, if it implies that the medical staff will use it more often.)

- The chosen award criteria **should not confer an unrestricted freedom of choice:**

  Criteria should be clear, not vague and allow for an objective comparison between the tenders. It should in other words be clear for tenderers how they can win points.

  In the framework of the willingness to pay method (see infra), one should not put a value next to an internal cost or bonus proposed by the tenderers without providing this information upfront to tenderers or use an objective method fixed before the opening of the tenders.

- The chosen criteria should **ensure the possibility of effective and fair competition** :

  One shall not use criteria that de facto exclude some undertakings in a way that would not be proportionate or necessary in relation to the subject matter of the contract.

  Moreover, the contracting authority should ensure that the award criteria allow comparison of comparable tenders/propositions (for example: the calculation and content of the life-cycle cost should be the same for all tenderers and the parameters for this calculation should be provided upfront in the procurement documents)

- The selected criteria shall be **accompanied by arrangements that allow the information provided by the tenderers to be effectively verified**.

  The contracting authority should be able to verify the realistic character of the tenders and the answers to the award criteria. Courts do not hesitate to sanction contracting authorities that accept unrealistic prices, delivery terms etc. without verifying if they would be justifiable or feasible.[13]

1.4.2.2 Value based procurement criteria

Value based award criteria can be determined via the Value Based Procurement Framework[14].

This framework is a multidisciplinary procurement tool leading towards the most economically advantageous tender. Using the MEAT-VBP framework, supports the identification of award criteria valued from the perspective of patients, healthcare actors and health systems in order to achieve better outcomes and/or provide safe, cost-efficient high quality care alongside the full process of care delivery.

The framework provides a list of generic criteria that can be used by the contracting authorities as a starting point. These criteria can be adapted or modified and aim to facilitate the work of the public procurers .

[13] For example in Belgium: Belgian Council of State n° 236.575 of 29 November 2016; n° 223.427 of 7 May 2013; n° 220.269, 10 July 2012; .n° 206.993 of 26 August 2010; n° 208.286 of 21 October 2010..
[14] Source: MedTech Europe and BCG.

This framework was adapted, in the context of the Euriphi Project, for the rapid diagnostic and integrated care topics[15].

1.4.2.3 The "willingness to pay" method[16]

The willingness to pay method (hereafter "W2P") is an innovative way of assigning weightings to award criteria. This method assigns a monetary value to non-monetary criteria such as outcomes or other benefits for healthcare practitioners (HCPs). The method aims for comparability between monetary and non-monetary terms and is opposite to the traditional method, which translates costs from monetary terms into points or weights.

In the framework of a Value-Based Procurement, it is possible to use the W2P method to put a monetary value on the key outcome and other benefits criteria. The cumulated monetary value of the fulfilled outcome and other benefit criteria is then subtracted from the total supplier bid and procurer total cost of care impact to identify the most economically advantageous offer.

The main advantage of W2P method is the involvement of clinicians and other stakeholders in prioritizing and valuing the clinical and patient reported outcomes and making comparable monetary and non-monetary items. It also helps overcome limitations from traditional score-based approaches (e.g., ranking paradox and relative scoring manipulation).

Use of the W2P value assignment method in healthcare public procurement is increasing, with the strongest rate of adoption in the Nordics and the Netherlands. The W2P value assignment method can be used in a wide range of health and social care product categories (e.g. OR theatre integration, hip implants, dialysis equipment).

If bids are evaluated according to a combination of price and quality, monetary value can be assigned to quality characteristics (quality-to-price scoring), rather than by transforming bid prices into scores (price-to-quality scoring).

[15] See presentations provided in the framework of WP2 of the Euriphi Project, in July 2019 (WP2 – Adapted VBP framework for Diagnostics – WP2 – adapted VBP framework for Integrated case).
[16] Source: Gunnar Goblirsch Swedish procurement consultant; Prof. Jan Telgen Dutch procurement consultant; Gunnar; Bergman and Lundberg (2013) Tender evaluation and supplier selection methods in public procurement; BCG analysis

2 Particularities related to cross-border PPI

2.1 Introduction

This section is the result of the responses to a questionnaire completed by 12 CMS public procurement departments (Austria, Belgium, France, Germany, Hungary, Italy, the Netherlands, Portugal, Switzerland, Poland and the U.K.) (hereafter the "Questionnaire").

In this questionnaire, we asked the countries involved how provisions on cross-border procurement are implemented in their jurisdiction, which elements should be taken into account when procuring cross-border, their experience with such projects, etc. We also asked similar questions regarding prior involvement of candidates or tenderers, procurement procedures and R&D with the aim to foster innovation.

We also describe in this section the experience we gathered in the context of the Euriphi Project itself. Indeed, together with several hospitals/institutions from different Member States, we worked on cross-border procurement solutions for the purchase of innovative solutions in the health care sector.

2.2 Principles – the possibility for cross-border procurement

One of the aims of the directives on public procurement is facilitating cross-border procurement. The directives therefore include new rules regarding this possibility. Those rules should "*determine the conditions for cross-border utilization of central purchasing bodies and designate the applicable public procurement legislation, including the applicable legislation on remedies, in cases of cross-border joint procedures, complementing the conflict of law rules of Regulation (EC) No 593/2008 of the European Parliament and the Council.*"[17]

As a principle, the directives on public procurement confirm that "*contracting authorities from different Member States may act jointly in the award of public contracts*".[18] The lawyers participating to this project confirmed that this article of the directive is implemented in their national laws.

On the basis of the answers to the Questionnaire, it seems that cross-border procurement is rather uncommon in practice. The lawyers involved only reported a limited number of cross-border procurement procedures. We summarize hereunder the reported examples:

EXAMPLES			
	European Commission	 Supply of medical equipment to support the breathing of patients with suspected or confirmed novel coronavirus (COVID-19).	The European Commission acted on behalf of the Member States.

[17] Consideration 72 of Directive 2014/24. Article 39 of Directive 2014/24 includes the rules regarding procurement involving contracting authorities from different Member States. All CMS offices report that this article is implemented in their national laws and that there are no noteworthy particularities in this context. Under Austrian law it is clarified that the provision does not apply if the contracting authority is responsible for conducting the procurement procedure has its seat in a Third-Country. The purchase of services, works or supplies of a contracting authority from the responsible contracting authority on the basis of such joint procedure are indeed excluded from the applicability of the Austrian public procurement Act. In Portugal there is another relevant particularity regarding the use of centralised purchasing activities offered by central purchasing bodies located in other Member States, as these central purchasing bodies can only be used insofar they offer more advantageous terms and conditions than the national central purchasing bodies.

[18] Article 39 of Directive 2014/24 and article 57, 1 of Directive 2014/25.

Confidential	 Construction of a tunnel between two Member States.	The procurement procedures are in this case organised by a new legal entity established by both Member States.
Confidential	 Renovation of the railway network between two Member States.	No further information.
France & U.K.	 Interconnector Project – Interconnexion -France-Angleterre (IFA-2), connecting the electricity systems of Great-Britain and France. Aiming to be operational by 2020, IFA2 will involve the laying of over 200 km of undersea cables between the Hamphire coast and Normandy with converter stations at each end connecting into the national transmission system.	This project is being carried out through a joint venture, IFA-2 SAS, set up between the French RTE (electricity transmission system operator) and the UK National Grid Interconnectors Limited, which are both contracting entities. The joint venture is a legal entity governed by French law and registered in France.
Germany [19] and Austria	Cross-border procurement procedures organised by Municipality Hospitals (Dienstleistung) und Einkaufgemeinschaft Kommunaler Krankenhäuser) (GDEKK), seated in Cologne for the Hospital of the City of Vienna.	The Municipality Hospitals acted on behalf of the Hospital of the City of Vienna.
Poland	 Implementation of a joint infrastructural project and the contracts are to be jointly awarded for the purposes of this venture	No further information
Hungary	 A crossborder bike system in Esztergom (Hungary) and Párkány (Slovakia). This was a joint procurement of two cities on the Hungarian-Slovakian border divided by the Danube. Due to this geographical background probably cross-border procurement was the only way to realise a common bike system (https://ekr.gov.hu/portal/kozbeszerzes/eljarasok/EKR000322122019/reszletek).	No further information

All of the above mentioned examples relate to situations in which the circumstances made the organisation of a cross-border procurement procedure necessary (the most telling example is the tunnel; it is indeed necessary to award a public works contract for the construction of a tunnel that will be carried out in both Member States via a joint procedure).

[19] CMS Germany also mention that they see joint procurement procedures organized in the defense sector based on inter-governmental agreements.

2.2.1 Advantages of cross-border procurement

Cross-border procurement can have important advantages:

- *First, cross-border procurement can have a positive impact on the conditions under which contracting authorities can purchase. It could also give more leverage to the contracting authority during the negotiations.*

  Cross-border procurement does however not necessarily imply that contracting authorities will get better conditions. In order to get advantageous conditions, the contracting authority should examine which is the most relevant market (are the products/services available on a European/global level or are there any national differences?) and what is the value of the products (will there be economies of scale – or will the price in a cross-border tender be higher as small undertakings will no longer be able to participate?).

- *Secondly, cross-border procurement can foster the professionalization of the procurement procedures.*

  Contracting authorities can jointly make more resources available for the drafting and organisation of the procurement procedure. This leads to time, resource and energy savings and fosters best practices sharing between several entities.

2.2.2 Constraints and disadvantages of cross-border procurement

There may however be several reasons for the limited number of cross-border tenders:

- *Language*

  One of the challenges is that people often speak different languages from a Member State to another. When organizing a joint procurement procedure it is likely that the people in charge will have to work in a different language than the one they are used to. Moreover, national legislations also contain mandatory rules on the use of national language(s) for public entities (this is the case in Belgium for example).

  This is however not an issue for cross-border tenders between Member States in which people speak the same language, for example French in France, Belgium, Luxemburg and Switzerland; Dutch in the Netherlands and Belgium; German in Germany, Austria and Switzerland, etc...

- *Administrative burden*

  Contracting authorities must indeed agree on the way they want to cooperate: it is important to consider the allocation of risks, responsibilities, payment, etc. Contracting authorities that do not have an extensive legal service or enough resources available might fear such discussions or not be aware of the concrete consequences.

- *No specific framework/template*

  The absence of a framework/template has of course the advantage, on the one hand, that contracting authorities are free to decide how they want to work. On the other hand however, a cross-border procurement will require a considerable effort to draft documents related to it. The fact that there are no concrete guidelines/frameworks results, according to CMS Poland, in a high degree of uncertainty as to how to implement it in practice. Consequently, there are only very limited uses cross-border procurements.

- *Difficulties can arise in having a common understanding of the subject matter.*

Not all contracting authorities are on the same page when it comes to the description of the subject matter or the contractual terms. It can be difficult to align the needs of multiple institutions. This is even more the case if one adds the complexity of a cross-border multi-institutions contract. The Euriphi Project clearly demonstrated this: even at a quite upfront stage of the procurement procedure – where parties have already discussed the subject matter – contracting entities involved often did not have a common understanding of some elements of the subject matter of envisaged purchases in the learning process. Each entity tends to have its own focus and requirements.

- *SMEs acting locally (not at a European level):*

  SMEs can be discouraged to participate in large scale tenders, as they are only active in one or a limited number of Member States. It is possible that they lack the capacity to provide services/supplies on a European level and that they are not able to support full-scale cross-border projects and the implementation of (innovative) solutions. Cross-border procurement includes risks that the volume required is too high and that it can only be delivered by a limited number of suppliers, endangering competition in general and excluding SMEs. This can however be countered by using lots for example (see *infra*).

- *Alignment in prices?*

  Prices of some devices/products/solutions provided by one supplier can be different from country to country. Centralising these purchases cross countries presents the risk that the prices could be aligned towards the higher price.

- *Differences in local product – solution - and support offering;*

- *Possibly even leading to single supplier awarding, impacting negatively the viability, growth and jobs of the others on the market;*

- *Differences in context and local needs of the members in cross-border projects;*

- *Procurement legal framework, culture and case law can be different from country to country*

  There can be differences in national legislations as a result of the national transposition of the directives on public procurement. Experience also shows that the case law interprets some legal procurement constraints in different ways from country to country.

The challenges are therefore considerable, which is the reason why a cross-border procedure requires thorough preparation.

2.3 Different approaches for collaborative-cross-border procurement

Collaborative procurement can take many different forms, ranging from coordinated procurement through the preparation of common technical specifications for works, supplies or services that will be procured by a number of contracting authorities, each conducting a separate procurement procedure to situations where the concerned contracting authorities jointly conduct one procurement procedure either by acting together or by entrusting one contracting authority with the management of the procurement procedure on behalf of all contracting authorities.[20] Hereunder, we summarize some of the different feasible approaches.

[20] Recital 71 of Directive 2014/24.

2.3.1 Central purchasing bodies

One option is for a contracting authority to use "*centralised purchasing activities offered by central purchasing bodies located in another Member State*." This article is implemented in all jurisdictions as mentioned above[21].

A central purchasing body is a "*contracting authority*" which "*acquires supplies and/or services intended for contracting authorities*" or "*awards public contracts or concludes framework agreements for works, supplies or services intender for contracting authorities*".[22]

When a contracting authority buys through a central purchasing body and this entity complies with the rules set out in the directives and the national laws, the contracting authority is also considered to be compliant with these rules and does not have to organize its own public procurement procedure.

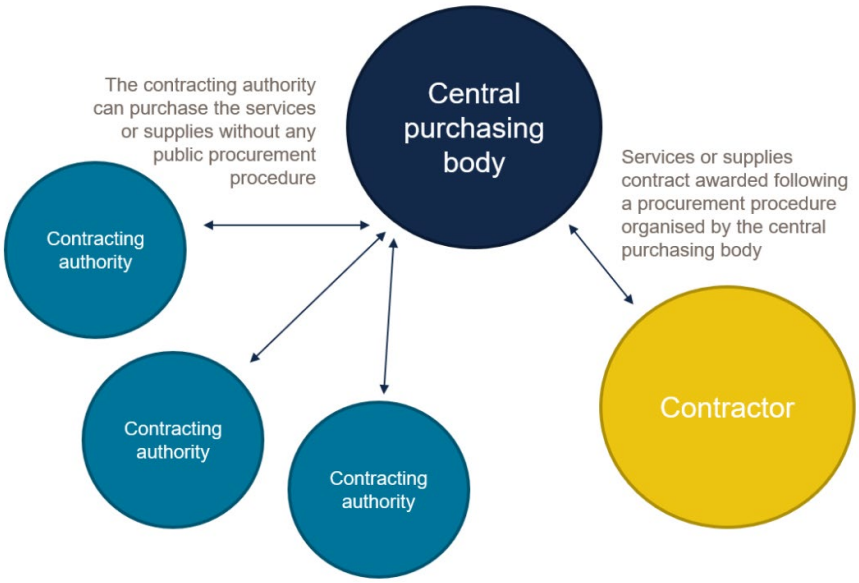
These central purchasing bodies can be located in another Member State provided that the procurement documents clearly identify the potential beneficiaries of the central purchasing body.[23]

Hereunder, we briefly describe the functioning of central purchasing bodies:

- *The acquisition of supplies and/or services intended for contracting authorities.*

  This approach implies that the centralized purchasing body acquires supplies and/or services from the undertaking who won the procurement procedure. There is, in other words, a direct contractual relationship between the central purchasing body and the undertaking.

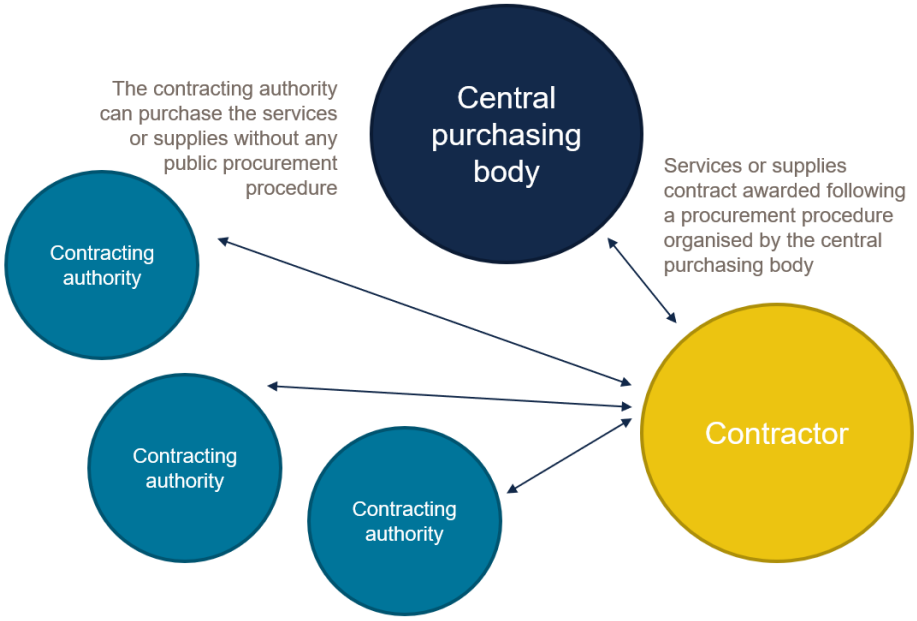
  Contracting authorities can acquire these supplies and/or services from the centralized purchasing body without any public procurement procedure. There is, in other words, another contractual relationship between these contracting authorities and the centralized purchasing body.



- *The award of public contracts or the conclusion of framework agreements for works, supplies or services intended for several contracting authorities.*

[21] Please note that Under Hungarian law we note however that it is not possible to use the central purchasing body of another Member State if Hungarian law prescribe procurement through a given central purchasing body.
[22] Article 1(10) of Directive 2014/24.
[23] CJEU 19 December 2018, C-216/17. Although this case is ruled on the basis of a framework agreement, we believe these principles are also valid for central purchasing bodies.

This approach serves the same purpose. However, according to this approach, there will be a direct contractual relationship between the contracting authorities and the contractor.



The directive does not mention according to which law the central purchasing body should award the public contract. We can assume that the central purchasing body will apply the national public procurement law where it is located.

The directive does, however, confirm that contracting authorities using central purchasing bodies can be located in another Member State. A Dutch contracting authority could, for example, purchase services and/or supplies from an Italian central purchasing body that previously organized a procurement procedure.

In this case, the provision of centralized purchasing activities by a central purchasing body located in another Member State shall be conducted in accordance with the national provisions of the Member State where the central purchasing body is located.

In the example mentioned above, this means that the Dutch contracting authority can purchase from the Italian central purchasing body in accordance with the Italian applicable provisions (the contract being governed by Italian law).

An obstacle might be that contracting authorities buying from the central purchasing body are not familiar with the public procurement law of the Member State of the said central purchasing body and the nation provisions which will govern the contract.

It would, in our opinion, be reasonable to ask a warranty from the central purchasing body that it conducted the public procurement procedure to the best of its ability in accordance with the provisions of the applicable public procurement law, and an overview of the contractual provisions.

An attention point will be the fact that the central purchasing body will have to be sufficiently transparent with the tenderers. In this view, it shall:

- list the potential beneficiaries of the procurement contract;[24]

[24] CJEU 19 December 2018, C-216/17.

- give sufficient information on the future purchases and, notably describe the maximum volumes that will be ordered under its procurement contract[25]

2.3.2 Occasional joint procurement between contracting authorities from different Member States

Two or more authorities may act together to purchase an item for joint use, or may jointly procure research and development services for the actual development of new products or services.[26]

The process of the award procedure can take many different forms:

- a contracting authority can take the lead and act solely;
- different contracting authorities can work closely together regarding all aspects of the award procedure; or
- one contracting authority can take the lead and the others have a more limited involved.

One contracting authority takes the lead	*Contracting authorities working closely together but one takes the lead*	*Contracting authorities working together*
The more one contracting authority takes the lead, the more the advantage and disadvantage *mentioned hereunder is* ***true***		*The more contracting authorites work together, the more the advantage and disadvantage mentioned hereunder is true*
Efficient, limiting time, the leading contracting authority might have the expertise required		All contracting authorities have equal decision-making rights
Limited involvement of the other parties entails a risk that the contract finally does not meet the other contracting authorities' needs		Risk of indecisiveness, possibly not efficient and time-consuming
Example : public procurement procedure organised by the European Commission for medical equipment to support the breathing of patients with		Example: the Interconnector Project

[25] According to the case law of the European Court of Justice, contracts based on a framework agreement must be awarded within the limits of the terms laid down in the agreement. It follows that the contracting authority that is an original party to the framework agreement can make commitments on its own behalf or on behalf of the potential contracting authorities that are specifically indicated in that agreement only up to a certain quantity and, once that limit has been reached, the agreement will no longer have any effect (C.J.U.E. 19 December 2018, C-216/17, point 61).

[26] S. ARROWSMITH, *The law of public and utilities procurement, regulation in the EU and the UK*, London, Sweet & Maxwell, 2014, 375.

suspected or confirmed novel coronavirus	

This decision on which scenario to apply obviously depends on the circumstances and how the contracting authorities intend to cooperate. If, on the one hand, there is a great number of contracting authorities involved, it does not seem very efficient to work closely together at all stages of the procedure. A better option could be that one contracting authority takes the lead. If, on the other hand, two contracting authorities from different Member States want to launch a tender, they could work closely together to launch the project.

In any case, contracting authorities will have to conclude an agreement[27] to determine:

(i) how they will cooperate;

(ii) the responsibilities of the parties, the relevant applicable national provisions, and the internal organization of the procurement procedure, including the management of the procedure;

(iii) the distribution of the works, supplies or services to be procured, and the modalities of the conclusion of the particular contracts (payments, particular delivery terms, technical particular specifications per entity (if any), etc.).

A participating contracting authority fulfils its obligations pursuant to the public procurement directive when it purchases works, supplies or services from a contracting authority which is responsible for the procurement procedure.[28]

Should two contracting authorities (possibly located in different Members States) jointly organize a procurement, both contracting authorities are legally responsible for compliance with public procurement rules.[29]

However, as mentioned above, contracting authorities may also allocate specific responsibilities among themselves and determine the applicable national law of either Member State involved. The allocation of responsibilities and the applicable national law shall be referred to in the procurement documents for jointly awarded public contracts.

Finally the role of the different contracting authorities during the implementation of the contract should be clear: which contracting authority will pay for the works, supplies or services carried out, which contracting authority will supervise the proper execution of the agreement, proceed to provisional acceptance, etc… This should be clarified between the contracting authorities, but is also important vis-à-vis the contractor(s).

This joint procurement modality is represented in Model 2 (cross-border collaborative procurement with lots per locality) and in Model 3 (cross-border collaborative framework agreement(s) followed by specific contracts per locality) of the "cross-border collaborative procurement model" identifying three collaborative procurement Models that can be used in the framework of cross-border value based innovation procurement.

2.3.3 Framework agreements with lots or mini-competitions per country/institution

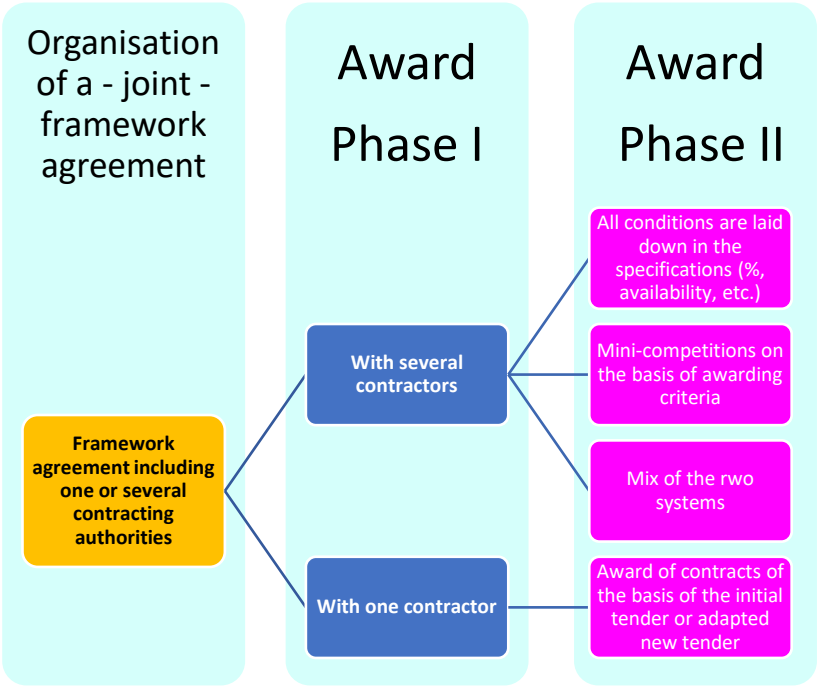
Another way of performing a collaborative/cross-border procurement process is organizing a framework agreement.

[27] Unless the necessary elements have been regulated by an international agreement concluded between the Member States concerned.

[28] Article 39, 4° of Directive 2014/24.

[29] S. ARROWSMITH, *The law of public and utilities procurement, regulation in the EU and the UK*, London, Sweet & Maxwell, 2014, 380-381.

Under article 33 of the Directive 2014/24, a framework agreement means 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[30].



Several contracting authorities can organize a framework agreement together.

The framework agreement could be organized centrally and provide for :

- lots per country/entity involved; if the contract is divided into lots per country, undertakings can choose the countries for which they want to submit a tender. This can be interesting for undertaking who are not active in the entire European Union, but only in one or a few countries.

- mini competitions per country/entity involved; the framework agreement under which Member States can organize mini-competitions allows them to apply the awarding criteria they find relevant to their purchases and to take their own awarding decision, with the preselected undertakings deriving from the award of the framework agreement; this two phases approach can however seem rather complex for economic operators who are not familiar with public procurement law. It is therefore important to explain this approach in a comprehensible way in the initial specifications of the framework agreement.

If economic operators believe or find the procurement procedure too complex and the chances of winning a substantial part of the assignment are too small, they might not participate. The focus of the procurement procedure should indeed not only be on how a cross-border procurement process can be organized, but also on how can a contracting authority persuade the market to submit tenders.

2.3.4 Particular questions on applicable law

[30] See, regarding framework agreements, article 33 of EU Directive 2014/24 and recitals 60, 61 and 62 of the Directive.

Many of the lawyers who contributed to our questionnaire (Austria, Belgium, France, Germany[31], Italy, the Netherlands, Poland) underline that when organizing a cross-border procurement procedure, it is necessary to clarify which law is applicable (for both the organization of the public procurement procedure and the implementation of the contract).

- **National law applicable for the organization of the public procurement procedure:**

A joint entity comprising several contracting authorities from different Member States[32], must, by a decision of the competent body of the joint entity, agree on the applicable national procurement rules of one of the following Member States:

- the national provisions of the Member State where the joint entity has its registered office;

- the national provisions of the Member State where the joint entity is carrying out its activities.

The first bullet, seems to imply that the joint entity has a registered office, which will often not be the case unless this would be required under national law. Besides, the joint entity could carry out its activities in several Member States.

- **National law applicable for the implementation of the contract:**

When organizing a cross-border procurement process, contracting authorities should be attentive to the law that will be applicable during the performance of the contract.

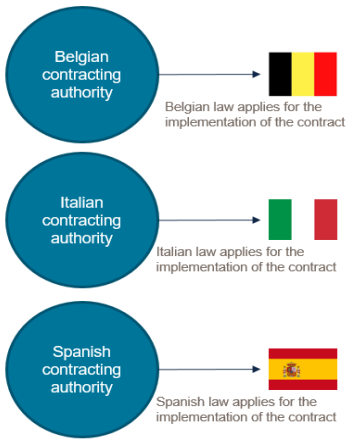
With regard to central purchasing bodies, the provision of centralised purchasing activities shall be conducted in accordance with the national provisions of the Member State where the central purchasing body is located.

The conduct of a reopening of competition under a framework agreement will also be conducted under the national provisions of the Member State where the central purchasing body is located.

In order to avoid any discussion, and because it is inconvenient for a contracting authority, part of a joint entity, not to be familiar with the law that will actually be applicable to the public contract, it seems, in our opinion, important to explicitly provide that the contract will be governed by the national law of the contracting authority for which the works, services or supplies are carried out. If a cross-border contract has several beneficiaries coming from different Member States, such clause will result in the following situation:

[31] Germany also mentions that according to the federal structure of the Federal Republic of Germany, there are public procurement regulations of the states, which include special provisions in individual sub-areas and may be alongside EU public procurement law. This has to be taken into consideration if the German contracting authority cooperating with the authority from another Member State is not a Federal entity.

[32] Including European Groupings of territorial cooperation under Regulation (EC) No 1082/2006 of the European Parliament and of the Council (1) or other entities established under Union law, the participating contracting authorities.



National law governing the implementation of contracts can be very different from country to country. Indeed, the EU Directives of 2014 mainly govern the award of the contracts and are transposed in all EU Members States. From our experience of sharing know how with lawyers from numerous Members States (and other countries like Switzerland and Norway), the national laws regarding the award of public contracts are in many aspects very similar. However, except for the rules on modification of contracts, the national laws on the implementation of contracts are specific to each State.

In Belgium for example, public contracts are governed by the Royal Decree of 14 January 2013, which is applicable even when its provisions are not mentioned in the specifications. This Royal Decree governs for example the payment terms, the penalties and fines, the liability of both parties, the acceptance of the works, supplies, services, etc. One should also be aware of particularities in other Member States. We note for example that, under French law, the contracting authority has the right to modify unilaterally the contract and even the right to unilaterally terminate the contract for grounds of public interests, even if it this is not stipulated under the contract.

Although the awarding of the contract can happen according to, for example, Dutch law, the contract can be governed by the laws of different Member States depending on which contracting authority the works, services and supplies are carried out for. This implies some difficulties as, for a same price for the same device, an economic operator could be confronted with multiple applicable national laws (with different regimes on delay fines, liability caps, termination possibilities, etc.).

2.4 The choice of the procurement procedure in the context of cross-border procurement

The choice of the award procedure can have a substantial impact on the course of the tender procedure, especially in the context of cross-border procurement.

The key differences between these procedures, their constraints and their advantages and disadvantages for the Project are summarized above, in section 1.3 of the present document.

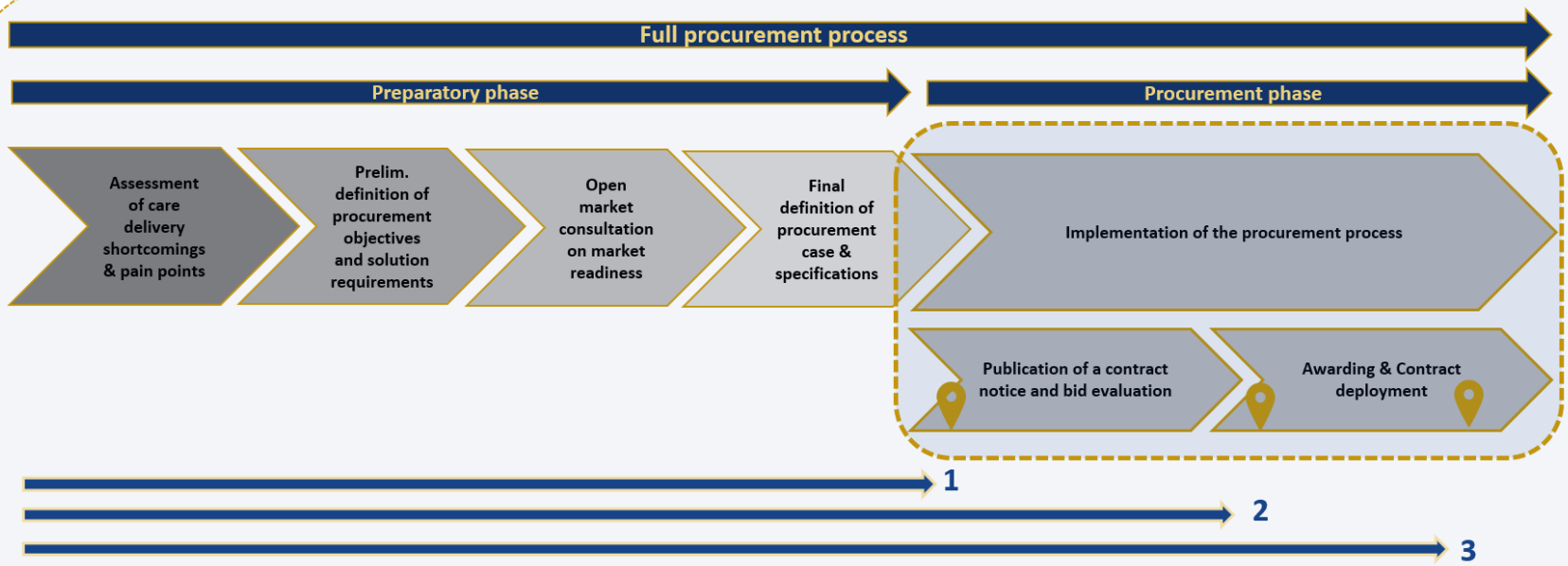
Hereunder, we discuss the choice of the procedure, taking the cross-border aspect into account.

During the Euriphi project, we identified 3 options to enable localized (distributed) decision making within a cross-border procurement project context.

- Full preparatory collaboration followed by the issue of individual local procurement procedures (Model 1);
- Full cross-border collaborative procurement with lots per locality (Model 2);
- Full cross-border collaborative procurement resulting in framework agreement(s) followed by specific contracts per locality (Model 3).

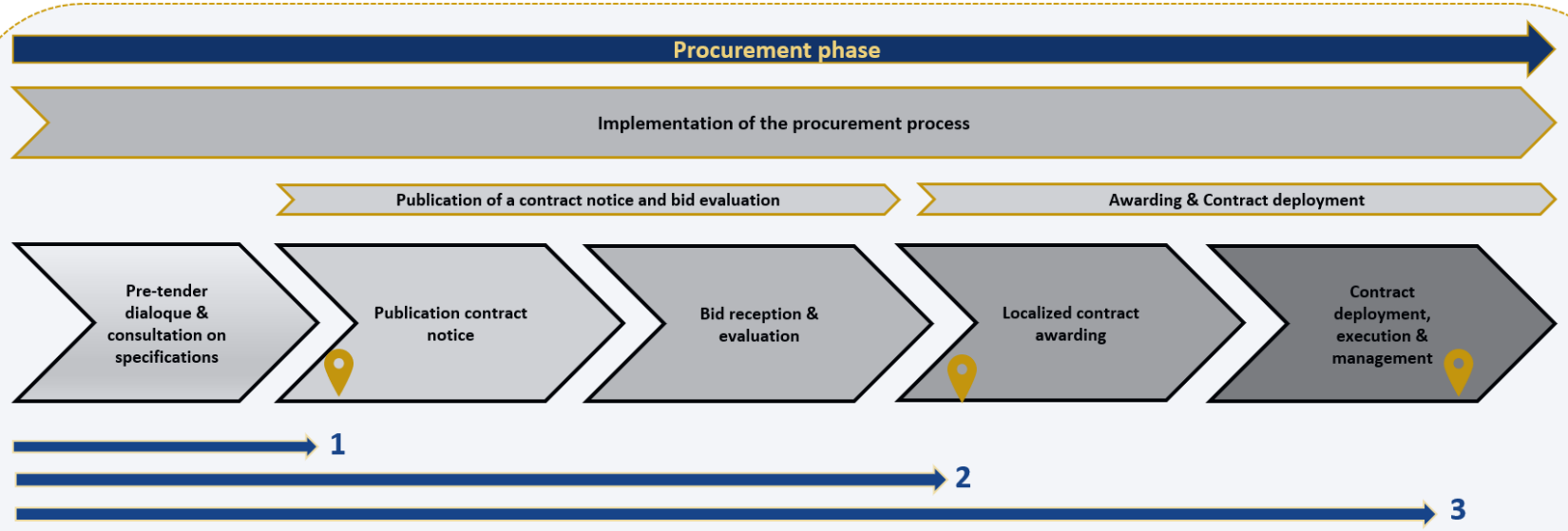
These three options are visually summarized on the next two pages.

‘Cross-border collaborative procurement model’ enabling local decision making (1)



- **Model 1**: **Full preparatory collaboration followed** by the issue of **individual local procurement procedures**
- **Model 2**: **Full cross-border collaborative procurement** having **lots per locality**
- **Model 3**: **Full cross-border collaborative procurement** resulting in **framework agreement**(s) followed by **specific contracts per locality**

‘Cross-border collaborative procurement model’ enabling local decision making (2)



- **Model 1**: Full **preparatory collaboration** followed by the issue of **individual local procurement procedures**
- **Model 2**: Full **cross-border collaborative procurement** having **lots per locality**
- **Model 3**: Full **cross-border collaborative procurement** resulting in **framework agreement**(s) followed by **specific contracts per locality**

The three different Models have different advantages and disadvantages:

MODEL 1: ***Full collaboration in the pre-tender phase, followed by individual local procurement procedures organised by the different contracting authorities concerned***

The advantages?	The disadvantage?
(i) More resources to undertake the preparatory work, (ii) contracting authorities can adapt according to their desires and (iii) no questions regarding the liability or national law application	The individual contracting authorities still have to take the initiative to organise/launch the procurement procedure

MODEL 2: ***Full cross-border collaborative procurement procedure with lot(s) per entity/country***

The advantages?	The disadvantages?
(i) A different contractual regime can be provided per lot, so that no questions arise regarding the liability or application of national law during the implementation of the contract and (ii) no exclusion of economic operators who are not active in all of the different Member States concerned	(i) An increase of the administrative burden for both the contracting authority and the economic operators (including, for the contracting authorities involved, the conclusion of a contract determining their ways of collaboration, liability during the award phase, application law for the award procedure, language, etc.) and (ii) organizing a procurement procedure with several lots per country can be rather complex (regarding the application of discounts when awarding several lots for example; + the contractual terms of the different lots – to be included in the tender documents – will differ from country to country in function notably of the national legislations)

MODEL 3: ***Full cross-border collaborative procurement resulting in framework agreement(s) followed by specific contracts per entity/country***

The advantages?	The disadvantages?
(i) When organising mini-competitions, a contracting authority can make adjustments (this should however be foreseen in the initial procurement documents of the framework) and (ii) different contractual regimes can be provided per lot, so that no questions arise regarding the liability of the different entities during the implementation of the contract or application of national law for the implementation of the contract	(i) An increase of the administrative burden for both the contracting authority and the economic operators (including, for the contracting authorities involved, the conclusion of a contract determining their ways of collaboration, liability during the award phase, application law for the award procedure, language, etc.) and (ii) it can be rather complex as most of the modalities of the award of the mini competitions have to be anticipated in the initial framework agreement tender documents,.

In the following scheme, we describe the procedure that would be the most suitable for each of the described models[33]:

Procurement procedures	Model 1: Full preparatory collaboration & issue of individual local procurement procedures	Model 2: Full cross-border collaborative procurement and lots per locality	Model 3: Framework agreement(s) followed by specific contracts per locality
Open Procedure (OR)	✓	✓	✓
Restricted Procedure (RP)	✓	✓	✓
Competitive Procedure with Negotiation (CPN)	✓	✓	-
Competitive Dialogue (CD)	✓	✓	-
Innovation Partnership (IP)	✓	-	-
PCP / PPI (PCP per locality / PPI distributed awarding)	✓	-	-

[33] Please note that the table underlines the *most suitable* procedure per option; this does not mean that other procedures are not legally possible or justifiable; just that we do not especially recommend them or do not see a specific base justifying the concerned specific procedure for this option.