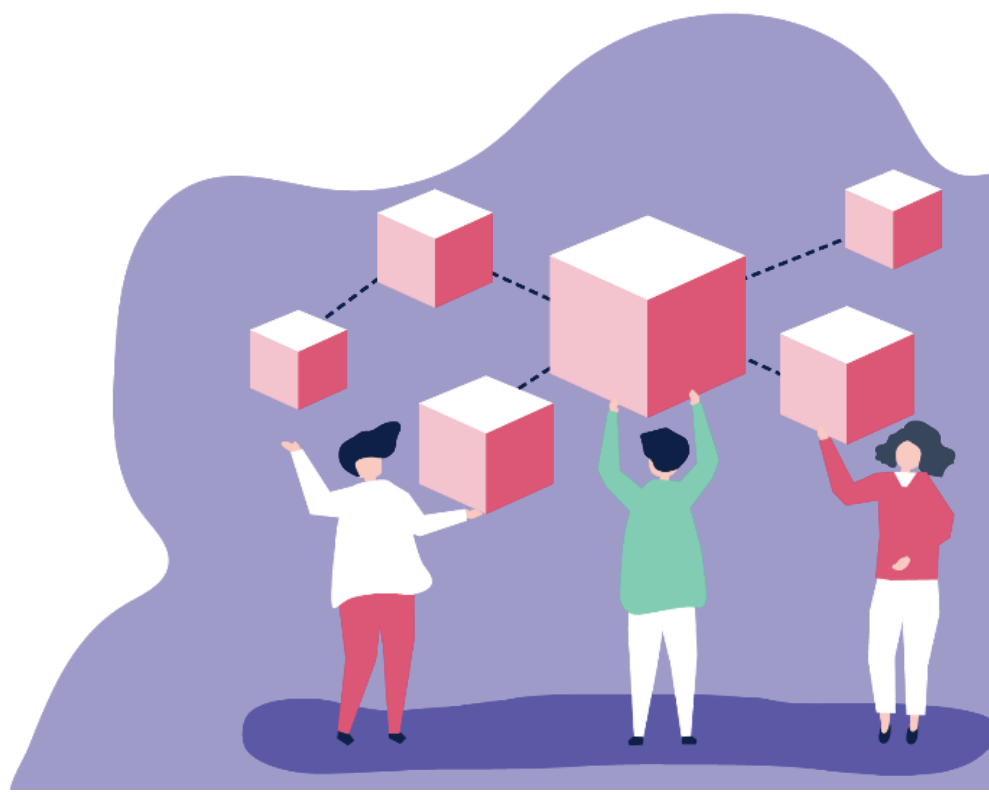




# GATE KEEPER

## D8.5 Initial Plan of the Overall Governance for Procurements

<b>Deliverable No.</b>	D8.5	<b>Due Date</b>	30/September/2021
<b>Description</b>	Analysis of the status of the EU PPI in Healthcare, barriers, best practices, and framework for the definition of GK solutions procurement		
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## Abstract

This document is the first of the two deliverables that are going to be produced under **task 8.4 Governance for Procurements**. In this first deliverable, the authors have analysed the current status of the Public Procurement of Innovation in Europe, focusing on the legislation, ongoing European initiatives in the field, practical examples and experience in the execution of these kind of procurements among the different healthcare authorities involved in the GATEKEEPER consortium.

The main conclusions extract from this document will be used as a point of discussion among the key stakeholders involved in the PPI value chain that will participate in the upcoming focus groups and co-creation workshops that will take place between end of 2021 and mid 2022 in the context of task 8.4. The ultimate objective of these activities is to **define the guidelines and framework for the Procurement of the GATEKEEPER solutions**.

## Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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## Glossary

Table 1. Acronym glossary

ACRONYM	DEFINITION
<b>BCG</b>	Boston Consulting Group
<b>CIO</b>	Chief innovation Officer
<b>CMO</b>	Chief Medical Officer
<b>CNO</b>	Chief Nursering Officer
<b>COI</b>	Community of Interest
<b>COP</b>	Community of Practice
<b>CSA</b>	Coordination and Support Action
<b>DHCW</b>	Digital Health and Care Wales
<b>DHCW</b>	Digital Health and Care Wales
<b>EAFIG</b>	European Assistance for Innovation Procurement
<b>EPPU</b>	Expenditure and Procurement Policies Unit
<b>EU</b>	European Union
<b>EURIPHI</b>	European wide Innovation Procurement in Health and Care
<b>GK</b>	GATEKEEPER
<b>HC</b>	Healthcare
<b>HSPPA</b>	Hellenic Single Public Procurement Authority
<b>ICT</b>	Information and Communications Technology
<b>KPI</b>	Key Performance Indicator
<b>MEAT</b>	Most Economically Advantageous Tendering
<b>MS</b>	Milestone
<b>N/A</b>	Not Applicable
<b>NHS</b>	National Health System
<b>OMC</b>	Open Market consultation
<b>PCP</b>	Pre-Commercial Procurement
<b>PiPPi</b>	Platform for Innovation of Procurement and Procurement of Innovation
<b>PLN</b>	Polish złoty

<b>PPD</b>	Public Procurement Directorate
<b>PPI</b>	Public Procurement of Innovation
<b>R&amp;D</b>	Research and Development
<b>SBRI</b>	Small Business Research Initiative
<b>SBRI</b>	Small Business Research Initiative
<b>SDR</b>	Special drawing rights
<b>SFIs</b>	Standing Financial Instructions
<b>SFIs</b>	Standing Financial Instructions
<b>SME</b>	Small and Medium Enterprise
<b>SMTL</b>	Surgical Materials Testing Laboratory
<b>SSP</b>	Shared Services Partnership
<b>SSP</b>	Shared Services Partnership
<b>VBHC</b>	Value based Healthcare
<b>VBP</b>	Value-based procurement
<b>WTO</b>	World Trade Organization

# 1 About this Deliverable

This document has been developed for **WP8 – Standardization and certification mechanisms** under **Task 8.4 Governance for procurements**. One of the main objectives of this WP is to develop and specify a model of procurement process for the outcomes of the GATEKEEPER platform.

Aligned with this overall WP objective, Task 8.4's major aim is to define and implement a co-creation process involving different stakeholders to enable the procurement of the innovative services and solutions facilitated by the GATEKEEPER platform for European Healthcare Authorities. This will be done by developing the following activities:

- Analysis of the status of the EU Public Procurement of Innovation (PPI) in healthcare
- Barriers and best practices in PPIs
- Legal framework of PPIs
- Definition of a common methodology and guideline for the procurement of GATEKEEPER solutions

Public Procurement of Innovation is one of the pillars of the GATEKEEPER exploitation and sustainability because, as we can see under section **Error! Reference source not found.**, the acquisition of the GATEKEEPER services and solutions by public Health & Care Agencies, such as hospitals and regional authorities, can only be done following the country legal regulations of public procurement.

The scope of this deliverable is to analyse the current state of the art of the Public Procurement of Innovation in Europe taking in consideration the current legislation (section 2), ongoing initiatives (section 3.3) and examples of published PPIs (section 4.2). All this information, in addition to the feedback received from the different healthcare authorities involved in the GATEKEEPER project on their experience in these kinds of procurements (section 5.2 and 8), will help as to lay the basis for the preparation of the focus groups and co-creation workshop for the ultimate task goal of defining the PPI guidelines for the procurement of the GATEKEEPER solutions.

Throughout this document, we have focused on the analysis of the current situation of public procurement in the countries in which GATEKEEPER is developing their pilot sites. This selection has been done because, as members of the GATEKEEPER project, these countries will be first users of the GATEKEEPER services and solutions, they will be what we call *early adopters*, and therefore, we will be able to analyse hand to hand with them how they are currently purchasing these innovative solutions and which are the barriers and current best practices that we can incorporate to the guidelines that will be produced during the execution of task 8.4.

The work that is being done under this task 8.4 is closely related with *task 2.1 Ecosystem Management, Enlargement and Collaboration with other Initiatives* – collaborating in the ecosystem definition and Community of Interest – and *task 9.3 GATEKEEPER Exploitation, Business and Sustainability* – contributing to the exploitation and future sustainability of the GATEKEEPER platform.

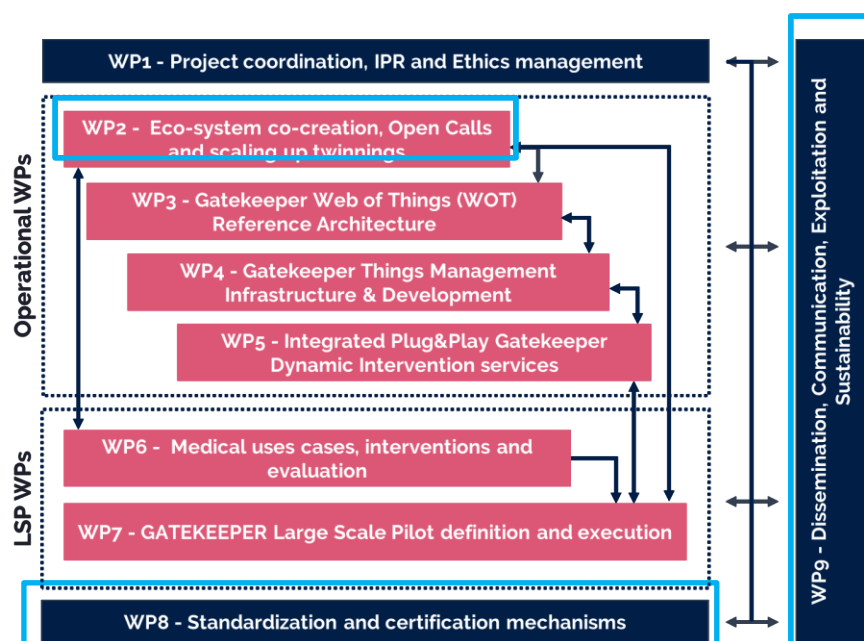


Figure 1. Relation with other WPs

## 1.1 Deliverable context

Under the following table, it is shown the relation of D8.5 with the overall expected outcomes.

Table 2. Deliverable context

PROJECT ITEM	RELATIONSHIP
Objectives	This deliverable is directly contributing to meet <i>Og: Impact Framework Available for key decisions</i> , as this document is setting the basis of the public procurement framework for the acquisition of the GATEKEEPER services and solutions from the HC authorities.
Exploitable results	This deliverable and its next version are going to contribute to develop a methodology for the Procurement of the GK solutions.
Workplan	D8.5 is attributed to the WP8, Standardization and certification mechanism. The task involved in the preparation of this deliverable is T8.4 Governance for procurements
Milestones	D8.5 is contributing to the overall GATEKEEPER sustainability that will be one of the key activities to be achieved on <i>MS5, LANDING</i> phase of the project.
Deliverables	D8.5 is performing an analysis of the status of the EU PPI in Healthcare, identifying its barriers, best practices, and framework for the definition of GK solutions procurement.
Risks	There is no foreseen related risk to this deliverable/task

## 2 Legal framework and definition of the Public Procurement

With regard to Public Procurement (acquisition of works, goods and services by Public Administrations), we can find an important legislative framework that defines the procedures to carry out and materials to be used in these initiatives. This chapter will describe the European Directive on Public Procurement and its transposition in each of the EU member countries present in GATEKEEPER, as well as the legislation in force in the non-EU countries present in the consortium. Likewise, the most frequent models of public procurement nowadays will be commented.

### 2.1 Legal Framework

#### 2.1.1 European Directives in Public Procurement

The first European rules dealing with public procurement are:

- Directive 2004/18/EC of the European Parliament and European Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts and
- Directive 89/665/EEC of the European Council 21 December 1989 on the coordination of the laws, regulations and administrative provisions relating to the application of review procedures to the award of public supply and public works contracts

In 2014, the European Parliament and European Council adopted Directive 2014/24/EU on public procurement, transposed into national law in the EU member states.

This Directive created a more flexible framework for public procurement with the aim of using instruments that enable smart, sustainable and inclusive growth, ensuring the most efficient use of public funds. In addition, it positions research and innovation as one of the main drivers of future growth. [1] .

In this respect, one concept included in this Directive was the European "most economically advantageous tender" (MEAT) principle. The European Union legislation promotes a methodological framework for making use of the Best Price to Quality Ratio (BPQR), with which to boost innovation, while taking into account the costs including the price of procured goods, services and solutions [2].

On the other hand, an important element of Directive 2014/24/EU is the defence of the SME sector. Contracting Authorities are encouraged to make use of the "European Code of Best Practices Facilitating Access by SMEs to Public Procurement Contracts" and to divide large contracts into lots to improve competition in two areas: (i) quantitatively, to match the size of the contract to the operational capacity of SMEs; and (ii) qualitatively, so that lots are tailored to SMEs specialised sectors [1].

Also, in this Directive there are concepts indicated such as Joint Procurement, the process by which different buyers from different Member States join together, in a single process, with the objective of increasing volume and obtaining better prices or access to [2].

In addition, the EU promotes the adoption of Artificial Intelligence in the public sector, by preparing an "Adopt AI programme". This and other actions in order to boost AI can be found in the White Paper On Artificial Intelligence - A European approach to Excellence and trust [3].

Finally, this Directive should consider the United Nations Convention on the Rights of Persons with Disabilities when choosing means of communication, technical specifications, award criteria and contract conditions. In fact, contracting authorities have the possibility to exclude economic operators which violate rules on accessibility for disable people [1].

## 2.2 Types of Public Procurement

Public procurement is the purchase by governments or public entities of a country of goods and services. Innovation and public procurement are closely linked.

The most common public procurement models include the following ones:

- Open tender: It is the main tendering procedure and allows anyone to submit a tender to supply the goods or services required and offers an equal opportunity to any organization to submit a tender. The main requirements are to be open to all interested bidders, advertised at an appropriate level, clear technical specifications and clear evaluation criteria [4].
- Low-value contracts: It occurs when a procurement does not exceed a certain quantity (established usually by each national regulation), thus simplified rules apply. Based on EU, the tender should not be valued more than between €15,000 and €144,000.
- Negotiated purchase: It occurs when a contracting authority approaches a single supplier based on their track-record or a previous relationship. The terms of the contract are then negotiated [5].
- Accelerated public tender: It is considered as an Open Tender, but with accelerated timeframes, used in states of urgency [6].

According to the OECD, innovation has become a recurrent strategy pursued by public authorities. Moreover, between 2010 and 2012, between 14% and 36% of companies that had participated in public procurement processes reported having included innovation elements in their procurement strategies.

Despite this, and according to the OECD, public procurement and innovation are not fully aligned at the moment, although it is recognised that Contracting Authorities are gradually including more strategies and initiatives to boost innovation and SMEs' participation, as indicated in section 2.1 of this [7].

In this regard, the European Commission's vision for innovation procurement includes two different initiatives, as detailed below (see Table 3):

- Pre-Commercial Procurement – PCPs: The co-development of innovative solutions through the procurement of research and development services. PCP is used when there are not solutions that meet the needs and requirements of the payers nor close to be launched to the market, so R&D alternatives have to be developed. One of the benefits of PCPs is the reduction of the risk of acquiring innovative solutions, as they are designed, prototyped and developed in real time. [8] [9].
- Public Procurement of Innovative solutions – PPIs: The procurement of innovative solutions that do exist and are in their final stages of creation but are not yet widely available on the market. This initiative is undertaken when there is evidence that there are early adopters willing to purchase the innovative solution [10][11].

Below is a table comparing the two procurement of innovation frameworks [8]:

Table 3. Comparative table between PCP and PPI

PCP vs PPI		
	PCP	PPI
What?	Public Administrations buy R&D according to their needs.	Public Administrations act as an early adopter or first buyer of solutions that are very close to the market or have just arrived
When?	The problem is clearly defined, but the pros and cons have not been compared or validated	There is no R&D involved and a solution is required around market entry without large-scale implementation
How?	R&D is purchased from several suppliers, to compare their performance and impact	Public sector acts as a facilitator for the industry to scale up its production.

## 2.3 The Procurement Landscape across Europe

The European Directives in Public Procurement have different transpositions on the different countries. Hence, under the following subsections, we have done a first analysis on the situation of the Public Procurement policies and its process in the different countries in which GATEKEEPER is developing its pilot sites. The selection of those countries has been because, as members of the GATEKEEPER project, these countries will be first users of the GATEKEEPER services and solutions (the early adopters) and therefore, their state of the art of the procurement landscape will help us to understand how their situation can foster or not the acquisition of those services and solutions in their regions.

### 2.3.1 Spain

European Directive 2014/24/EU is mainly transposed in Law 9/2017, of 8 November, on Public Sector Contracts, which replaced Royal Decree-law 3/2011, of 14 November, approving the Consolidated Text of the Public Sector Contracts. Two other important laws concerning public procurement in Spain are: Law 14/2011, of 1 June, on Science, Technology and Innovation; and Royal Decree 3/2020, of 4 February, on urgent measures transposing into Spanish law various European Union directives in the field of public procurement in certain sectors; private insurance; pension plans and funds; taxation and tax litigation. Following Royal Legislative Decree 3/2011, the MEAT criterion was established. However, the basic and sole award criterion was usually based exclusively on the price. For this reason, Law 9/2017 introduced the reference to the best Price-quality ratio, emphasizing the conceptual swift.

This national legislation is further developed at regional level, as the Spanish public procurement system is decentralized among 17 regions and 2 autonomous cities with contracting authorities at all levels. However, Ministry of Science and Innovation, through



the General Secretariat for Innovation, is the body responsible for the provision of funding for innovation procurement projects under the European Structural and Investment Funds (ESIF). The Centre for the Development of Industrial Technology (CDTI) is the national competence centre for public procurement of innovation, together with Carlos III Health Institute (ISCIII) and the National Institute for Aerospace Technology (INTA). The public bodies, although they do not usually consider allocation of resources for public procurement of innovation as part of their budgets, do support work on different public procurement of innovation projects funded by the European Regional Development Funds (ERDF).

### 2.3.1.1 The procurement process in Madrid - SPAIN

As explained in section 2.3.1, the Spanish national public procurement system is decentralized among 17 regions and 2 autonomous cities. One of these regions, the Community of Madrid, is committed to the Public Procurement of Innovation (PPI) as one of their strategic lines. The Regional Ministry of Health specifically contemplates the implementation of PPI procedures to develop and incorporate new products and services to improve the quality of care.

*The Consejería de Sanidad de la Comunidad de Madrid, through the Dirección General de Investigación, Docencia y Documentación, is in charge of promoting and leading the PPI in the healthcare sector, developing innovative projects to achieve new products and services that increase the efficiency and effectiveness of healthcare services.*

With this aim, the Community of Madrid envisions the PPI as a strategic instrument to cover 5 main objectives:

1. **Development of the business sector:** The procurement is mainly aimed at fostering the participation of companies in the bidding process, especially SMEs and innovative start-ups.
2. **Attraction of investment and large companies:** The procurement encourages reference large companies in their sector to participate and commit investments in the Community of Madrid.
3. **Cultural change of the Public Sector:** The aim is to integrate innovation into the daily dynamics of public administrations.
4. **Procurement of goods and services:** The procurement is focused on meeting the needs of the public administrations at the best cost/benefit ratio.
5. **Innovation in Public Service:** The procurement seeks to incorporate innovations that improve service delivery, even though this may entail a higher initial investment.

The PPI is conceived as a cycle that goes from the definition of the strategy to the execution of the project; aligned with the international best practices fostered by the European Commission [12]

This model, defined in 6 different steps, responds to the need of sequencing the necessary actions to get from the design of the intervention to its implementation but, above all, to solve the potential successive problems to be faced by the different agents involved: the political decision-maker, the technical manager of a public service (who is the "owner of the need), the project's financier (often an innovation agency different than the procuring entity), the contracting manager, the contracting officer (accompanied by the legal and budgetary controller) and the potential supplier companies.

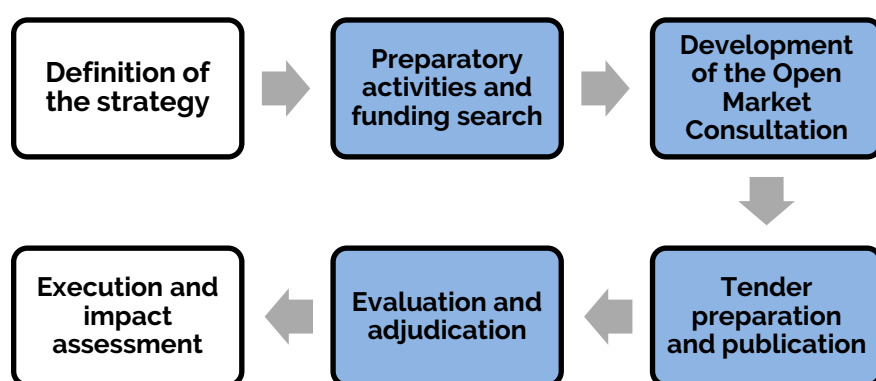


Figure 2. PPI stages in the Comunidad de Madrid Region, Spain

1. **Definition of the strategy:** first step is to define the objectives in order to design the instruments accordingly. It is also understood that the nature of the "owner" of the policy determines to a large extent the strategy.
2. **Preparatory activities and funding search:** this step refer to all the related necessary activities prior to starting the project. The most important is **training**. Before undertaking new procurements, a training program has to be performed to cover the legal and budget control services. These trainings not only set the basis for future projects, but it is also essential for cultural change and to overcome prejudices. Other key activity in this step is to **define the unmet challenges** and create a list of potential projects. There are various techniques and approaches for this, the most recommended is involving the "need owners" and, when possible, the citizens who are users of public services.
3. **Open Market Consultation:** this process is where the procurer dialogues with the market, starting from the identified challenge, with the aim of obtaining the necessary information for the procurement process in an efficient way, balancing the interests of the institution with those of the potential suppliers.
4. **Tender preparation and publication:** one of the key aspects of this step is the validation of the tender by the legal services. Madrid City Council has created PPI tender templates covering key recurrent aspects such as IP management, that have been validated and approved by their legal teams. These templates have enabled to speed up the process of the PPI tender publication, making possible to publish 8 PPI tenders in 2018.
5. **Evaluation and adjudication:** for this step, it is crucial to ensure transparency before the submission of tenders indicating the timeline and awarding criteria.
6. **Execution and impact assessment:** In the case of PPIs, provider company must develop a solution hand in hand with the public procurer, who is the real owner of the project, and under the provisions of contracting law. These PPIs tend to be long period contracts, between 1 and 4 years, so robust management methodologies have to be applied.

### 2.3.2 Italy – Puglia Region

The European directive 2014/24/EU at national level is implemented by the **Legislative Decree of 18 April 2016** which replaced the Code of Public Contracts issued on 12 April 2006 which implemented the two European directives 17 and 18 of 2004. The new decree allowed for the regulation of the adjudication of concession contracts, public tenders and procedures procurement by supplying entities in the water, energy, transport and postal

services sectors, as well as for the reorganization of the regulations in force on public contracts relating to works, services and supplies.

Among the objectives of the new code there are:

- make the **use of public funds more efficient** through procedures based on simplification, flexibility and fairness fees.
- guarantee the **European dimension** of the market for public contracts for works, services and supplies, ensuring the protection of competition, prohibiting discriminatory practices, also protecting small and medium-sized enterprises.
- make strategic use of public procurement as an economic and social policy tool, **promoting innovation**.
- promote the fight against corruption through **simple and transparent procedures**, removing regulatory uncertainties.
- have **innovative and flexible adjudication tools**, such as the partnership for innovation and a wider use of competitive dialogue.
- support the use of **electronic negotiation** and adjudication tools.

Other regulations have been issued both at national and regional level such as:

- the **Law on the Consolidation of the role of Regional Purchasing Centres** (Law no. 296 of 27 December 2006).
- the **Digital Administration Code** (Art. 1, Paragraphs 449-458), Legislative Decree 7 March 2005, n. 82 (updated to Law no.147 of 27 December 2013).
- laws on urgent interventions in health expenditure such as the **Decree promoting the adhesion of health and hospital Trusts to the Consip conventions** (Legislative Decree 18 September 2001, no. 347 converted, with amendments, by Law no. 405 of 16 November 2001).
- agreement concerning the activities of InnovaPuglia S.p.A. as an **"Aggregator" of the Puglia Region** (Regional Council Decree n. 1385 of 2 August 2018).

### 2.3.2.1 The procurement process in the Puglia Region – ITALY

Within the service market, the Procurement Code based on the Directive 18/2004/EU has codified the figure and role of central purchasing bodies.

The European Community impulse was followed by the rapid start of the process of implementing the **network system** regulated by national law, operated by means of an agreement reached at the State-Regions Conference. In order to contain and rationalize public spending for procurement and to consolidate entities already operating in the territories, the Italian regions have thus been able to set up purchasing centres operating on the model outlined by the Procurement Code.

A **central purchasing body** is a contracting authority that purchases supplies and/or services intended for contracting authorities or awards public contracts or concludes framework agreements for works, supplies or services intended for contracting authorities.

The **Aggregator** is a qualified purchasing centre for the aggregate provisioning of goods and services on behalf of the Public Administration.

Based on the legislative references described in the previous section (Regional Council Decree n. 1385 of 2 August 2018), the Puglia Region has designated **InnovaPuglia S.p.A** as the Regional Aggregator; the decree allowed for the implementation of a procurement centralization project that would involve, in addition to health care, also various areas of regional activities, whose digital platform has taken the name of **EmPULIA**.

EmPULIA integrates:

- services for the **management of the regional system of Conventions** with the possibility of issuing orders starting from the relative published catalogues (electronic shop).
- services for the management of the **dynamic purchasing system**.
- services for the **unified management of the online Register of Suppliers** for goods, services and works.
- services for the **fully telematic management of tender procedures** (open, restricted and negotiated, both above and below the EU threshold) with adjudication criteria based on the lowest price or the most economically advantageous offer.
- services for the **publication on the EmPULIA portal of tenders carried out in traditional mode** (paper tenders) with archiving and search functions for all tender documentation.

The **Dynamic Acquisition System** is an entirely electronic process of purchasing goods, services and works, open for the entire period of its validity to any economic operator requesting admission.

The dynamic system consists of a two-phases procedure:

- **Phase 1** - publication by the Aggregator of a call for proposals for one or more product categories to which suppliers can request admission.
- **Phase 2** - calling and adjudication of specific contracts in which, having defined the quantities, the value and the specific characteristics of the contract, all the participants admitted submitting a proposal are invited according to the rules of the restricted procedure

In detail, the process initially provides that all candidates admitted to the system at the date of the call for the specific contract are invited to submit a specific offer in relation to the product category of admission under the SDA. At the same time, a **Selection Committee** is defined whose members have no type of bond or relationship with one of the participants in the call.

At the expiry of the terms established in the call, all the offers received by the Selection Committee are opened and presented. The latter meets in session and evaluates through a predefined template which shows a series of **characteristic/score pairs** which offer is most appropriate to the supply. If at least one of the offers has exceeded the minimum required score, the successful bidder is established, otherwise a new call is made.

### 2.3.3 Greece

European Directive 2014/24/EU is mainly transposed in Law 4412/2016 on public sector contracts, which was recently revised by Law 4782/2021 with the aim of clarifying and simplifying several articles, expanding the use of electronic tools (e-procurement) and improving the effectiveness of tendering procedures.

Public Procurement of Innovation (PPI) has not been defined in the Greek legal framework yet, but the above laws provide the legal basis to implement it. A definition of PPI and a description of its procedural framework are provided in a technical guidance document published by the Hellenic Single Public Procurement Authority (HSPPA) on the 10<sup>th</sup> September 2018 (in Greek): [13].

### 2.3.3.1 The procurement process in Greece

According to the Guidance note on Innovation Procurement by the Hellenic Single Public Procurement Authority on 7/9/2018, PPI procedures are usually activated after the completion of PCP procedures, though not exclusively. In any case, they follow the regulatory framework of the Directives on public contracts, therefore:

- For the preparation of the invitation to tender, articles 40-47 of the Directive 2014/24/EU and articles 58-66 of the Directive 2014/25/EU are applied. This stage includes market consultation, search on confidentiality and intellectual property rights aspects and then the selection of the tendering process to be followed, the subject of the contract, the technical specifications, and the exclusion and supplier selection criteria.
- For the publication of the invitation to tender, the necessary supporting documents of the submitted offers and in order to ensure transparency, articles 48-55 of the Directive 2014/24/EU and articles 67-75 of the Directive 2014/25/EU are applied.
- For the selection of the supplier and for the contract signing, articles 56-69 of the Directive 2014/24/EU and articles 76-86 of the Directive 2014/25/EU are applied.
- For the monitoring of the execution of the contract, articles 70-73 of the Directive 2014/24/EU and articles 87-90 of the Directive 2014/25/EU are applied.

Given the above framework, it is crucial for the procurer to select the tendering process to be followed. This decision is based on the information collected in the preparation phase, specifically during the preparatory market consultation phase.

It should be noted that in Greece innovation procurement is at an early stage and with essential developmental elements still pending, so only few procurers and in specific sectors (i.e. defense, national security) have already implemented it.

Greece's national competence centre for innovation procurement, which will contribute towards promoting it, is to be established under the country's Ministry of Development and Investment; specifically, under the General Directorate for Public Procurements (which is the national central purchasing body responsible for supplies and services). The centre will mainly aim to expand innovation procurement practices within the Greek public sector, but also has more specific objectives. The current Greek Competence Centre website is [14].

Actions to develop a framework for innovation procurement and PCP in the digital policy area are also envisaged in the National Digital Strategy 2016-2021. The strategy, prepared by the General Secretariat for Digital Policy of the Ministry of Digital Policy, Telecommunications and Information, reports in its Priority 4.1 "Support for research and development Research Technological Development (ETA)" and includes among its objectives: "a framework for the procurement of innovative services and pre-commercial procurement" as shown in [15] (in Greek).

### 2.3.4 Cyprus

EU Directives have been transposed into Cypriot Law via several acts. Directive 2004/18/EC and Directive 2004/17/EC have been respectively transposed by Law 12(I) of 2006 governing procurement of public works, public supply and public service, and Law 11(I) of 2006 regulating procurement procedures of entities operating in the water, energy, transport and postal services sectors. In addition, defense and sensitive security procurement are regulated by the Law 173(I) 2011, which transposed Directive 2009/81/EC. Review procedures concerning the award of public contracts are regulated by the Law 104(I)/2010 which transposed Directive 2007/66/EC.

EU procedures are followed below threshold as well as above for all contracts of value of 50,000 and more, with the one exception that publication to the Official Journal of the EU is not mandatory. Below EUR 50,000, there are a series of increasingly simplified procedures based on value. For contracts whose value does not exceed EUR 2,000, direct award is allowed. For contracts between EUR 2,000 and EUR 15,000, the contracting authorities may invite only a restricted number of economic operators to bid. For contracts below EUR 50,000 the contracting authority may award a contract without prior publication provided that it has invited at least four tenderers and given reason for such choice.

Cyprus has a decentralised public procurement system with a single administrative body at the State level and around 700 contracting authorities at the State and local levels responsible for their own procurement. The Public Procurement Directorate (PPD) within the Cyprus Treasury is the single centralised body responsible for all matters regarding public procurement in Cyprus. It is responsible for drafting public procurement legislation and ensuring its proper implementation. It supports contracting authorities for proper implementation of the procurement rules through circular guidance and continuous training. Its management board is also entitled to carry out checks upon contracting authorities to ensure compliance with procurement law. It also issues compliance certificates to contracting authorities for some projects whose value is below the EU thresholds.

In addition to the PPD, two other bodies oversee public procurement in Cyprus. First, the Audit Office of the Republic of Cyprus is an independent body which performs external controls of the execution of the national budget. It audits all the public funded activities, including public procurement documents, procedures and award decisions. It publishes its findings in an annual report but does not have the authority to issue sanctions or to launch judicial proceedings. It can notify the Attorney General of violations in the procurement area, who has the authority to commence judicial proceedings where in his opinion there is a legal issue. Second, the Internal Audit Service of the Republic of Cyprus conducts internal audits of Cypriot public organisations and EU-funded programmes, including public procurement procedures. Appeals regarding procurement decisions and practices can be lodged with the independent Tenders Review Authority (TRA) of Cyprus, which is charged with maintaining equal treatment, transparency and non-discrimination in the procurement process. Prior complaint to the contracting authority itself is a precondition for judicial review. The TRA has the authority to cancel or amend award decisions. The decisions of the TRA may be challenged before the Supreme Court, which can grant damages to aggrieved bidders.

#### 2.3.4.1 The procurement process in Cyprus

The field of public procurement in Cyprus is regulated by the Law for the adjustment of procurement procedures and related subjects (N. 73(I)/2016) and the Law on procurement by entities operating in the water, energy, transport and postal services sectors



(N.140(I)/2016) transposing the Directives 2014/24 and 2014/25/EU respectively. Law 173 (I)/2011 regulates the procedures for the award of public contracts in the defense and security sectors transposing the EU Directive 2009/81/EU.

The public procurement system has a decentralized approach since contracting authorities/entities are responsible for their own tenders, even though the Competent Authority for Public Procurement and review body are centralized at the State level. Cyprus has a decentralised public procurement system with a single administrative body at the State level and around 700 contracting authorities/entities at the State and local levels.

The Public Procurement Directorate (PPD) of the Treasury of the Republic of Cyprus is the single Competent Authority for Public Procurement responsible for all matters regarding public procurement in Cyprus. It is responsible for drafting public procurement legislation and ensuring its proper implementation. It is also entitled to carry out checks upon contracting authorities/entities to ensure compliance with procurement law. Additionally, it is competent for policymaking in the field of public procurement, and it provides assistance to contracting authorities for proper implementation of the procurement rules through guidance and training.

In Cyprus, there is an official definition for R&D procurement, while the legal framework only provides a legal basis for "innovation procurement", "Pre-Commercial Procurement" (PCP) and "Public Procurement of Innovative solutions" (PPI).

There is no definition of "innovation procurement" in Cyprus. However, the Law for the adjustment of procurement procedures and related subjects of 2016 defines innovation in its introductory provisions (Chapter 1, Article 2.1) as "the realisation of a new or significantly improved product, service or process, including but not limited to production, building or construction processes, new marketing methods or new organizational methods to business practices, workplace organization or external relations , inter alia, to contribute to addressing societal challenges or supporting the Europe 2020 Strategy for smart, sustainable and inclusive growth". This definition is applicable countrywide and coherent with the EU definition.

A definition of R&D is only provided in the Law 173 (I)/2011 that transposes the Defence and security Directive 2009/81/EU. Part I (Introductory provisions) provides a definition of Research and development "as all the activities involved basic research, applied research and experimental development, where the latter may include the implementation of technological demonstration projects, that is to say devices that will demonstrate the performance of a new method or technology to relevant or representative environment". This definition is only applicable in the defence sector (i.e., not countrywide) and is in line with the EU definition. The Law for the adjustment of procurement procedures and related subjects of 2016 identifies in Chapter 3, article n. 18 (Special cases section) R&D as "activities that have the CPV codes for fundamental research, applied research and industrial development". This article also transposes the exclusion for R&D services, which forms the legal basis for implementing in PCP, namely: "the law only applies to R&D services procurements following the cumulative conditions of "(a) products belong exclusively to the contracting authority for its own use at pursuing its activity; and (b) the service is wholly remunerated by the contracting authority". Therefore, no definition exists, but there is a legal basis which is applicable to all public procurers in the country.

A PPI definition is not available in the legal framework, and neither present in any policy document or guideline. However, the Law for the adjustment of procurement procedures and related subjects (2016) provides the legal basis to implement PPI (allowing procurers to award contracts and monitor contract performance not only based on price but also based on innovation criteria). In particular, article 76 (2) states that "contracting authorities

may take into account the need to safeguard its quality, continuity, accessibility, affordability, accessibility availability and completeness of services, the specific needs of the various categories of users, including disadvantaged and vulnerable groups, involvement and empowerment of users and innovation". Therefore, no definition exists, but there is a legal basis which is applicable to all public procurers in the country.

Public procurement and entrepreneurship policies are the areas in which is currently present a reference to innovation procurement.

The Public Procurement Directorate of the Ministry of Treasury of the Republic of Cyprus in line with its role which involves the formulation of a public procurement policy and the provision of guidance to Contracting Authorities and Contracting Entities, published a Public Procurement Best Practice Guide. This Guide is structured around 7 chapters one of which refers to the strategy on public procurement. In this chapter promotion of innovation is included as one of the objectives of public procurement.

The Policy Statement on the reinforcement of the Entrepreneurial Ecosystem in Cyprus (2017) includes one concrete activity on Innovation Procurement. In particular activity 3.1.2 of the axis on Entrepreneurial Innovation refers to the promotion of Innovation Partnerships as they are defined in the EU Directive 2014/24. The establishment of the regulatory framework on Innovation Partnerships and training programs to raise awareness on the benefits and the way this procedure works is described as concrete activities in the framework of the above-mentioned action.

The Digital Cyprus Strategy [16] foresees under the Objective Entrepreneurship, Measure entrepreneurship (goal 5, action 17.4) a concrete action on Pre-Commercial Procurement. In particular, it foresees a new funding Programme to support Pre-Commercial Procurements in the ICT sector launched by public organizations where innovative companies or research organizations could participate [17].

In Cyprus no sectorial policy explicitly recognizes the role of innovation procurement within its strategy. Cyprus has not a dedicated/stand-alone Action Plan for innovation procurement. In Cyprus there is no specific spending target for innovation procurement.

Cyprus has not put in place systematic targeted measures to improve procurers' know-how and increase the adoption of innovation procurement.

The Public Procurement Directorate (PPD) of the Ministry of Treasury of the Republic is the single Competent Authority for Public Procurement responsible for all matters regarding public procurement in Cyprus. Among its responsibilities, it is competent for policymaking in the field of public procurement, and it provides assistance to contracting authorities for proper implementation of the procurement rules through guidance and continuous training. However, training and assistance measures are not specifically tailored for innovation procurement.

Cyprus is still lacking a structured approach to capacity building on innovation procurement across the country. Apart from some limited awareness raising sessions that are not specifically tailored for innovation procurement, no dedicated capacity building measures for innovation procurement have been implemented in a systematic, regular way.

e-PPS is a web-based, collaborative system to facilitate the full lifecycle of a tendering process, for both buyers and suppliers. It offers a secure, interactive, dynamic environment for procurements of any nature, size, complexity or value (above or below EU thresholds), enforcing (where appropriate) and encouraging recognised best practices. e-PPS supports the process of procuring works, services and supplies electronically. All public procurement procedures foreseen by the law are supported for both one-off or repetitive purchases through several dedicated sub-modules providing facilities for user



registration, competition notification, tender preparation and submission, online tender evaluation, upholding of auctions, contract awarding, contract management, creation and management of catalogues, placement of electronic orders, and much more.

e-PPS can support the effort for achieving efficiency gains, while promotes core principles of the laws and regulations on public procurement such as transparency, security, availability, non-discrimination and equality of treatment.

### 2.3.5 Poland

The provisions on the implementation of public procurement are regulated in the Act - Public Procurement Law (Journal of Laws of 2021, item 1129, as amended). It is a new legal act prepared in 2019, adjusting Polish regulations to the provisions of Directive 2014/24 / EU of the European Parliament and of the Council on public procurement. The provisions of the Act apply to the award of classic and sectoral contracts by public and sectoral awarding entities throughout the country.

Detailed regulations of the above-mentioned Act were included in the Regulations to the Act.

The act regulates the rules of purchasing goods, services or construction works above the amount of PLN 130,000 net (approx.29,000 EUR). Below this amount, the rules are set out in the internal University Regulation entitled 'Regulations on application of public contracts' to which the Act - Public Procurement Law does not apply. In addition, the procedure for submitting applications and awarding contracts in the field of science or cultural activity at the University with an estimated value equal to or exceeding PLN 130,000 net (approx.29,000 EUR) was also regulated.

#### 2.3.5.1 The procurement process in Poland

For a long time, The Public Procurement Law has contained a number of elements and instruments conducive to the implementation of public procurement for innovation. The new Public Procurement Law links the procurement of innovations by public entities with a broader perspective of the national policy and strategy in this area. According to the act, it is necessary to develop a separate government document, which is the state purchasing policy. Pursuant to Art. 21 of the Public Procurement Law, the state purchasing policy defines the priority activities of the Republic of Poland in the field of public procurement, as well as the desired direction of the contracting authority's activities in the field of contracts awarded, which includes, in particular, the purchase of innovative or sustainable products and services, taking into account:

- 1) standardization aspects.
- 2) cost calculation in the life cycle of products.
- 3) corporate social responsibility.
- 4) disseminating good practices and purchasing tools.
- 5) applying social aspects.

The state purchasing policy is adopted by the Council of Ministers, as a resolution, at the request of the minister responsible for economy, whose task is to prepare a draft document as well as to coordinate the implementation of the policy. The document is prepared every 4 years, specifying the planned activities of the government administration while taking into account the goals and directions set out in the country's medium-term development strategy.

Pursuant to Article 22 of the Public Procurement Law, awarding entities, being central government administration bodies, are required to prepare their own management strategies for individual purchasing categories, consistent with the state purchasing policy. Such strategies define orders of a key nature for the implementation of the state's purchasing policy.

The new act introduced a number of new instruments of importance from the perspective of Public Procurement for innovation, including:

1. **Analysis of the client's needs and requirements.** Such analysis includes, inter alia, market research in terms of alternative means of satisfying the identified needs or in terms of possible variants of the contract. Market research in terms of alternatives and variants may lead to the decision to include innovative solutions in the next steps as best suited to the needs of the contracting authority.
2. **Initial market consultations.** The contracting authority, prior to commencing the procurement procedure, may conduct preliminary market consultations in order to prepare the procedure and inform contractors of your procurement plans and requirements. When conducting market consultations, the contracting authority may, in particular, use the advice of experts, public authorities or contractors. This advice may be used in planning, preparing or conducting a procurement procedure, provided that it does not distort competition or infringe the principles of equal treatment of economic operators and transparency.
3. **Requirements related to the execution of the order.** The contracting authority may specify in the contract notice or procurement documents the requirements related to the performance of the contract, which may include aspects related to innovation. If the contracting authority provides for such requirements, the procurement documents shall specify the manner of documenting the fulfilment of these requirements by the contractor, the contracting authority's powers in the scope of control of the contractor's compliance with the requirements and sanctions for failure to meet them.
4. **Innovation-friendly public procurement modes:**
  - a) negotiation with publication
  - b) competitive dialogue
  - c) innovation partnership
  - d) negotiated without publication
  - e) competition.
5. **Exclusions from the act** - exclusion from the public procurement regime of supplies and services for research and development purposes. Pursuant to the Act, it does not apply to contracts with a value lower than the EU thresholds, the subject of which are supplies or services used solely for the purposes of research, experimental, scientific or development works, which are not aimed at mass production by the ordering party aimed at achieving market profitability or covering the costs of research or development.

### 2.3.6 Germany

The procurement directives 2014/24/EU were transposed into German law on 18 April 2016. In Germany, the Federal Ministry for Economic Affairs and Energy (BMWi) defines the principles and legal framework of public procurement. The Competition Register Act

was drafted by the ministry in 2017 in order to prevent the companies from committing white-collar crimes and also check if a company has violated any regulations. The procurement law regulates procuring goods and services and awarding concessions. Since January 1, 2020 there are EU thresholds, above which the contracts need to be advertised throughout the EU. These thresholds are, for instance: 5.350.000 EUR for public works, 428.000 EUR for public supply and public service contracts in the fields of drinking water, energy, transport, defence and security, 214.000 EUR for all other public supply and public service contracts and 139.000 EUR for public supply and public service contracts of supreme and higher federal authorities. Above the EU thresholds, the Act Against Restraints of Competition (GWB) transposes the general provisions of Directive 2009/81 and the remedies Directives 92/50 and 89/665 into national law. Finally, additional provisions transposed from Directive 2004/18/EC are laid out in specific delegated legislation, including the Regulations on Contract Awards for Public Works (VOB/A), Regulations on Contract Awards for Public Supplies and Services (VOL/A), and the Regulations on Contract Awards for Independent Professional Services (VOF). Public procurement below the EU thresholds is governed by national budgetary law at the federal level. In some federal states, below-threshold public procurement is governed by a system of state level legislation, while others govern via decree or administrative rules. Some municipalities also have their own laws, rules and regulations.

In Germany, procurement has been carried out on a centralized basis. Germany has developed a number of sectorial centralized purchasing bodies (CPB) at the federal level. The four main CPBs at the federal level in Germany are: the Federal Central Customs Authority (Generalzolldirektion, GZD), the Federal Procurement Office of the Federal Ministry of the Interior (Beschaffungsamt des Bundesministeriums des Innern, BeschA), the Federal Office of Bundeswehr Equipment, Information Technology and In-Service Support (Bundesamt für Ausrüstung, Informationstechnik und Nutzung der Bundeswehr, BAAINBw), and the Federal Institute for Materials Research and Testing (Bundesanstalt für Materialforschung und -prüfung, BAM), see Figure 3.

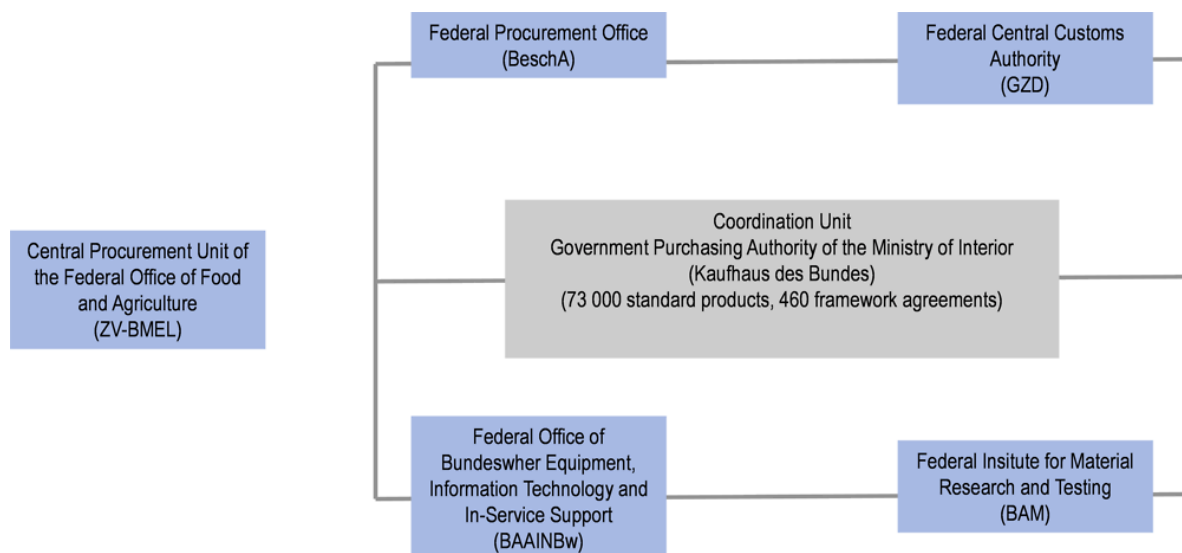


Figure 3. Central Purchasing Bodies at the federal level [18]

### 2.3.6.1 The procurement process in Germany

The earlier the procurement department is involved in the procurement processes, the better it can fulfil its task and have a corresponding leverage effect. This means that, ideally, it should be involved as early as the demand generation stage, since the necessary scope for action is then still available to be able to act strategically. Therefore, in order to

meet this requirement, the procurement function must be centralized and embedded in the organizational structure accordingly. This leads to a professionalization of the purchase and as a result increases the efficiency of purchasing activities. The procurement processes comprise four stages: demand management, market research for procurement, tender procedures for procurement and execution and usage.

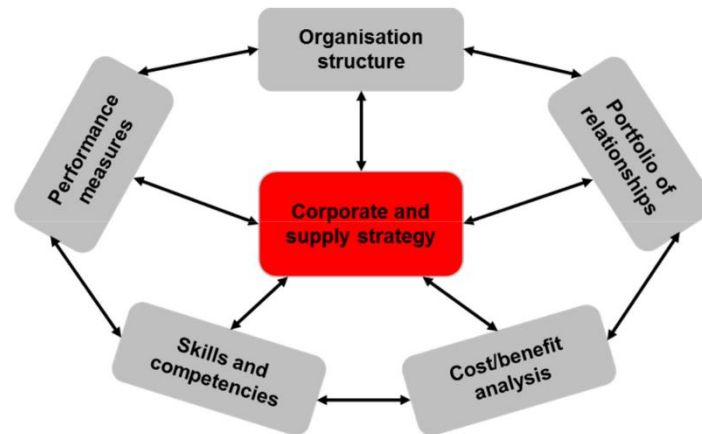


Figure 4. Strategic Supply Wheel- Contents of procurement strategy [19]

Consequently, in a procurement strategy for innovative procurement at least the following ranges should be worked out and specified:

- Scope of action, scope of application
- Legal basis and other relevant documents
- Objectives (innovation, long-term economic efficiency, etc.), values and principles
- Organizational structure (organization chart) or process descriptions (procurement process) with competencies (requirement profile) and responsibilities/limits
- Dealing with suppliers - Instruments to be applied or other measures to implement the objectives and to ensure process efficiency
- Definition of aspects for performance measurement or evaluation
- Reporting/reporting system

[20] [21] [22] [23]

## 2.4 The Procurement Landscape outside the European Union

Within the GATEKEEPER consortium, we have representatives from outside of the European Union that are not affected by the European directive for the development of the PPI in their regions. Therefore, under this section, we are going to analyse their procedures and local legal legislation that apply.

### 2.4.1 United Kingdom

European Directive 2014/24/EU had been received by the UK in October 2014 and pushed to adoption under the guidance of the Crown Commercial Service handbook [24]. The latest rules about procurement rules in the UK are available on the Government website [25]. The Government released specific guidelines for specific area.

The procurement policies for technology, [26], defining the thresholds and cases requiring a centralized assessment of procurement by the Government Digital Service, the 'cloud-first' policy and the 'red lines' about the conditions of contracts:

- no IT contract will be allowed over £100 million in value – unless there is an exceptional reason to do so, smaller contracts mean competition from the widest possible range of suppliers
- companies with a contract for service provision will not be allowed to provide system integration in the same part of government
- there will be no automatic contract extensions; the government won't extend existing contracts unless there is a compelling case
- new hosting contracts will not last for more than 2 years

For procurements over the £100 million threshold, the UK Government refers to 2012 guidelines for ICT contracts:

- [27]

All UK nations (England, Wales, Scotland and Northern Ireland) follow the same procurement regulation. The main difference between nations concerns the organization of procurement services in terms of the administrative bodies collecting and supporting procurement for different sectors and regions. In the case of Wales, there is a pan-wales service body, the Shared Services Partnership (SSP) [28] providing, among others, procurement services.

#### 2.4.1.1 The procurement process in Wales, UK

Procurement in Wales is centralized as part of the Shared Services Partnership (SSP) [28] services. SSP publishes a manual for procurement including thresholds and processes.

The Digital Health and Care Wales (DHCW) is the body overseeing digital healthcare services for both primary and secondary care. The DHCW board provides advice for the adoption of as well coordinates the assistance (servicedesk) for all digital services of the Wales National Health System (NHS).

PPI in Wales is managed as regular procurement without a specific pathway. This is a critical limit to the current regulation framework. Special cases are possible but under the same general procurement rules and must be justified case by case and supported by strong evidences.

As for of practice rather than rule, PPI involves often a "Small Business Research Initiative" (SBRI) [29], a competitive programme for developing and piloting new solutions. The transition from a pilot and a structured service, however, does not have a preferential pathway. The practice involves the use of the specs and requirement identified in the pilot to prepare a regular open tender. The transition from a SBRI and a tender is not clearly defined as procurement rules allows for special cases of direct assignment (e.g., to extend the piloting period or participation). However, the complete transition from R&D to a service provision must follow the regular tendering process. Exceptions to procurement rules are possible for:

- Follow-up work where a supplier has already undertaken initial work in the same area (and where the initial work was awarded from open competition);
- A technical compatibility issue which needs to be met e.g. specific equipment required, or compliance with a warranty clause;
- A need to retain a particular contractor for genuine business continuity issues (not just preferences) e.g. to address additional matters not originally known at the outset.
- An interim agreement prior to joining an all-Wales collaborative agreement. Written confirmation must be provided by the Procurement Service confirming local agreements will be replaced by an all-Wales competition/National strategy and how best value will continue to be delivered.

In all such applications the requestor must provide evidence of adequate consideration to the Head of Procurement that best value for money will continue to be achieved. The Head of Procurement will scrutinise each request to ensure:

- Robust justification is provided;
- A value for money test has been undertaken;
- No bias towards a particular supplier;
- Future competitive processes are not adversely affected;
- No distortion of the market is intended;
- An "or equivalent" test has been considered proving the request is justified.
- An acceptable level of assurance is available before endorsing and presenting to the Director of Finance/ Chief Executive for approval.

The procurement process involves five main steps:

**1. Planning of new/renewal procurement.** This step involves also the assessment of the strategic importance of the purchase

**2. Definition of the competition requirements.** This step is used to draft specifications. Identify the best pathway, e.g. existing Framework Agreements, timescale, type of contract, documents for the procurement, type of payment and how the procurement will be advertised.

Goods/Services/ Works  Whole Life Cost Contract value  (excl. VAT)	Minimum competition  (subject to the existence of suitable suppliers)	Timescales  (excluding planning, preparation and implementation)	Contract Form
<£5,000	Evidence of value for money	1-5 Working Days	Purchase Order
>£5,000 - <£25,000	Evidence of 3 quotations	1-4 Weeks	Simple Form of Contract/ Purchase Order
>£25,001 – Prevailing OJEU threshold	Openly advertised call for competition	2-4 Weeks	Formal contract and Purchase Order
>OJEU threshold	Openly advertised call for competition	Min 4 months, max 12-18 months	Formal contract and Purchase Order

Figure 5. Type of contracts in the UK depending on the cost value

**3. Evaluating responses.** The evaluation process is usually supported by a multi-disciplinary Evaluating Team. The bids received are assessed, clarification obtained, and consensus scores awarded in preparation for forming a recommended outcome in accordance with a pre-determined project structure or Scheme of Delegation.



**4. Approval and reward.** The 'approval' process refers to the sign off processes in accordance with the Scheme of Delegation. The 'award' stage refers to the external and market facing publication informing the market of the outcome of the competition.

**5. Implementation and contract management.** The implementation and contract management stages are as equally important as the undertaking of the competition process. How well a contract is implemented and managed will have a direct impact in the delivery of healthcare and value for money. Careful consideration is also be given to the exiting of a contract when the time falls due.

The need for a procurement for innovation is usually initiated by clinical staff that rise the need for a new solution, such as the automatization of a process. This request is then evaluated by the relative clinical hierarchy. The definition of the requirements can involve a wide range of stakeholders according to the type of service / product requested. The teams in charge of defining procurement requirements and the evaluation of quotes are defined on a case-by-case basis.

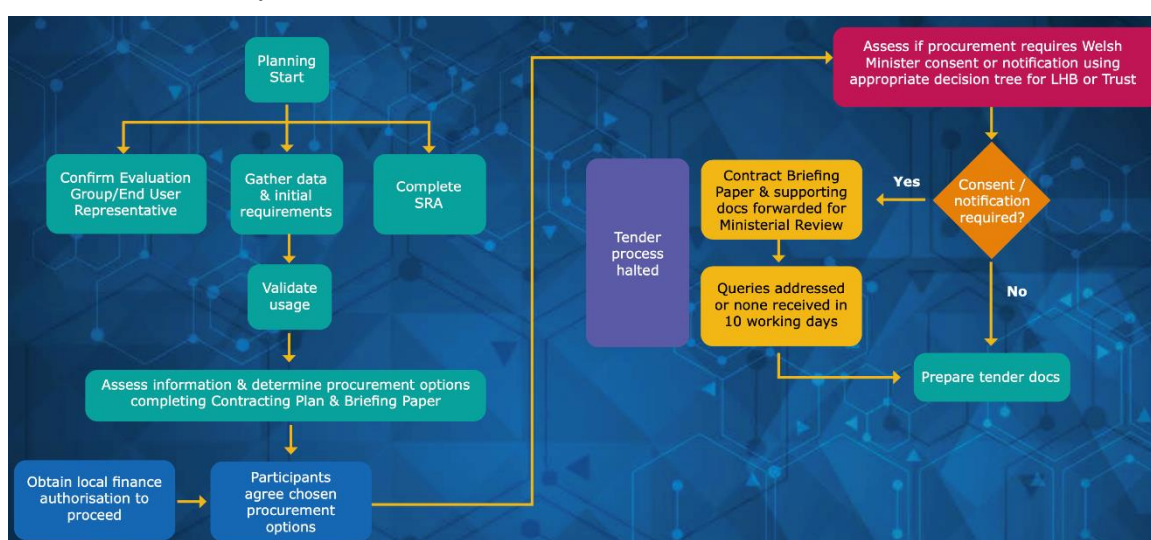


Figure 6. Procedures for the preparation of tenders in the UK

In general, there is the evaluation of the legal and finance units before bringing the request to the procurement service. Considering the budget, the request must be authorized by the Head of Finance or by the Wales Government. In case of digital services, DHCW can be involved in the definition of a tender.

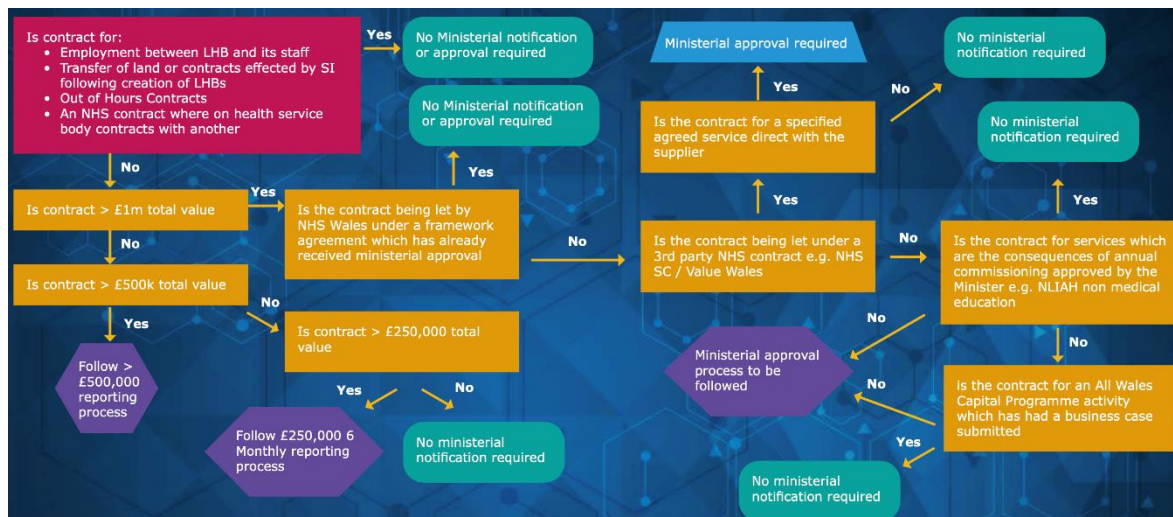


Figure 7. Approvals needed in the UK for the preparation of public tenders

When procurement involves materials or devices, the procurement process involves the independent evaluation of the Surgical Materials Testing Laboratory (SMTL) [30].

All specific rules about NHS Wales procurement are included in the Standing Financial Instructions (SFIs):

- [31]

Call for tenders are published on the Wales NHS website:

- [32]

Portal for tendering in Wales [33].

## 2.4.2 Singapore

Singapore deposited its instrument of accession to join the WTO Agreement on Government Procurement on 20 September 1997 [34] (The Government Procurement Agreement entered into force for Singapore on 20 October 1997). The Government Procurement Act, 1997, was gazetted on 2 January 1998. There is no centralized procurement agency in Singapore; procurement is carried out by individual ministries, departments and statutory bodies. Procurement policies are formulated by the Ministry of Finance, which seeks to ensure that public procurement remains transparent, open, and fair. Some centralized purchasing is carried out by the Ministries of Finance (the Expenditure and Procurement Policies Unit, EPPU), Defence, and Health, and by the National Computer Board.

All suppliers are required to be evaluated and registered with the relevant Government Registration Authorities as a criterion for award of tender. There are three registration authorities: The Expenditure and Procurement Policies Unit (EPPU), for general goods and services; the Pharmaceutical Department of the Ministry of Health, for medical supplies and healthcare related goods and services; and the Construction Industry Development Board, for construction and construction services. The financial and track records of the suppliers are evaluated by these registration authorities, which issue suppliers with certificates allowing them to participate in future procurement tenders without



undergoing separate evaluation for each tender. Registration, which requires payment of processing fees, is valid for three years.<sup>1</sup>

#### 2.4.2.1 The procurement process in Singapore

The procurement process can be broadly broken down into the following stages:

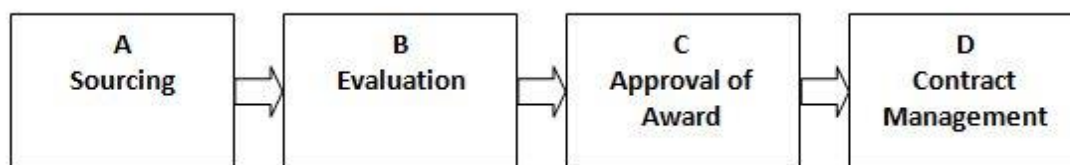


Figure 8. The procurement process stages in Singapore

### Public Private Partnerships

Public Private Partnership (PPP) is a long-term partnering relationship between the public and private sectors to deliver services. Through PPP, the public sector seeks to bring together the expertise and resources of the public and private sectors to provide services to the public at the best value for money.

Traditionally, the public sector has tended to engage the private sector merely to construct facilities or supply equipment. The public agencies will then own and operate the facilities or equipment or engage separate maintenance and operations companies to operate the facilities and equipment to deliver the services to the public.

With PPP as an alternative form of procurement, the public sector will focus on acquiring services at the most cost-effective basis, rather than directly owning and operating assets.

There are many possible PPP models, including joint-ventures, strategic partnerships to make better uses of government assets, Design-Build-Operate and Design-Build-Finance-Operate.

#### 2.4.3 Hong Kong

In regarding to public procurement in Hong Kong, there are specific guidelines listed under the Trade and Industry Department, The Government of the Hong Kong Special Administrative Region. As stipulated by the government, purchases of goods and services by government agencies with public resources and for public purposes are generally referred to as government procurement. The Agreement on Government Procurement (GPA) of the World Trade Organization (WTO) establishes rules requiring that open, fair, and transparent conditions of competition be ensured in government procurement.

<sup>1</sup> The requirements for registration include proof of financial and technical competence; a record of previous supplies of the product for which the contractor wishes to register; a summary record of trading transactions undertaken in the past; the names and addresses of two reputable clients who can attest to the quality and reliability of services provided by the contractor; and registration with the Registry of Companies and Businesses. In addition, in some cases, foreign contractors intending to register for a financial category above S\$500,000 need to be incorporated under Singapore Law as Endeshaw stated in 1999 [Harmonization of intellectual property laws in Asian: issues and prospects].

The GPA is a plurilateral agreement and applies only to those WTO Members who have agreed to be bound by it. Under the Agreement, each signatory (usually referred to as "Party") shall set out in a "coverage schedule" which procurement activity would be governed by the Agreement. A Party is only required to accord non-discriminatory treatment to goods, services, and suppliers from other Parties but not non-Parties. Hong Kong acceded to the GPA in June 1997.

With this regard, the procurement covered by Hong Kong, China's commitments under the GPA cover the procurement of goods, all construction services and eight major groups of non-construction services (i.e. Computer and Related Services; Rental/Leasing Services Without Operators; Other Business Services; Courier Services; Telecommunications and Related Services; Environmental Services; Financial Services; and Transport Services) by almost all government bureaux and departments and five public bodies provided that the contract value exceeds the respective thresholds:

- **Government entities listed in Annex 1 to Appendix I [35] to the GPA**

For contracts of a value not less than –

130,000 SDR<sup>Note</sup> (equivalent to about HK\$1.43 million) for procurement of goods and specified services; and 5,000,000 SDR (equivalent to about HK\$54.92 million) for construction services.

**Non-Government public bodies including the Airport Authority, the Hospital Authority, the Housing Authority and Housing Department, Kowloon-Canton Railway Corporation and MTR Corporation Limited**

For contracts of a value not less than – 400,000 SDR (equivalent to about HK\$4.39 million) for procurement of goods and specified services; and 5,000,000 SDR (equivalent to about HK\$54.92 million) for construction services.

## 3 Public Procurement of Innovation in Healthcare

As we have seen under section 2.2, there are different types of Public Procurements that can be implemented by public authorities for the acquisition of supplies and services. Selecting the correct kind of procurement that best fits with the type of service and solution that the public health authorities are intended to acquire is essential to make sure not only meets with the applicable legal framework, but also with the expected outcomes to be delivered.

### 3.1 Value-based Healthcare principles

Healthcare procurement generally focuses on the purchase price of both supplies and services. This perspective fails to address the needs of both the patients and healthcare providers; and ultimately, does not reflect the actual economic value of healthcare. Since 2006, the work of Professor Michael Porter has inspired a change in the healthcare delivery mindset, setting its overarching goal in achieving high value for patients.

Value has been defined as the *healthcare outcomes per dollar spent* [36].

$$\text{Value} = \frac{\text{Patient healthcare outcomes achieved}}{\text{Cost of care}}$$

Hence, value is measured by its outputs, depending on the patient actual health outcomes and not by the volume of the services delivered. It is important to highlight that cost reduction, without having in consideration the outcomes achieved, can jeopardize and limit the effect of healthcare. Focusing on value, and not just expenditure, avoids the fallacy of limiting treatments that are discretionary or expensive but has a high effectiveness. Therefore, all stakeholders (from patients, payers, healthcare providers and suppliers) can benefit while the economic sustainability of the healthcare systems increases [37].

*By following a **Value-based healthcare approach**, bringing a high value for patients becomes the paramount overarching goal of healthcare delivery.*

### 3.2 Value-Based Procurement (VBP)

Bringing the value-based principles to the innovative procurement approach enables the opportunity of innovating in healthcare delivery by investing in high value, personalized integrated care while addressing inefficiencies and avoiding unnecessary care expenditures. Thus, Value-Based Procurement (VBP) leads to Most Economically Advantageous Tendering (MEAT) by awarding the contract based on what patients and healthcare providers value.

VBP defines the framework for a collaborative, multidisciplinary approach providing solutions to efficient and effective healthcare of value to society. It provides opportunities to address the key challenges of providers and supplier relationships. VBP is a pragmatic way enabling value-based health care and the incorporation of value in decision making. This is in the interest to all healthcare stakeholders in both the public and private healthcare sector [38].



Figure 9. The need of a Value-Based Procurement [26] [27]

**Value-Based Procurement** is based on a collaborative approach to achieve the outcomes and overall costs across the whole cycle of healthcare delivery, instead of following the traditional silo purchasing budget approach.

Throughout the literature, there are different methodologies to conduct VBP. The “*Most Economically Advantageous Tendering (MEAT) Value-Based Procurement*” approach, developed by MedTech Europe [39], The Boston Consulting Group (BCG) [40] and other several procurement experts, consists of a multi-layered framework taking into account the outcomes that matter to patients, the benefits for key healthcare stakeholders and for the society as a whole, the cost along the full process of care delivery and the offering of innovative solutions.

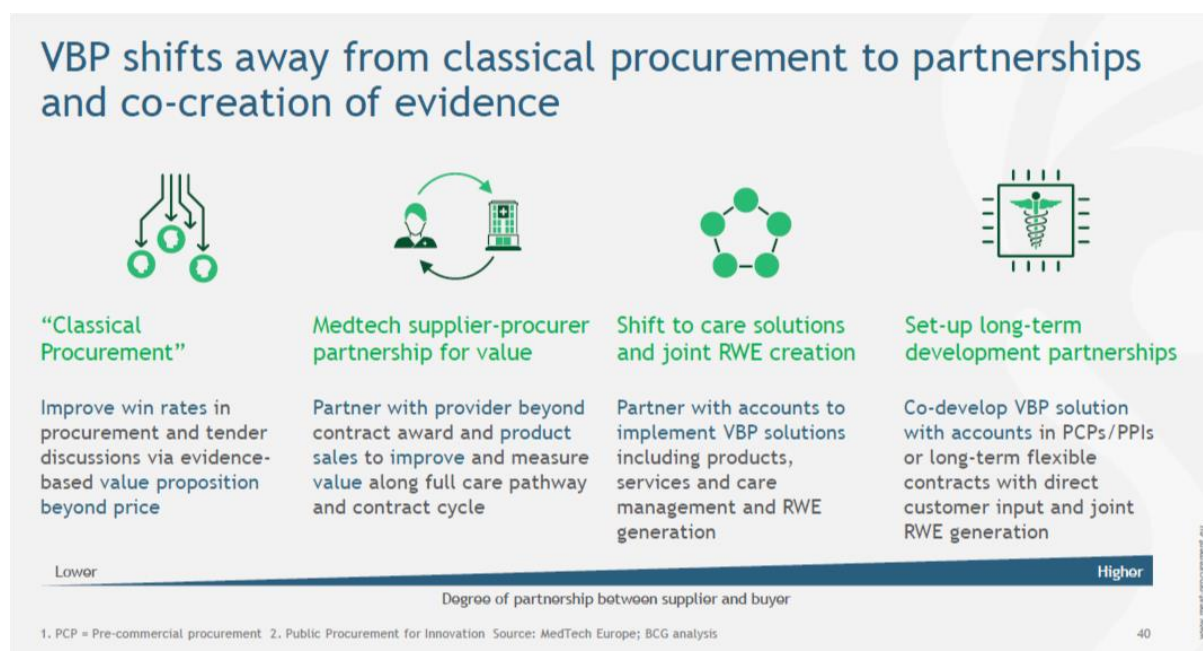


Figure 10. Value-Based Procurement shift from traditional procurement. Source: MedTech Europe and BCG analysis

Overall, the value-based innovation procurement enables, through a collaborative approach, a high quality and sustainable resilient healthcare following a patient centred perspective. These type of innovation procurements does not focus on the price of the products and services purchased, but on the cost-avoidance opportunity and the total cost of the care delivery. The contract is awarded to the supplier providing the technology, services or solution expected to generate the highest overall value and obtain the Most Economic Advantageous Tender (MEAT) compliant with the EU Public Procurement Directive 2014/24/EU (see section 2.1.1) and its national transposition. To assess the value generated by these solutions in the value-based innovation procurements, value-based agreements (VBA) are set-up based on the results of KPI in the daily practice, including incentives linked to the benefits obtained.

Beside procurers, clinicians, healthcare authorities and suppliers play a crucial part in further supporting the development of value-based innovation procurement. By working from the MEAT VBP perspective, they should identify customer needs and what is valued and addresses the inefficiencies and resource intensive activities that lead to higher total costs of care [41].

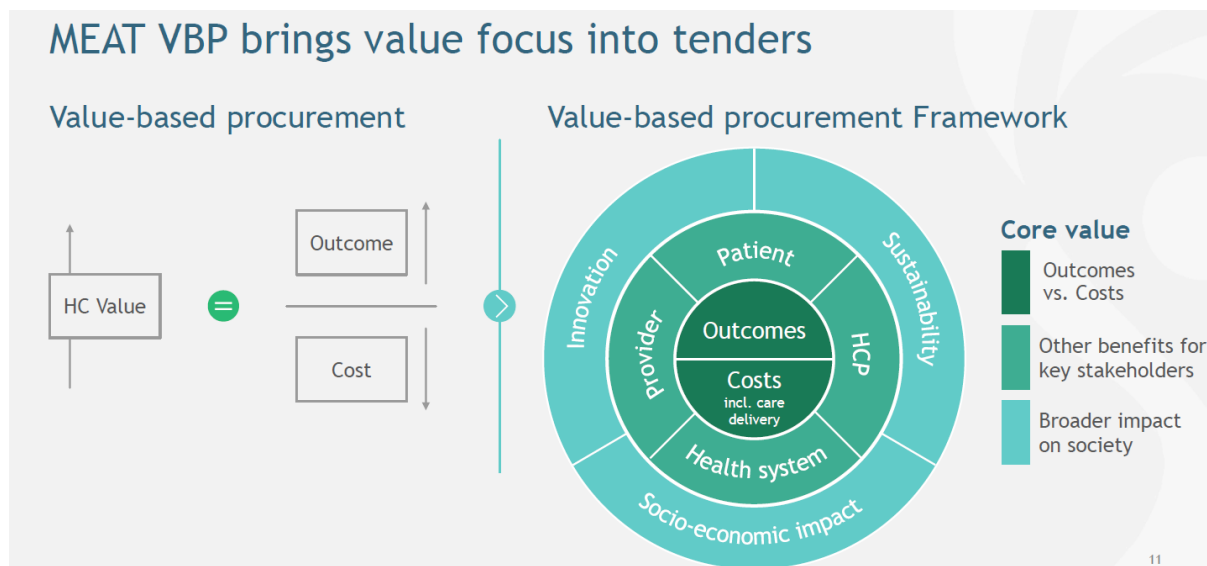


Figure 11. MEAT VBP Framework. Source: MedTech Europe and BCG Analysis

### 3.3 European initiatives fostering the PPI in Healthcare

The European Commission, throughout its different operational frameworks, has been fostering the development of the European Public Procurement of Innovation. Alongside with the European Directive 2014/24/EU (see section 2.1.1), other European projects and initiatives have been developed recently to increase the awareness, support public procurers and to develop the methodology of PPI in Healthcare.

Under this section, we will analyse four different European initiatives, to see which are their objectives and how GATEKEEPER can benefit from the work that they have already developed.

The four initiatives that we are going to analyse in the following sections are:

- The Value-Based Procurement Community of Practice (VBP CoP)
- European Assistance for Innovation Procurement (EAFIP)
- European wide Innovation Procurement in Health and Care (EURIPHI)
- Platform for Innovation of Procurement and Procurement of Innovation (PiPPI)

#### 3.3.1 The Value-Based Procurement Community of Practice (VBP CoP) [42]

To foster the adoption of the innovative procurement approach VBP (detailed in section 3.2 *Value-Based Procurement (VBP)*), the Value-Based Procurement Community of Practice is a community that was originally founded by MedTech Europe together with the Boston Consulting Group. In this Community, purchasers, medical technology companies and national association members of MedTech Europe can be found.



The mission of VBP CoP is to bring together purchasers and representatives of MedTech industry and to engage healthcare providers, health authorities and other stakeholders with a common interest in VBP. To this end, VBP CoP has the ambition to accelerate the adoption of "patient-centric, safe, high quality and affordable value-based health care by supporting the change of procurement practice". The objectives of VBP CoP according to the community itself are:

- To establish a cross-stakeholder vision to drive the adoption VBP in practice.
- To address the challenges and barriers to the adoption of VBP.
- To build a network for its members and partners.
- To foster partnership of procurers and MedTech suppliers in line with procurement and competition legislation.

On the other hand, the activities carried out by the members of this community can be grouped into 5 categories (see Figure 12):

1. Engage and Outreach activities in order to: (i) develop strategies to expand VBP awareness; (ii) explain the value of VBP; (iii) bring support of stakeholders such as healthcare professionals, hospital management and financial directors to change the current purchasing paradigm.
2. Education activities for members of the Community of Practice and beyond, aiming to increase their awareness of the benefits of VBP.
3. Collaboration between members of the Community of Practice and beyond to share learning, good practice, and the benefits of VBP through the organisation of seminars and support.
4. Derive learnings from VBP experiences to overcome barriers both within the CoP and outside, creating VBP starter guides.
5. Continuously enhance the toolkit to assist in the application of the VBP principles.

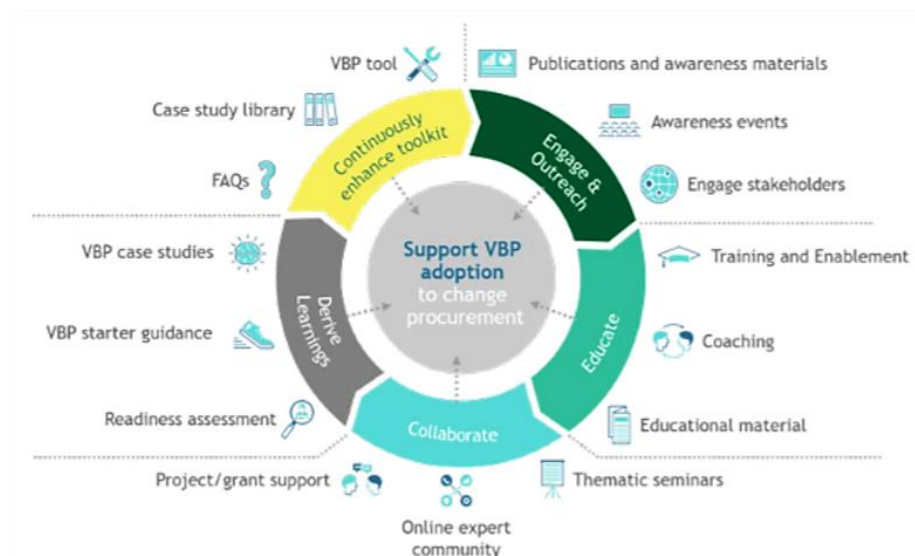


Figure 12. Infographic showing the activities carried out by the Value Based Procurement Community of Practice

This initiative will be shared amongst supply and demand sides from GATEKEEPER ecosystem to spread the basic principles of Value Based Procurement.

### 3.3.2 EAFIP [43]



Figure 13. EAFIP initiative logo

European Assistance for Innovation Procurement (EAFIP) is an initiative fostered by European Commission that supports procurers in developing and implementing innovation procurement strategies for ICT solutions. The aim of EAFIP is to provide local assistance to public procurers to promote good practices in innovation procurement.

This initiative started in 2015 and has so far developed activities among which the following can be highlighted:

- Events in different European countries such as France, Greece, and Estonia to inform about PCP and PPI
- Creation of an innovation procurement toolkit with 3 modules for policy makers, public procurers and legal staff on how to implement PCP and PPI: (Module 1) For policy makers, with economic and case evidence on the impact and benefits of PCP and PPI, as well as support on the use of these two initiatives in innovation strategies; (Module 2) For public procurers to clarify key requirements and steps to design and implement innovative public procurement processes; (Module 3) For legal services to clarify legal issues.
- Assistance to 12 PCP and PPI procurement processes of ICT based solutions
- Webinar "Opportunities to tackle the COVID-19 Crisis through Innovation Procurement"

Partners considered as procurers in GATEKEEPER project could leverage on lessons learnt and best practices from EAFIP's initiative, since GK aims at promoting and exploiting ICT solutions, particularly in healthcare sector.

### 3.3.3 EURIPHI



Figure 14. EURIPHI initiative logo

EURIPHI (European Innovative Procurement of Health Innovation) is an EU-funded initiative which ran from January 2019 to July 2020 and was aimed at supporting advancing cross-border cooperation of innovation procurement, applying a value-based approach.



This model shifts procurement away from a volume-price only approach and recognizes the specific needs of health systems and the value of the solutions to address them [2] [44].

This initiative has created methodologies and guidance for ensuring innovation procurement is of true value and supporting a European-wide community of practice of public procurement organisations in the healthcare sector collaboration even cross-border.

EURIPHI aimed at demonstrating healthcare system across Europe face common challenges and for the uptake of innovation solutions, value-based healthcare approach is needed. Their activities included develop guidance for the use of EU co-funded instruments such as PCP and PPI, and how to apply them in a cross-border procurement model, applying MEAT Value-Based Procurement approach (for more detail see section 3.2). This was applied in two different areas: Rapid Diagnostics and Integrated Care, undertaking Open Market Consultations with industry to identify procurement specifications and a strategy to launch cross-border calls [3].

This model of joint procurement consists of full collaboration in the preparatory phase, followed by cooperation for selecting one out of the three cross-border collaborative procurement modalities (see below) and applying the most appropriate procurement procedure.

Furthermore, to maximise the impact of cross-border procurement, differences between participant should have been considered: (i) national transposition of EU Directive and local regulations; (ii) healthcare organization, payment, and reimbursement models; (iii) languages and culture; (iv) general lack of capacity to support EU cross-border initiatives; and (v) excessive demand volume, endangering competition, innovation, and SMEs participation.

This initiative can be considered a guidance for GK procurers to ensure PPI tenders based on VBP, considering MEAT principle and cross-border collaboration between them across Europe.

**'Cross-border collaborative procurement model'**

During the preparatory phase and based on full collaboration, contracting authorities decide which one of the following models are more suitable:

**Model 1: Full preparatory collaboration followed by the issue of individual local procurement procedures**

Full collaboration in the preparatory phase followed by a collaboration in the pre-tender part of the procedure and issue of individual public tenders by the participating organizations/partners.

**Model 2: Full cross border collaborative procurement having lots per locality**

Full collaboration in the preparatory phase followed by the issue of a (single) joint public tender in which every participating organization/partner holds its dedicated lot. This lot is tailored to the specific needs of the organization and is awarded separately.

**Model 3: Full cross border collaborative procurement resulting in framework agreement(s) followed by specific contracts per locality**

Full collaboration in the preparatory phase followed by the issue of a (single) joint public tender resulting in the awarding of a framework agreement between one or more contracting authorities and one or more economic operators. Next, the local implementation of the framework agreement is executed through specific contracts individual participating organization/partner and the economic operators to the framework agreement

Figure 15. EURIPHI Cross-border collaborative procurement model

The complete process 'Cross-border collaborative procurement model' enabling decision making process can be consulted in Figure 16 and Figure 17:

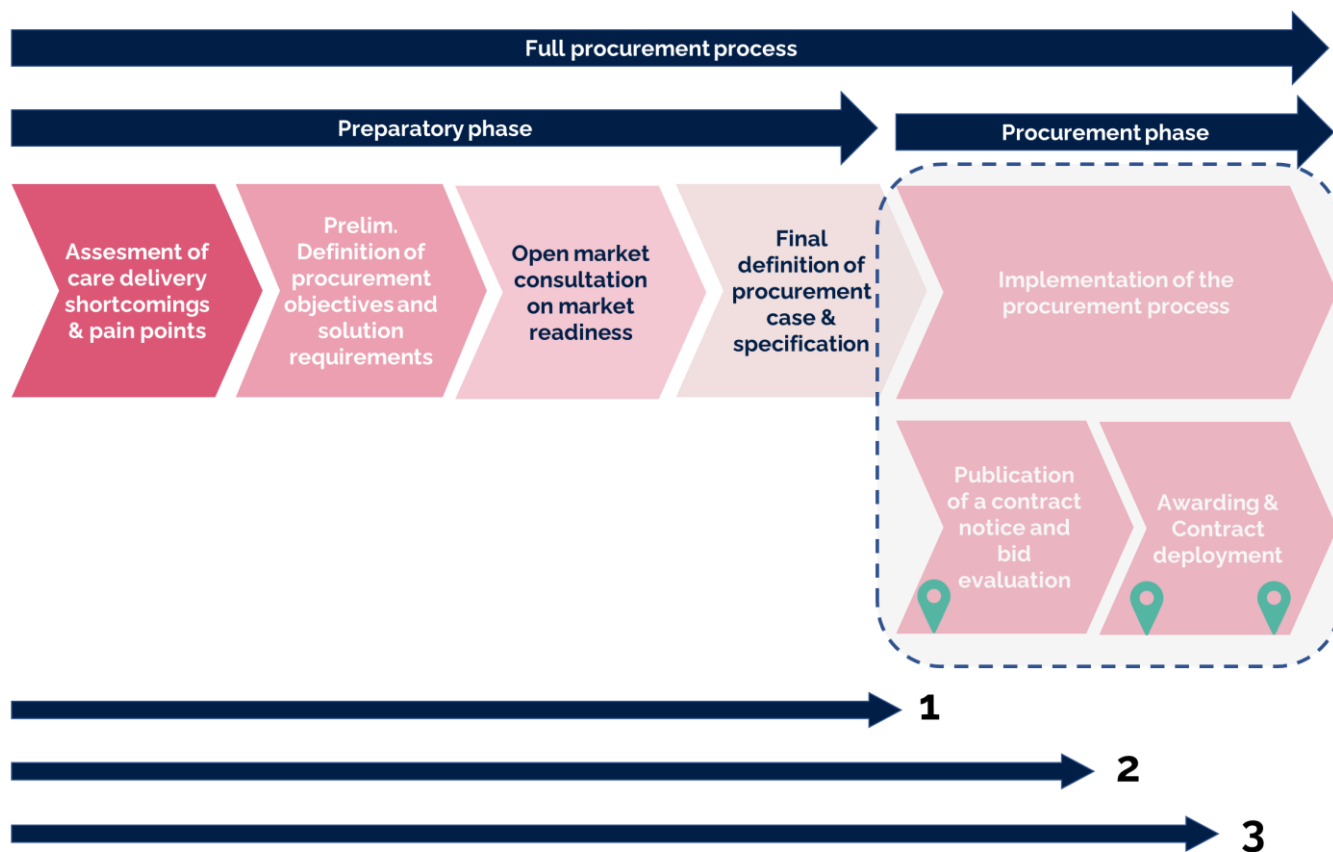


Figure 16. Full 'Cross-border collaborative procurement model' enabling decision making procurement process [2]

If we focus on the procurement phase, EURIPHI defines the following stages as it is represented in the following Figure 17:

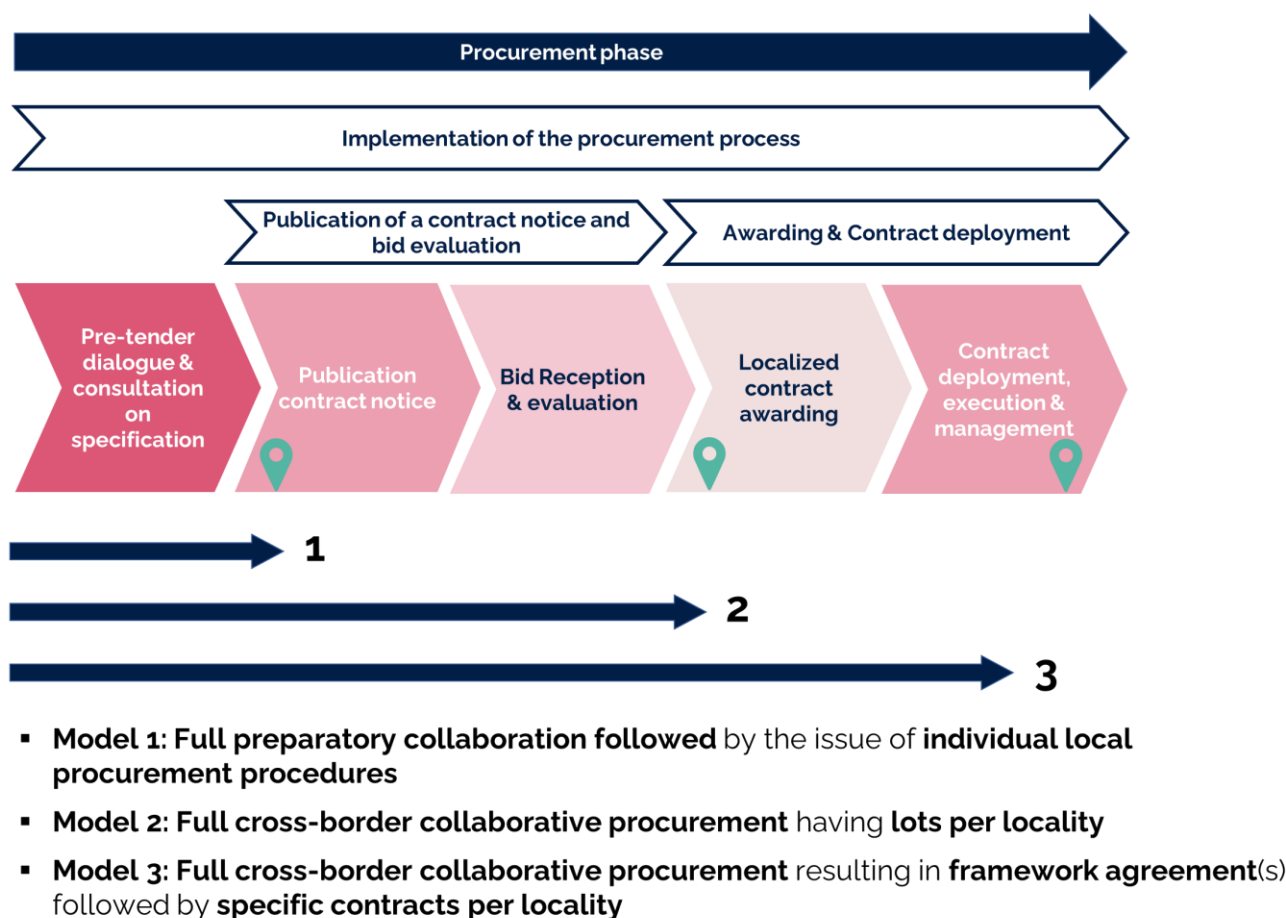


Figure 17. Procurement phase 'Cross-border collaborative procurement model' enabling decision making process [2]

### 3.3.4 Platform for Innovation of Procurement and Procurement of Innovation (PiPPi)

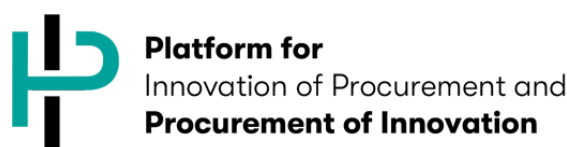


Figure 18. PiPPi Project logo

The **Platform for Innovation of Procurement and Procurement of Innovation (PiPPi)** project is an ongoing Coordination and Support Action (CSA) founded by the European Commission (the European Union's Horizon 2020 research and innovation programme grant agreement No 826157), under the topic *SC1-HCC-04-2018 - Digital health and care services – support for strategy and (early) adoption* [45].

The PiPPi project wants to foster the public-private collaboration for the procurement of innovation in order to achieve the digital transformation of healthcare. Currently, these collaborations are often reactive and not fully connected with healthcare needs and stakeholder's involvement. Under this premise, the PiPPi project, coordinated by the

Karolinska University Hospital in Sweden, aims **to create a cross-border Community of Practice of European university hospitals that will bring together experts from the demand and supply side to identify common clinical needs for digital healthcare solutions and procurement of innovation knowledge** [46].

The PiPPi consortium is formed by 7 major European university hospitals (Figure 19) offering expertise on digital healthcare, patient-centred care, and procurement with the ultimate aim to solve shared clinical challenges.

To achieve this objective, the PiPPi project has defined a process to support and provide guidance from the identification of the problems and opportunities, to the execution of the procurement plan. The process is detailed explained in Figure 20.



Figure 19. The PiPPi consortium. Source: PiPPi project

## PIPPi process

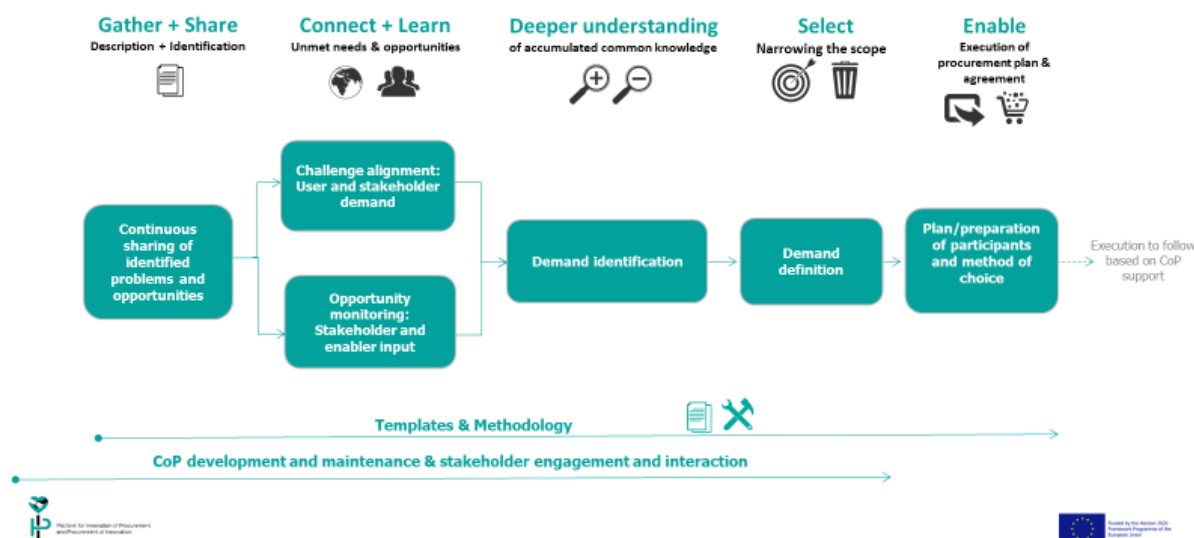


Figure 20. The PiPPi process. Source: The PiPPi project

This process is supported by the portfolio services offered by the platform that is being developed within the PiPPi project scope.



**PIPPi Community:** discussion among stakeholders regarding innovation and PPI learnings



**Training site:** training support regarding the PPI process and the legal and procedural particularities in each country or region



**Share & Innovate:** share met and unmet needs between the demand side, co-creation of PPI and PCP and establishing synergies between the supply side



**Personalized advise / support:** digital tool for personalized advice and support regarding the PPI process.

The GATEKEEPER and the PiPPI project have already started a collaboration to work together in the definition of the needs, barriers, and good practices to build the Public Procurement of Innovation in the healthcare domain. Within the GATEKEEPER project, the key identified types of stakeholders that are involved in the PPI process by the PiPPI are involved within the consortium. Therefore, the feedback and collaboration between both projects can build a fruitful synergy.

Some of the GATEKEEPER industry partners have already participated in the PiPPI workshops to share their vision and experience in the PPI process. In addition, the PiPPI project will also collaborate with the GATEKEEPER to share their knowledge regarding their conclusions in the findings of best practices and barriers.

### 3.4 PPI in Value-Based Healthcare as an enabler of GATEKEEPER sustainability and exploitation

One of the most important target users of the GATEKEEPER services and solutions as described in *D2.1 Initial Ecosystem Management Plan* [47] are **Health & Care Agencies**. These public and usually governmental organizations have the legal mandate to organize, finance and deliver health care to all population in a geographical region or country.

The acquisition of these kind of services and solutions by public Health & Care Agencies, such as hospitals and regional authorities, cannot be done by direct purchase through a marketplace, as it must meet with the current legislation of public procurement as it has been described in section 2. Hence, GATEKEEPER is going to leverage on the Public Procurement of Innovation as one of the pillars to enable the acquisition of the GATEKEEPER services and solutions by the public sector, as they are instruments that enable a smart, sustainable and inclusive growth, ensuring that the public funds are used in the most efficient possible way (see Section 2). In addition, this type of procurements positions the open innovation approach as one of the main drivers of future and sustainable growth.

On the whole, Public Procurements are one of the cornerstones of the exploitation and future sustainability of GATEKEEPER. Therefore, since the start of Task 8.4, it is working hand to hand with the GATEKEEPER Business Working Group as part of the activities being developed in the *Ecosystem, Market forces & practices* workstream [37].

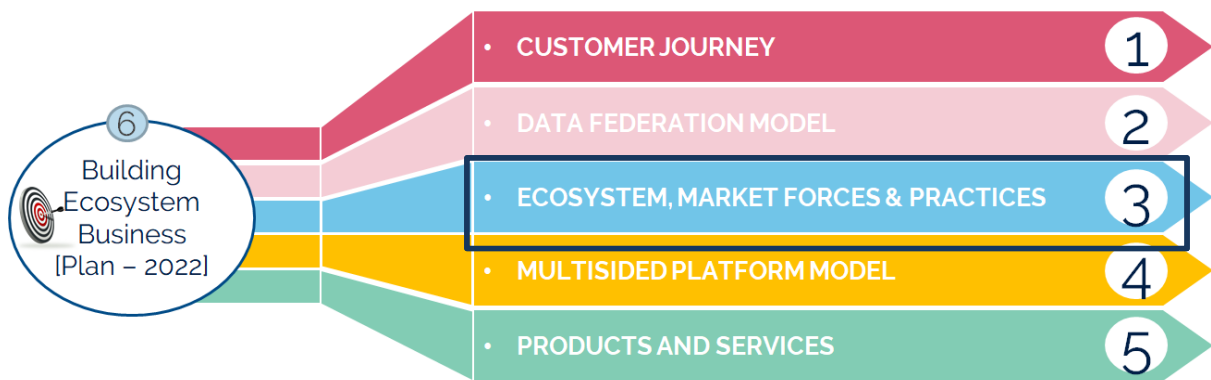


Figure 21. GATEKEEPER Business Working Group Streams



## 4 Analysis of the Public Procurement of Innovation process in Europe

Public Administrations of EU Member States are not using all existing possibilities in public procurement to modernise products and services. Moreover, only 11% of procedures are done in a cooperative way, which would allow better prices and offers opportunities for sharing know-how.

Innovation must play a crucial role in modernising the public procurement landscape to find ways to meet the new challenges at European and global level. As we have seen in section 2.2., there are models and tools that support the procurement of innovative solutions and products such as PCPs and PPIs [48].

Public procurement processes are fundamentally similar in all cases (see Figure 22Figure 22).

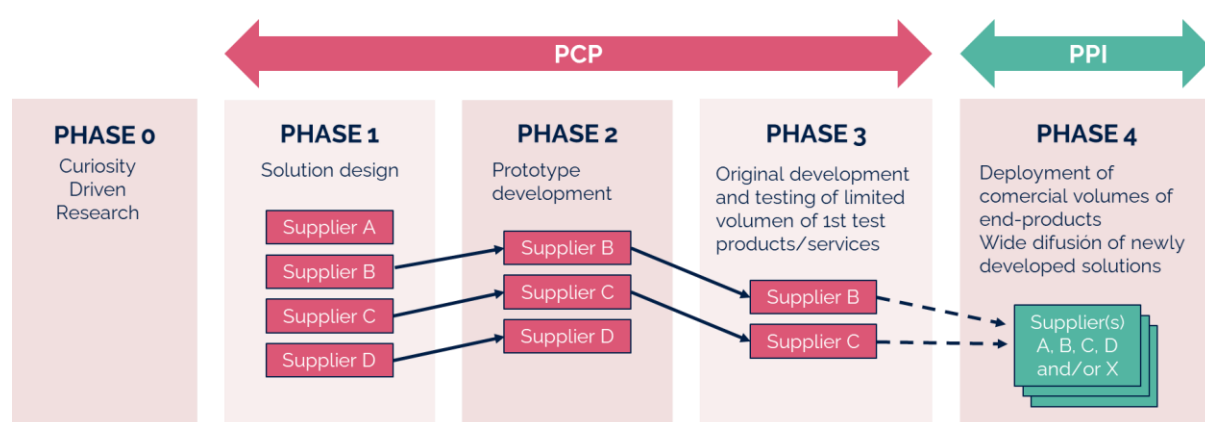


Figure 22. Innovation procurement phases [48]

However, public procurement procedures for innovation give special importance to the preparatory phase, where an analysis of unmet needs is carried out. As innovative elements are sought, it is not easy to know exactly which products or services are needed in each case. For this purpose, there is an instrument known as Open Market Consultation (OMC). OMCs are an instrument that allow the gap between the demand side and the supply side to be identified. OMCs have the following two main objectives [49]:

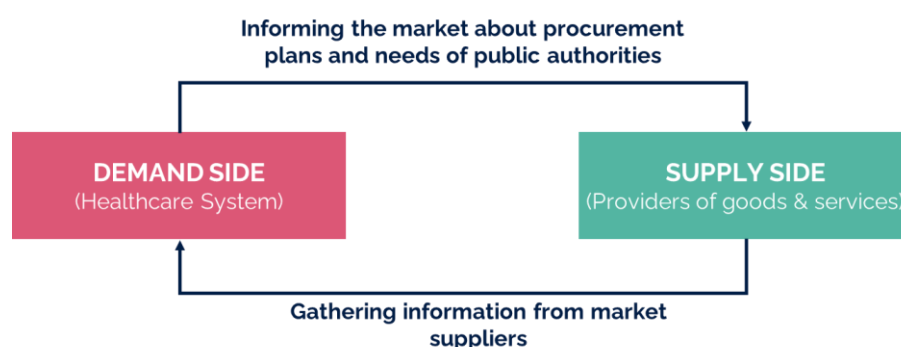


Figure 23. Open Market Consultation objectives

An example of a Public Procurement of Innovation process is shown [2] [13]:

### FULL PROCUREMENT PROCESS

#### 1. Preparatory phase

- a. Assessment of care delivery shortcomings & pain points
- b. Preliminary definition of procurement objectives and solution requirements
- c. Open market consultation on market readiness
- d. Final definition of procurement case & specifications
  - i. Draft specifications and criteria
  - ii. Prepare procedure documents
- e. Pre-tender dialogue & consultation on specifications

#### 2. Procurement phase

- a. Pre-tender dialogue & consultation on specifications
- b. Publication contract notice
- c. Bid reception & evaluation
  - i. Receipt and opening
  - ii. Apply exclusion grounds
  - iii. Select suitable tenders
- d. Localized contract awarding
  - i. Award and sign the contract
  - ii. Notify tenders and publish the award
- e. Contract deployment, execution & management
  - i. Manage and monitor the execution
  - ii. Issue payments
  - iii. Deal with modification or termination of contract (if needed)
  - iv. Close the contract

## 4.1 Key aspects to identify in the PPIs

As it has been stated throughout this document, the Public Procurement of Innovation nowadays is not a standardized process and it is being implemented in different ways depending on the type of organization body leading the tender, the country, and the region. Therefore, it is necessary to analyse the type of procurements that have been published and extract from them the most relevant key elements that should be considered:

1. Unmet needs – definition of the real unmet needs from the demand side
2. What is being requested? – the overall expected solution or service requested from the demand side to provide solution to the unmet needs
3. How is it being requested? – what specific modules and tools are being requested to undertake the overall objective
4. Project KPIs – the specific KPI that will be assessed during the project lifetime
5. Expected output – what improvements in healthcare outcomes are expected from this PPI

## 4.2 Practical examples of the current PPIs interesting for GATEKEEPER

To better understand the type of PPI in innovative services and solutions that can be created for the GATEKEEPER services and solutions, we have identified some already published PPIs across Europe that can be of interest for GATEKEEPER because they are targeting services and solutions aligned with what GATEKEEPER is offering (digital solutions for personalized risk detection, advanced health monitoring and early interventions).

### 4.2.1 INFOBANCO

NAME OF THE PPI			
INFOBANCO			
Country	Spain	Procuring Agency	Comunidad de Madrid
Budget	2,5 M€	Duration	3 years
Stage of the procurement		Preliminary Open Market Consultation	
Unmet need			
Spanish national solutions for clinical data does not necessarily consider standardized data model or interoperability requirements.			
What is being requested?			
To develop a regional health data network architecture, conceived as a standardized repository of health data, combining information generated from different sources, both clinical and administrative and research systems. INFOBANCO aims for this architecture to work as a platform that provides services to clinicians, managers, and researchers, and is intended to be equipped with governance tools as well as tools for obtaining, transforming, interrogating, visualizing and analysing data in order to obtain knowledge and support decision making.			
How is being requested?			
<ul style="list-style-type: none"><li>- To design a functional and technological architecture, based on the state of the art, that will allow to meet the proposed objectives.</li><li>- Implement the designed architecture in one or more SERMAS hospitals that meet the requirements established in the project.</li><li>- Evaluate the health data platform for general quality dimensions: uniqueness, completeness, consistency, multi-origin stability and accuracy</li><li>- Determine the validity of the human health data platform against the manual registry taken as "gold standard"</li><li>- To quantify the usefulness of the health data platform in research, knowledge generation and care improvement</li></ul>			
Project KPIs			
<ul style="list-style-type: none"><li>- Population covered by basic NHS eHealth services</li><li>- Population benefiting from chronic disease management or other specific services in the area of health and active and healthy aging</li><li>- Number of tele transferable procedures that are created or improve operations</li><li>- Number of people impacted by dissemination, awareness and dynamization actions aimed at promoting the use and demand for ICT networks, products and services</li><li>- Population covered by health services</li></ul>			

<b>Expected output</b>
<ul style="list-style-type: none"> <li>- A more accurate identification of the different procedures operating in the health and social care sector by having better information available.</li> <li>- A reduction in the duplication of unnecessary tests through the information obtained from the exploitation of large databases with information from the real world.</li> <li>- Improved diagnostic accuracy with the consequent improvement in efficiency in the provision of health services.</li> <li>- Increased quantity and quality of information will result in more efficient treatments with a consequent reduction in hospitalizations and improved efficiency in the sector.</li> <li>- Increased real-time visibility of operations, patient experience, patient opinions and behaviour of the different agents.</li> <li>- It will improve system intelligence and, therefore, also the quality and accuracy of the decisions to be made.</li> <li>- It will improve the user experience: greater availability of medical assistance, access to history, analysis and test results, possibility of early diagnosis and treatment of diseases, etc.</li> <li>- Healthcare professionals will be able to better detect, better predict, better alert, better relate and better catalogue information.</li> </ul>
<b>The Procurement Process</b>
<ol style="list-style-type: none"> <li>1. <u>Preparatory activities and funding search</u></li> <li>2. <u>Market Consultation</u></li> <li>3. <u>Tender publication</u></li> <li>4. <u>Evaluation and adjudication</u></li> </ol>
<b>Technological requirements</b>
<ul style="list-style-type: none"> <li>- ETL tools from architecture components as external systems</li> <li>- Tools for the extraction of structured data from unstructured text using NLP technologies</li> <li>- Data lake with different processing areas as a core element of the architecture</li> <li>- Model and terminology server (SNOMED-CT)</li> <li>- Standardized repository for secondary use (RWD) based on ISO 13606/openEHR/i2B2, OMOP standards.)</li> <li>- Platform for the elaboration of data collection notebooks.</li> <li>- Standards-based interfaces (FHIR, CDISC) for the integration of decision support and AI systems</li> <li>- Business intelligence tools</li> <li>- Tools for data quality evaluation</li> <li>- Tools to ensure data security and confidentiality</li> </ul>
<b>Related Links</b>
<a href="https://cpisanidadcm.org/infobanco/">https://cpisanidadcm.org/infobanco/</a>

This PPI has identified an important unmet need that not only concerns the clinicians, but also targets a broader scope, providing services and solutions to clinicians, researchers, and managers in more than one hospital. The KPIs and outputs are defined to measure the impact on the healthcare outcomes and its value generated (efficiency of treatments, patient experience, improve diagnosis, ...) following the VBP approach. It is also noteworthy that this PPI fosters the involvement of the suppliers within the tender preparation, in the open market consultation stage. Under this stage, the industry suppliers are invited to individually present and discuss their solutions and potential applications to meet the requested requirements. Thanks to these inputs, the final tender will be implemented. On the overall, this PPI is a good example of how to integrate all relevant stakeholders within the procurement value chain in defining the final tender.

#### 4.2.2 Personalized Big Data Medicine (MedP Bigdata)

##### NAME OF THE PPI

Personalized Big Data Medicine (MedP Bigdata)			
Country	Spain	Procuring Agency	<ul style="list-style-type: none"><li>Servicio Canario de Salud</li><li>Conselleria de Sanitat Universal i Salut Pública de la Generalitat Valenciana</li></ul>
Budget	4M€	Duration	4 years
Stage of the procurement		Tender preparation	
Unmet need			
Inefficiencies in providing care due to a lack of personalization in prevention, early detection, diagnosis, prognosis and integrated care.			
What is being requested?			
Technology platform to support multiple tools that operationalize the available data into useful functionalities for patient care during diagnosis, treatment and research on chronic, degenerative and rare disease, and cancer.			
How is being requested?			
Two different challenges to be addressed: <ul style="list-style-type: none"><li>- Development of a tool based on dialogue techniques supported by artificial intelligence, capable of mediating the flow of information between citizen, patient and HIS/EHR</li><li>- Clinical decision support tools for chronic patients</li></ul>			
Project KPIs			
<ul style="list-style-type: none"><li>- Reduction in pharmacy spending / year</li><li>- Reduction of avoidable admissions for more effective treatments</li><li>- Reduction of avoided complementary tests by more powerful and selective data processing in the evaluation of their demand</li></ul>			
Expected outputs			
<ul style="list-style-type: none"><li>- Increase treatments effectiveness</li><li>- Reduce the adverse effects of treatments</li><li>- Increase knowledge of individual determinants of treatment efficacy</li><li>- Increase adherence to treatment for complex chronic patients</li><li>- Improve the planning and coordination of the different devices for the care of chronic patients</li><li>- Obtain objective and reliable measures of the evaluation of chronic patient care</li><li>- Identify and detect the risk of progression to frailty</li><li>- Improve training and information on personalized treatments for associations and professionals in the care settings</li></ul>			
The Procurement Process			
<ol style="list-style-type: none"><li><u>1. Preparatory activities and funding search</u></li><li><u>2. Market Consultation</u></li><li><u>3. Tender publication</u></li><li><u>4. Evaluation and adjudication</u></li></ol>			
Technological requirements			
<ul style="list-style-type: none"><li>- Allow pairing with sensors, smartwatches and other fitness devices or specific apps. Even automated diagnostic devices, such as auto-analysers or automatic sphygmomanometers.</li><li>- Facilitate PREMS and PROMS</li><li>- Multi-channel accessible by screens or voice. Even technologies such as VR or AR</li><li>- Accessibility strategies for people with functional and language diversity</li><li>- Empathy with the user in order to maintain attention and trust</li><li>- Open to interoperability with other healthcare applications</li><li>- Bidirectionality, including data capture and access by patients</li></ul>			
Related Links			

[https://contrataciondelestado.es/wps/portal/!ut/p/b0/04\\_SigCPykssyoxPLMnMzovMAfGizOKdqiosHJoMHQoszJ1cDBzNXI3NTAMNjQycifULshoVAXIVzSI!pw/Z7\\_BS88AB1AoGIL2oAMMG1VR100L7/ren/p=CTX=QCPLACE\\_esQCPNoticiasQCASiteQCPNoticiasQCPCPMQCADireccionQCAdeIQCAServicioQCACanarioQCAdeQCASaludQCA-QCAMEDP-BigD/-/?param1=MenuHistorico](https://contrataciondelestado.es/wps/portal/!ut/p/b0/04_SigCPykssyoxPLMnMzovMAfGizOKdqiosHJoMHQoszJ1cDBzNXI3NTAMNjQycifULshoVAXIVzSI!pw/Z7_BS88AB1AoGIL2oAMMG1VR100L7/ren/p=CTX=QCPLACE_esQCPNoticiasQCASiteQCPNoticiasQCPCPMQCADireccionQCAdeIQCAServicioQCACanarioQCAdeQCASaludQCA-QCAMEDP-BigD/-/?param1=MenuHistorico)

Under this PPI, two different Spanish healthcare regions have come together identifying a common unmet need that will be considered in both regions. This will enable the implementation of the acquired interoperable solutions in two different regions, ensuring the sustainability and further exploitation of the solutions and services in other regions and countries. The expected outcomes and KPIs have been defined following the Value-Based Healthcare approach (better healthcare outcomes). As in the INFOBANCO PPI, this PPI fosters the involvement of the suppliers within the tender preparation, in the open market consultation stage. Under this stage, the industry suppliers are invited to individually present and discuss their solutions and potential applications to meet the requested requirements. Thanks to these inputs, the final tender will be implemented. On the overall, this PPI is a good example of how to integrate all relevant stakeholders within the procurement value chain in defining the final tender.

### 4.2.3 Development and application of telemedicine methods

Name of the PPI	Development and application of telemedicine methods		
Country	Greece	Procuring Agency	South Aegean Region's Managing Authority
Budget	994.000 EUR	Duration	3 years
Stage of the procurement		Execution of contract	
Unmet need			
Access of citizens of remote regions (small islands) to specialized healthcare services without needing to travel, in the aim of improving the life of citizens			
Access of health professionals to high quality education infrastructure irrespective of the location of their unit			
What is being requested?			
Twenty (20) new telemedicine stations on the islands of Agathonissi, Anafi, Antiparos, Kythnos, Kea, Kimolos, Leipsoi, Serifos, Sikinos, Folegandros, Chalki, Kos, Donousa, Irakleia, Thirassia, Koufonissia, Schoinoussa, Telendos, Pserimos and Arkioi, which will be interconnected with the existing points of the existing National Network of Telemedicine			
How is it being requested?			
<ul style="list-style-type: none"><li>20 stations for telemedicine functioning independently and with direct connection to existing infrastructure in continental Greece (software development, equipment for broadband access and high-definition video conferencing, smart medical equipment for diagnosis, telemedicine application). Main functionalities: remote diagnosis, remote education, teleconferencing, home monitoring, home care.</li><li>Home monitoring system for 50 different patient homes with direct connection to existing data centre</li></ul>			
Expected outputs			
<ul style="list-style-type: none"><li>Equal access of small island residents and visitors to specialised medical services, irrespective of their residence and of the weather conditions (that may not permit travelling to a central hospital)</li><li>Improvement of health and raise of life expectancy</li></ul>			

<ul style="list-style-type: none"> <li>Action and exploitation of the "golden hour" for emergency cases</li> <li>Increased feeling of security in remote island residents and visitors</li> <li>Medical personnel access to a high level of education and training in remote islands</li> <li>Support of new doctors in remote islands</li> <li>Decrease of travel expenses for citizens and the medical institutions, and of lost work hours/days dedicated to patient transfer</li> </ul>
<b>The Procurement Process</b>
<ul style="list-style-type: none"> <li>Public consultation of technical specifications</li> <li>Approval of the invitation for tender documentation by the procuring agency</li> <li>Public open tendering process</li> <li>Selection of supplier with the most economically advantageous offer, contract signing</li> <li>Execution of contract</li> </ul>
<b>Technological requirements</b>
<ul style="list-style-type: none"> <li>Interoperability (use of open standards etc.)</li> <li>Security and privacy: data integrity and confidentiality, data protection, backup plans, physical security plans</li> <li>Reliability</li> <li>User friendliness</li> <li>Maintainability/Extensibility</li> <li>Connection of stations/ home monitoring systems with existing infrastructure</li> <li>Requirements for medical diagnosis equipment</li> <li>Video conferencing system</li> <li>Telemedicine application to offer device interconnection, data collection and transfer, doctor-patient appointments, usage statistics, doctor shift coordination, educational material</li> </ul>
<b>Related Links</b>
<a href="https://edit.gov.gr">https://edit.gov.gr</a>

The procurement process described above is not defined as a PPI, as PPIs are not yet defined in the Greek legislation. It is included as an example of the procurement of innovative services in the health domain and taking into account that a PPI would follow similar steps under the current legal framework.

#### 4.2.4 Hausarzt mit Telemedizin (HaT)

NAME OF THE PPI			
Hausarzt mit Telemedizin (HaT)			
Country	Germany	Procuring Agency	Landkreis Osnabrück
Budget	N/A	Duration	15 months
Stage of the procurement		N/A	
Unmet need			
Demographic change poses major economic and organizational challenges for medicine and care if medical care is to be secured at a high level. At the same time, family doctor care is becoming increasingly difficult, especially in rural areas. The challenge is to care for more patients with fewer physicians. In addition to this, not only is the average age of primary care physicians increasing,			



but also is the average age of patients. In addition, there is a shortage of personnel in the medical sector, especially in rural areas.

### What is being requested?

The aim is to strengthen medical care by reducing the workload through delegation in rural areas: In the HaT project the collection of vital data is to be delegated to the care assistant in the family doctor's office. Another goal is to obtain a settlement agreement with the health insurance companies to enable telemedical services in the form of digitization and the use of devices for data collection and transmission in Lower Saxony.

### How is being requested?

- "TeleArzt- Koffer" (Tele-doctor kit) that ensures data transfer from home visit patients to the family doctor's office.
- After the data is received on the tablet, the data is forwarded directly to the GP via pseudonymization and deleted on the tablet.
- If necessary, it is possible to set up a video conference with the patient via the tablet, so that the doctor can hold a video-based consultation.
- Training of the physicians, care assistant in the family doctor's office and non-physician practice assistants, in order to ensure that the technology is ready for use.

### Project KPIs

- Population in the rural areas covered by basic physician and care services
- Population benefiting from chronic disease management
- Population covered by telemedicine services

### Expected output

- Overcoming demographical challenges for medicine and care
- By the use of technology avoiding long home visits to the rural areas and hence bringing physician care to the rural areas where very few inhabitants live and have very low access to the hospital services
- To open the way up for new innovations
- In addition, the use of technology helps to secure the future of social systems by making it easier to avoid unnecessary duplication of services and to better compensate for shrinking human and financial resources.

### The Procurement Process

1. Demand management
2. Market research
3. Tender procedures
4. Execution and usage

### Technological requirements

- Devices for measurement of vital parameters (such as EKG, Spirometer and a tablet computer)
- Tools for data quality evaluation
- Tools to ensure data security and confidentiality

### Related Links

<https://www.gesundheitsregion-os.de/netzwerke-und-projekte/hausarzt-mit-telemedizin-hat>

### 4.2.5 Competition 17 – Urgent and Emergency Care

NAME OF THE PPI			
Competition 17 – Urgent and Emergency Care			
Country	Wales	Procuring Agency	SBRI
Budget	4M€	Duration	4 years
Stage of the procurement		Tender preparation	
Unmet need			
<p>The ever-increasing pressures on hospital emergency departments (EDs) are well documented globally and not just in the NHS and, despite many years of innovation, growth in numbers arriving at the doors of the ED continues. The reasons for this growth are multifactorial and some demographics show particular issues: children and young people have a significantly higher inappropriate/non-urgent attendance at ED than adults and the proportion of those of all ages with respiratory conditions has grown rapidly over the past few years.</p> <p>There are some signs of ability to reduce this growth significantly from the work done in the Vanguard, which recognise the need to address the wider system and not simply provide point solutions.</p> <p>This is referenced in the NHS Long Term Plan that has very ambitious targets for reducing hospital admissions. This competition seeks to address two primary issues, taking into account the systemic complexity and recognising some of the key demographic differences.</p>			
What is being requested?			
<p>Innovation solutions that will:</p> <ol style="list-style-type: none"><li>1. Reduce demand<ol style="list-style-type: none"><li>1.1. Recognising differences for adults vs children and young people</li><li>1.2. Recognising that respiratory conditions in all ages account for a rapidly growing proportion of attendances</li></ol></li><li>2. Reduce the length of stay in the Emergency Department<ol style="list-style-type: none"><li>2.1. By more efficient triage, streaming and treatment</li><li>2.2. By more efficient discharge or admission to the hospital</li></ol></li></ol>			
How is being requested?			
<p>Applicants are invited to tender for projects under the SBRI Healthcare programme to develop technology-enabled solutions addressing the challenges outlined in the following category, further details of which are outlined in the competition brief "Urgent and Emergency Care".</p> <p>The invitation to tender is published online on the SBRI portal <a href="https://sbrihealthcare.co.uk/wp-content/uploads/2020/08/SBRI_17_P1_Invitation-to-Tender.pdf">https://sbrihealthcare.co.uk/wp-content/uploads/2020/08/SBRI_17_P1_Invitation-to-Tender.pdf</a></p>			
Project KPIs			
<ul style="list-style-type: none"><li>- What will be the effect of this proposal on the challenge outlined in the brief? 25%</li><li>- The project plan, deliverables and risk mitigation strategy appropriate? 15%</li><li>- Will the technology/device/solution have a competitive advantage over existing and alternative solutions, how innovative is the proposal and are the arrangements surrounding the use and development of Intellectual Property appropriate? 20%</li></ul>			

- Does the proposed project have appropriate commercialisation and implementation plans? 20%
- Does the company and project team appear to have the right skills and experience to deliver the project? 15%
- Are the costs justified and appropriate? 5%

### Expected outputs

This competition seeks to address two primary issues, taking into account the systemic complexity and recognising some of the key demographic differences. So the request is for solutions that will:

1. Reduce demand
  - a. Recognising differences for adults vs children and young people
  - b. Recognising that respiratory conditions in all ages account for a rapidly growing proportion of attendances
1. Reduce the length of stay in the Emergency Department
  - a. By more efficient triage, streaming and treatment
  - b. By more efficient discharge or admission to the hospital

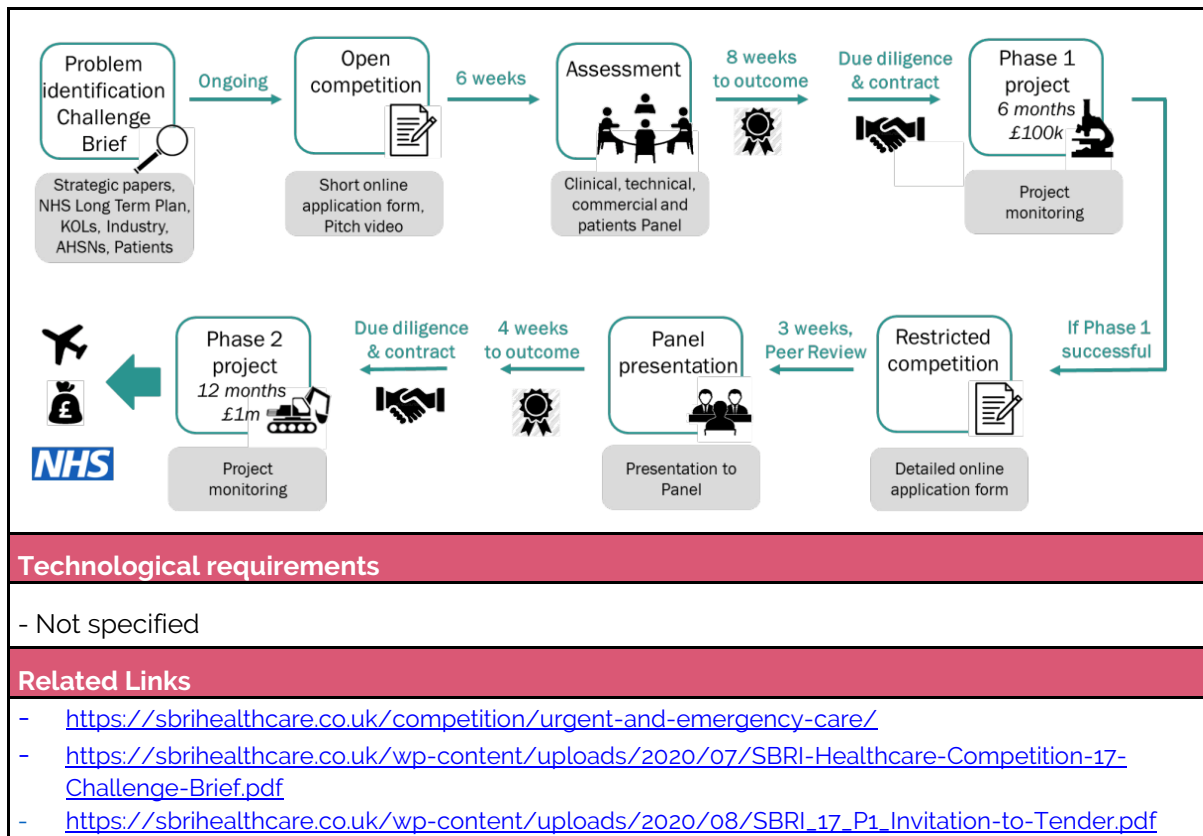
### The Procurement Process

SBRI Healthcare competitions are open to all organisations that can demonstrate a route to market for their solution. The SBRI Healthcare scheme is particularly suited to small and mediumsized business, as the contracts are of relatively small value and operate on short timescales. Developments are 100% funded and focused on specific identified needs, increasing the chance of exploitation. Suppliers for each project will be selected by an open competition process and retain the intellectual property generated from the project, with certain rights of use retained by the NHS. This is an excellent opportunity to establish an early customer for a new technology and to fund its development.

The competition will have two phases (subject to availability of budget in 2021):

- Phase 1 is intended to show the technical feasibility of the proposed concept. The development contracts awarded will be for a maximum of 6 months and £100,000 (incl. VAT) per project.
- Phase 2 contracts are intended to develop and evaluate prototypes or demonstration units from the more promising technologies in Phase 1. Only those projects that have completed Phase 1 successfully will be eligible for Phase 2. The development contracts awarded in Phase 2 will be for a maximum of 12 months and £1,000,000 (incl. VAT) per project.

Applicants should state their goals and outline their plan for Phase 2, as an explicit part of the path to full commercial implementation, in their Phase 1 proposal.



## 5 Building the GATEKEEPER Public Procurement framework: preliminary analysis on stakeholders

The following sections are dedicated to analysing the value chain of public procurement and discovering the stakeholders involved, with special emphasis on the situation in the GATEKEEPER value chain and how the project's Healthcare Authorities are involved in this type of procedures. This preliminary analysis aims to know the State of the Art of these initiatives within consortium members, and together with them, co-create and design the processes that enable the purchase of services and solutions facilitated by the GK platform.

### 5.1 Stakeholders involved in the value chain

In order to carry out public procurement processes for innovation and investments in healthcare which drive value-based approaches, it is necessary to involve the different stakeholders that are part of the value chain.

Stakeholders directly involved in public procurement processes can be divided into two categories:

- Contracting authorities: entity that promotes the public procurement process and will acquire the works, goods or services that are the subject of the contract.
- Economic operators: organisation offering the execution of work and/or the provision of products or services [50].

Thus, if we analyse the healthcare ecosystem, we can see that there are many different types of actors. Some of them participate directly in the public procurement of innovation processes, while others influence aspects such as regulation, definition of needs or decision making. The stakeholders identified are:

- Healthcare providers: Hospital management, Labs, HC institutions
- Clinician
- Key Opinion Leaders
- Procurement officials/department-payers
- Innovation Units in Hospitals
- Institutional leadership
- Research Institutions
- Industry
- Policy makers & Government
- Patients and Patient Association
- Carers
- Society

Some of the general benefits of involving different stakeholders in these processes are: (i) increasing value; (ii) building trust-shared value and mutual understanding; and (iii) new knowledge and perspectives [51].

However, according to the Value-based procurement (VBP) initiative, there are many other specific benefits for key stakeholders, as shown in Table 4:

Table 4. Benefits for key stakeholders according to Value-based Procurement [51]

<b>Patients</b>	<ul style="list-style-type: none"> <li>▪ Patient and/or relative comfort and convenience</li> <li>▪ Patient flexibility and mobility</li> <li>▪ Impact on treatment adherence</li> <li>▪ Better outcomes, less variation</li> <li>▪ Outcome information more relevant for patient</li> </ul>
<b>Healthcare Providers</b>	<ul style="list-style-type: none"> <li>▪ Security</li> <li>▪ Ease-of-use/handling and functionality</li> <li>▪ Training and access to education</li> <li>▪ Patient centric care pathway</li> <li>▪ Improved financial performance/stability</li> <li>▪ Breakdown internal functional silos</li> <li>▪ Best practice sharing between providers</li> </ul>
<b>Procurers</b>	<ul style="list-style-type: none"> <li>▪ Stronger strategic role within hospital</li> <li>▪ More influence on business objectives</li> <li>▪ More holistic framework/toolkit</li> <li>▪ Procurement methods harmonized and professionalized</li> </ul>
<b>Clinicians</b>	<ul style="list-style-type: none"> <li>▪ Clinicians structurally more involved in buying decisions</li> <li>▪ More influence on buying decisions (clinical, patient, user benefits)</li> <li>▪ Pain points understood by procurement</li> </ul>
<b>MedTech/industry</b>	<ul style="list-style-type: none"> <li>▪ Innovation and value created is rewarded</li> <li>▪ Improved dialogue and common vocabulary with buyers</li> <li>▪ Closer, more long-term partnerships with providers</li> <li>▪ R&amp;D cycle times reduced</li> </ul>
<b>Providers</b>	<ul style="list-style-type: none"> <li>▪ Maintainability, warranty and technical service support</li> <li>▪ Support improving efficiency along patient pathway</li> <li>▪ Alignment and support with reimburse structure</li> <li>▪ Support on admin., storage or logistics</li> <li>▪ Strategic fit for provider and support of strategy</li> </ul>
<b>Healthcare systems</b>	<ul style="list-style-type: none"> <li>▪ Reduction of rehospitalization/number of treatments</li> <li>▪ Reduced long term costs of treatment</li> <li>▪ Improved patient's health outcome</li> <li>▪ Reduction of total cost of care</li> <li>▪ HC expenditures more sustainable</li> <li>▪ Patient-centric care model</li> <li>▪ Innovation in care delivery enhanced</li> <li>▪ Less friction, better integration of care sectors</li> </ul>

### 5.1.1 GATEKEEPER Stakeholders within the PPI value chain

In this section, GATEKEEPER project partners will be classified as type of stakeholder in terms of procurement. The results are shown in Table 5:

Table 5. GATEKEEPER partners classified as stakeholders within PPI value chain

No	Partner	Type of stakeholder regarding procurement	No	Partner	Type of stakeholder regarding procurement
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1	MDT	Industry	25	SALUD	Healthcare providers Clinician
2	ENG	Industry	26	OSA	Healthcare providers Clinician
3	SAM	Industry	27	S4C	Industry
4	HPE	Industry	28	TUD	Research Institutions
5	UPM	Research Institutions	29	CCS	Institutional leadership
6	CERTH	Research Institutions	30	OU	Research Institutions
7	STM	Industry	31	HUA	Research Institutions
8	MyS	Industry	32	DCCG	Industry
9	W3C	Key Opinion Leaders	33	UPAT	Research Institutions
10	HL7	Key Opinion Leaders	34	AMEN	Healthcare providers Carers
11	ECHA	Key Opinion Leaders	35	PSKF	Patients and Patient Association
12	UDG	Key Opinion Leaders	36	IBR	Industry
13	MI	Key Opinion Leaders	37	KG	Research Institutions
14	UU	Research Institutions	38	RSCN	Key Opinion Leaders
15	CIB	Research Institutions Institutional leadership	39	BB	Industry
16	UOI	Research Institutions	40	CSS	Healthcare provider Clinician
17	TEC	Research Institutions	41	BIO	Industry
18	UoW	Research Institutions	42	MUL	Healthcare provider
19	FPM	Research Institutions	43	OK	Industry
20	MME	Industry	44	HKU	Research Institutions
22	OE	Key Opinion Leaders	45	IMT	Research Institutions
23	FUN	Industry	46	ASUS	Industry
24	RPU	Policy makers & Government	47	M+	Industry



## 5.2 GATEKEEPER Healthcare Authorities and their relation to Public Procurement

After identifying the stakeholders in the Procurement Value Chain, and more specifically the role that each of them assumes in it, a questionnaire was shared with the Healthcare Authorities (PUGLIA, CSS, SALUD, OSA, CCS, MUL, DCCG, KRONIKGUNE, PASIKAF and AMEN). The results of the questionnaire provided by Healthcare Authorities can be found in Appendix A.

The aim of this questionnaire was to collect the requirements, problems and needs that the Healthcare Authorities, as Contracting Authorities, have. By doing so, State of the Art of PPI processes in Europe can be understood, as well as barriers and best practices in all regions considered in GATEKEEPER project. This preliminary work will be used as the basis to replicate and develop efficient procedures to adapt current PPIs in healthcare sector to procure data-based services and solutions, which GK intends to promote and exploit.

Among these HC Authorities we can find entities of different types: regional authorities, private and public HC service providers, research institutes, patient associations and elderly nursing homes. We have observed that none of the respondents mentioned that models such as PPI or PCP are widely used (at least to their knowledge) in their organisation for the procurement of data-driven health solutions. This indicates that such initiatives, although promoted by the European Commission and other bodies, are not fully materialized in practice.

With regards to the prescribers of the solutions to be purchased, one of the important profiles are the Heads of Departments, which seems to be a profile to be considered when promoting the public procurement of innovative works, goods and services.

With regard to the development, approval and execution of the public procurement investment plan of these organisations, the actors involved are many according to the respondents, with great variability: Regional authorities, Hospital managers, Chief Medical Officers/Chief Nursing Officers, Economy directors, Chief Information Officer, Innovation Units and Head of department.

More than a half of the organisations do not have a Technology Assessment Group and as mentioned above, there is not much experience in participating in PPI processes, although those that have participated indicate that some of the important profiles in the process are Regional Authorities, Hospital managers, CMO/CNO, Economy Director, CIO, Innovation Units and Head of department. However, they do have Legal services who state they are familiar with PPI processes.

Interesting comments about the success points of Innovative Procurement Processes are: market development oriented to public need assessment, positive feedback of the market

in IPR to SMEs, narrow the gap between supply and demand, competitive products, innovative results and clear definition of procedures; as well as the pain points: information asymmetry between public procurer and might may affect the choice, lack of administrative risk management, weak knowledge of PCP/PPI execution by SMEs, bureaucracy and process management, change of attitude, results may not meet initial expectations, companies don't perform innovation, organisations have to choose the cheapest option and they are too time consuming.

## 6 Definition of the co-creation workshop: Building the PPI of the GATEKEEPER services and solutions

One of the main objectives of *Task 8.4 Governance for procurements* is to define and implement the co-creation process involving the different stakeholders to enable procurement of the innovative services and solutions of the GATEKEEPER platform. As stated in section **Error! Reference source not found.**, the GATEKEEPER consortium is comprised by representatives from the most relevant key stakeholders involved in the definition of the public procurement of innovation value chain. This will enable us to have all the main participants that will bring the key inputs for the co-creation workshop.

In order to prepare this co-creation workshop, we are going to conduct the following activities:

1. **Previous work:** to guarantee a successful workshop, it is essential that all relevant participants are aware of the topics that are going to be discussed, so preparatory materials such as forms and explanatory documentation will be shared in advanced with the workshop participants to convey the aim, the context and objectives of this co-creation workshop.

With this objective, two focus groups are going to take place as a previous preparation activity. Each focus group will be organized with different stakeholders' clusters, one involving the demand side (healthcare providers, regional healthcare authorities and enablers) and the other with the supply side (industry). Each focus group will target the definition of the already existing barriers and best practices in the PPI.

2. **Co-creation workshop set-up:** once both focus groups have taken place and its conclusions have been analysed, the co-creation workshop will take place involving all partners that participated in each focus group. This will bring together the demand and supply side to discuss about the barriers and best practices concluded from the focus groups and to define jointly the procurement process of the GATEKEEPER solutions.

In normal conditions, these focus groups and co-creation workshop would take place physical, concurring with one of the face2face project meetings, but due to the current Covid-19 situation, in which travels are still on hold, these sessions will be redefined to take place remotely. To be able to perform these activities remotely, the following tools will be used:



**Zoom Cloud Meetings:** This software program allows participants to have virtual communications. It is compatible with most of the OS, and it has a simple interface and usability. As this tool is the official one provided by the coordinator that we are using in the GATEKEEPER project, all participants are already familiar with the use of this tool.



**MURAL:** This online workspace tool for visual collaboration. It provides blank spaces to create and share digital walls where everyone can jot down and organize ideas. This tool has already been used in the co-creation workshops conducted in WP2. (We will use this tool or any similar in the market).



**Etherpad:** is an open-source, web-based collaborative real-time editor, that allows authors to simultaneously edit a text document, and see all of the participants' edits in real-time. This tool will enable us to gather all the comments and minutes from the meeting in real time.

## 6.1 Preparation and previous work

Firstly, two focus groups are going to be organized with different stakeholders to extract the information that will be necessary to prepare the co-creation workshop. Each of these focus groups will target different clusters. One will be for the demand side (healthcare authorities and healthcare providers) and the other one will target the supply side (industry and tech providers).

The aim of these focus groups is to obtain the barriers and best practices in the current public procurement of innovation process. The conclusion of these focus groups will be used to conduct the final co-creation workshop.

### 6.1.1 Session 1: Focus Group - Barriers and Best Practices with Procurers

The first focus group will target the demand stakeholders that enable the preparation of these tenders. The stakeholders participating in this focus group will be:

- Clinicians
- Patients (represented by the patient associations)
- Healthcare authorities
- Regional authority
- Research Institutes
- Policy makers & Government

As a preparatory activity for the preparation of this focus group, all healthcare authorities within the GATEKEEPER consortium have been requested to complete a form that collects the requirements, problems, needs and functional and non-functional requirements from their organization regarding public procurement with special focus on public procurement of innovation. This form gathers relevant information as what kind of procurement model they follow and with what frequency; and who are the prescriber, approver or executor of these PPI.

The form template and the preliminary feedback received from the healthcare authorities can be found in 8. Although preliminary conclusions have been extracted in section 5.2 of this document, all these forms will be further analysed for the preparation of the focus

group and its conclusions presented in the next version of this deliverable D8.6 Report on the overall governance for procurements (M36, Sept 2022).

This focus group will take place at the beginning of 2022 (January – February 2022). As previously commented, in a normal situation, this focus group would take place physically, concurring with one of the face2face recurrent project meetings, but due to the current Covid-19 situation, in which travels are still on hold, this focus group will be redefined to take place remotely. The agenda of this focus group will have the following structure:

Duration	Activity
0:15:00	<b>Welcome and introduction of participants</b>
0:10:00	<b>Exercise to get familiar with the online tools</b>
0:50:00	<b>Brainstorming: best practices and barriers in PPI for procurers</b>
0:15:00	<b>Conclusions of the brainstorming and next steps</b>

### 6.1.2 Session 2: Focus Group - Barriers and Best Practices with Suppliers

The second focus group will target the suppliers' that will participate in these tenders. The stakeholders participating in this focus group will be:

- Large Industries
- SMEs
- Research Institutes

As a preparatory activity for the preparation of this focus group, all suppliers within the GATEKEEPER consortium will be requested to complete a form to collect their experience in participating in PPIs, the barriers and good practices identified in the PPI participation process. All these forms will be analysed for the preparation of the focus group and its conclusions presented in the next version of this deliverable D8.6 Report on the overall governance for procurements (M36, Sept 2022).

This focus group will take place during the first quarter of 2022 (March - April 2022). As previously commented, in a normal situation, this focus group would take place physically, concurring with one of the face2face recurrent project meetings, but due to the current Covid-19 situation, in which travels are still on hold, this focus group will be redefined to take place remotely. This focus group will have a duration of 1 hour and 30 mins and the agenda of this focus group will have the following structure:

Duration	Activity
0:15:00	<b>Welcome and introduction of participants</b>
0:10:00	<b>Exercise to get familiar with the online tools</b>
0:50:00	<b>Brainstorming: best practices and barriers in PPI for suppliers</b>
0:15:00	<b>Conclusions and next steps</b>

## 6.2 Co-creation workshop: Building the PPI of the GATEKEEPER services and solutions

Once both focus groups have taken place and the conclusions have been analysed, a co-creation workshop will be conducted with the aim of *Building the PPI of the GATEKEEPER services and solutions*. Firstly, we will focus on the analysis of the conclusions extracted from the different focus groups to discuss on how to address the key barriers identified. This will enable to define during the co-creation workshop the structure of the theoretical PPI of the GATEKEEPER services and solutions. This co-creation workshop will count with the participation of the participants of both previous focus groups:

- Clinicians
- Patients (represented by the patient associations)
- Healthcare authorities
- Regional authority
- Research Institutes
- Policy makers & Government
- Large Industries
- SMEs
- Research Institutes

In addition, we will also rely on other Key Opinion Leaders within the consortium, to enrich the discussion and provide another point of view beyond the procurer and suppliers perspective.

This co-creation workshop will take place during the second trimester of 2022 (between April – June 2022). As previously commented, we will try to arrange this co-creation workshop physically, concurring with one of the projects face2face meetings. In case this workshop cannot take place physically due to the Covid-19 travel restrictions, we will take advantages of the online tools already mentioned and perform it remotely.

This co-creation workshop will have a duration of 2 hours and the agenda will have the following structure:

Duration	Activity
0:10:00	<b>Welcome and introduction of participants</b>
0:30:00	<b>Presentation of the conclusions of the Focus Groups</b>
0:35:00	<b>Discussion on how to address key pain points (Procurers and suppliers' perspectives)</b>
0:35:00	<b>Brainstorming: Definition of the ideal PPI for the GK services and solutions</b>
0:10:00	<b>Conclusions</b>

The conclusions of this co-creation workshop will be included in the next version of this deliverable D8.6 – September 2022.

## 7 Conclusions and future work

As stated throughout this document, *Task 8.4 Governance for Procurement* is intended to define and implement a co-creation process to enable the procurement of the innovative services and solutions facilitated by GATEKEEPER involving all key stakeholders. The implementation of these kind of procurements is essential for the exploitation and future sustainability of the GATEKEEPER services and solutions, as they are the only enablers for its acquisition by the public health and regional authorities.

In a first approach to achieve this milestone, this deliverable has already identified some of the main key points that have to be taken into consideration to enable the framework definition of the GK solution procurements.

Firstly, it is important to understand the legal framework that applies in the public procurements. As we have seen, although the EC has defined European Directives for the coordination of procedures for the award of public works and contracts, each country has its own transpositions of the law, which in some cases, this national legislation has been further developed at a regional level.

In addition, the EC is promoting the adoption of these type of Public Procurements of Innovation by creating several initiatives such as the EAFIP, EURIPHI or PIPPI, that have the aim of supporting the creation of new PPIs and to enable the collaboration between procurers and suppliers in of public procurements. The work that has been done in those initiatives will help GATEKEEPER to better understand the overall PPI procedure and how to manage the collaboration between the relevant stakeholders involved in the prescription, development, approval, and execution of the public investment plans in the different public procurement organizations.

Preparing and executing a Public Procurement of Innovation requires the implication of heterogeneous profiles within the healthcare sector. In this context, the GATEKEEPER project has an added value as it has representation within this consortium of all the relevant stakeholders. This will enable to perform during the second year of development of the task, the focus groups and co-creation workshop to gather the needs, pain points and best practices that will allow to define the guidelines for the Public Procurement of Innovation of the GATEKEEPER services.

Thanks to the close collaboration with *task 2.1 Ecosystem Management, Enlargement and Collaboration with other Initiatives*, the Public Procurement of Innovation has been defined as one of the main topics to be addressed within the different activities that will be carried out by the Community of Interest (COI) during 2022. This will let us to validate the conclusions drawn from the co-creation process and to enrich the guidelines and methodologies for PPI with the feedback received from the members of the COI.



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## Appendix A Healthcare authorities Procurement information

The following form has been circulated among the different health authorities within the GATEKEEPER project to gather their requirements, needs regarding the public procurement.

Public Procurement Form
G A T E K E E P E R

### GATEKEEPER FORM TO CAPTURE NEEDS, REQUIREMENTS AND PROBLEMS TOWARDS PUBLIC PROCUREMENT PROCESS

This form will allow us to collect the requirements, problems, needs and functional and non-functional requirements from your organization regarding public procurement with special focus on public procurement of innovation, to offer you the most suitable information, support and training adapted to your needs.

#### CONTACT DETAILS

- Entity Name:
- Country:
- Region:
- Department/Unit:
- Main contact point:
- Type of entity:

☐ Public healthcare service provider
☐ Private healthcare service provider

☐ Municipality
☐ Regional authority

☐ Policy maker
☐ Patient Association

☐ Other:

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## Public Procurement Form

## G A T E K E E P E R

## PUBLIC PROCUREMENT PREPARATION SURVEY

## 1. Which purchase or procurement model(s) does organization follow? What is their frequency?

☐ Open tender<sup>1</sup>☐ Direct Purchase<sup>2</sup>Frequency: Frequency: ☐ Negotiated purchase<sup>3</sup>☐ Accelerated public tender<sup>4</sup>Frequency: Frequency: ☐ Pre-Commercial Procurement<sup>5</sup>☐ Public Procurement of Innovation<sup>6</sup>Frequency: Frequency: ☐ Other: Frequency: 

(\*Frequency: number of contracting models prepared per year – i.e. 2 tenders/year)

<sup>1</sup> Open tender: It is the main tendering procedure and allows anyone to submit a tender to supply the goods or services required and offers an equal opportunity to any organization to submit a tender (<https://www.opuskinetic.com/2019/04/4-types-of-tender-and-tendering-processes/>)

<sup>2</sup> Low-value contracts: It occurs when a procurement does not exceed a certain quantity (established usually by each national regulation), thus simplified rules apply ()

<sup>3</sup> Negotiated purchase: It occurs when a contracting authority approaches a single supplier based on their track-record or a previous relationship. The terms of the contract are then negotiated ([https://www.designingbuildings.co.uk/wiki/Negotiated\\_tendering](https://www.designingbuildings.co.uk/wiki/Negotiated_tendering))

<sup>4</sup> Accelerated public tender: It is considered as an Open Tender, but with accelerated timeframes, used in states of urgency (<https://blog.tendersdirect.co.uk/2014/05/01/the-new-eu-directive-on-public-procurement-accelerated-procedures/>)

<sup>5</sup> Pre-Commercial Procurement: An approach for public procurers in which R&D is bought from several competing suppliers in parallel to compare alternative solution approaches and identify the best value for money solutions that the market can deliver to address their needs (<https://digital-strategy.ec.europa.eu/en/policies/pre-commercial-procurement>)

<sup>6</sup> Public Procurement of Innovation: An approach when the public sector uses its purchasing power to act as early adopter of innovative solutions which are not yet available on large scale commercial basis (<https://digital-strategy.ec.europa.eu/en/policies/ppi>)

Public Procurement Form	G A T E K E E P E R
<p><b>2. Within your organization, who is the prescriber of solutions to be purchased?</b></p> <div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"> <input type="checkbox"/> Regional authorities         </div> <div style="width: 50%;"> <input type="checkbox"/> Hospital manager         </div> <div style="width: 50%;"> <input type="checkbox"/> Chief Medical Officer/Chief Nursing Officer         </div> <div style="width: 50%;"> <input type="checkbox"/> Economy director         </div> <div style="width: 50%;"> <input type="checkbox"/> Chief Information Officer         </div> <div style="width: 50%;"> <input type="checkbox"/> Innovation Units         </div> <div style="width: 50%;"> <input type="checkbox"/> Head of department         </div> <div style="width: 50%;"> <input type="checkbox"/> Other: <input style="width: 150px;" type="text"/> </div> </div> <p><b>Brief explanation:</b></p> <div style="border: 1px solid black; height: 120px; margin-top: 10px;"></div>	
<p><b>3. Within your organization, which stakeholders are involved in the development of the healthcare services and equipment investment plan?</b></p> <div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"> <input type="checkbox"/> Regional authorities         </div> <div style="width: 50%;"> <input type="checkbox"/> Hospital manager         </div> <div style="width: 50%;"> <input type="checkbox"/> Chief Medical Officer/Chief Nursing Officer         </div> <div style="width: 50%;"> <input type="checkbox"/> Economy director         </div> <div style="width: 50%;"> <input type="checkbox"/> Chief Information Officer         </div> <div style="width: 50%;"> <input type="checkbox"/> Innovation Units         </div> <div style="width: 50%;"> <input type="checkbox"/> Head of department         </div> <div style="width: 50%;"> <input type="checkbox"/> Other: <input style="width: 150px;" type="text"/> </div> </div> <p><b>Brief explanation:</b></p> <div style="border: 1px solid black; height: 120px; margin-top: 10px;"></div>	

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## Public Procurement Form

## G A T E K E E P E R

6. Within your organization, is there any health technology assessment group for the acquisition of new products or services?

☐ Yes

☐ No

7. Within your organization, are stakeholders involved in the investment of goods and equipment aware of the Innovative Public Procurement process?

☐ Regional authorities

☐ Hospital manager

☐ Chief Medical Officer/Chief Nursing Officer

☐ Economy director

☐ Chief Information Officer

☐ Innovation Units

☐ Head of department

☐ Other: 

Brief explanation:

8. Does your organization have its own legal services?

☐ Yes

☐ No

8.1. If yes, do they provide their advice on the Innovative Public Procurement process?

Brief explanation

## Public Procurement Form

## G A T E K E E P E R

**9. Based on your experience in participating in PPI/PCP, please list the points of success you would highlight:**

**10. Based on your experience in participating in PPI/PCP, list the pain points detected:**

**11. Other interesting observations and/or comments:**



The following table reflects the feedback received from the different Healthcare authorities:

	PUGLIA	CSS	SALUD	CCS	MUL	DCCG	KRONIKGUNE	PASIKAF	AMEN	BANGOR/OU
<b>Type of entity</b>	Regional authority	Private HC service provider	Public HC service provider	-	Public HC service provider	Public HC service provider	Research Institute	Patient Association	Elderly Nursing Home	Regional Authority
<b>Procurement models</b>	Open Tender Direct Purchase Negotiated purchase Pre-Commercial Procurement Dynamic purchasing system plus Restricted procedures	Open Tender Direct Purchase Negotiated purchase	Open tender Direct Purchase Negotiated purchase Accelerated purchase	N/A	Open tender Direct Purchase Negotiated purchase	Open tender Direct purchase Accelerated public tender	Open tender Direct Purchase	Negotiate purchase with min 3 supplier	Open tender Direct Purchase Negotiated purchase	Open tender Direct Purchase Public Procurement of Innovation SBRI (pathway for innovation pilots)
<b>Prescriber of solutions</b>	Regional authorities Innovation Units Head of departments	Head of department	Regional authorities Economy director Innovation Units	N/A	Dział Zamówień Publicznych	Regional authorities Hospital manager CIO Head of department	Economy director General Director	CMO/CNO Head of department Officer	Director	Hospital manager CMO/CNO Head of department Clinicians
<b>Stakeholders in development of investment plan</b>	Regional authorities Hospital manager Innovation Units	Hospital manager CMO/CNO Economy director	Regional authorities Economy director Innovation Units	N/A	Regional authorities Hospital manager CMO/CNO	Regional authorities Hospital manager CMO/CNO	Economy director General Director	CMO/CNO Head of department	CMO/CNO Director	Regional authorities Hospital manager CMO/CNO Economy director

	PUGLIA	CSS	SALUD	CCS	MUL	DCCG	KRONIKGUNE	PASIKAF	AMEN	BANGOR/OU
	Head of Department	CIO Innovation Units Head of department HTA/Clinical Engineering Unit	Head of Department		Economy director CIO Innovation Units Head of departments	Economy director CIO Head of department				Chief Information Officer Innovation Units Head of department Testing lab
<b>Stakeholders approve investment plan</b>	Regional authorities Head of department	Hospital manager	Regional authorities Hospital manager CMO/CNO Economy director Innovation Units Head of department	N/A	Hospital manager	Regional authorities Hospital manager	General director Minister of Health of Basque Country Director of Health Research and Innovation of Basque Ministry of Health General Director of Public Health Service provider of the Basque Country (OSA)	Head of departments Board of Directors	Board of Directors	Economy director Government
<b>Stakeholders execute</b>	Regional authorities	Hospital manager	Regional authorities	N/A	Hospital manager	Hospital manager	Economy director	CMO/CNO	CMO/CNO	Regional authorities

	PUGLIA	CSS	SALUD	CCS	MUL	DCCG	KRONIKGUNE	PASIKAF	AMEN	BANGOR/OU
<b>investment plan</b>	Economy director Head of department Regional Central Purchasing Body	CMO/CNO Economy director CIO Head of department	Hospital manager CMO/CNO Economy director Innovation Units Head of department			Economy director	General Director	Head of department		Hospital manager CMO/CNO Economy director Chief Information Officer Innovation Units Head of department
<b>Technology assessment group</b>	Yes	Yes	Yes	No	No	No	No	No	Yes	Yes
<b>Stakeholders in PPI</b>	Regional authorities Innovation Unit Head of department Regional Central Purchasing Body	N/A	Regional authorities Hospital manager CMO/CNO Economy director CIO Innovation Units Head of department	N/A	Not currently involved in PPI	Regional authorities	Not involved	N/A	CMO/CNO Director	Procurement service
<b>Legal services: advice on PPI</b>	Yes, as part of Central Purchasing Body (InnovaPuglia)	Yes, any process	Yes, for PPI	No	Yes, for PPI	Yes	Yes	No	Yes	Yes, legal assessment carried out in parallel with finance assessment

	PUGLIA	CSS	SALUD	CCS	MUL	DCCG	KRONIKGUNE	PASIKAF	AMEN	BANGOR/OU
<b>Points of success in PPI/PCP</b>	Test on the field new solutions  Positive feedback of the market in IPR to SMEs  Market development oriented to public need assessment	No previous experience	Narrow the gap between supply and demand  Competitive products  Innovative results  Clear definition of procedures	N/A	N/A	N/A	No experience	N/A	Process in European and Cyprus Legislation is very helpful	N/A
<b>Pain points in PPI/PCP</b>	Multiple phases might be long  Information asymmetry between public procurer and might may affect the choice  Lack of administrative risk management  Weak knowledge of PCP/PPI execution by SMEs	No previous experience	Bureaucracy and process management  Change of attitude  Results may not meet initial expectations  Companies don't perform innovation	N/A	N/A	N/A	No experience	N/A	Organisations have to choose the cheapest option  Too time consuming	PPI is handled as a regular procurement so lack of flexibility and not having a specific pathway for innovation
<b>Other observations</b>	DG REGIO initiative: on	N/A	N/A	N/A	N/A	N/A	No experience	N/A	N/A	N/A

	PUGLIA	CSS	SALUD	CCS	MUL	DCCG	KRONIKGUNE	PASIKAF	AMEN	BANGOR/OU
	the goals is to define risk-assessment procedure from PCP to PPI									

## **Forms received from the HC Authorities**

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## PUBLIC PROCUREMENT PREPARATION SURVEY

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Frequency:

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Frequency:

Frequency:

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Yes

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**Brief explanation:**

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Yes

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Brief explanation



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## GATEKEEPER FORM TO CAPTURE NEEDS, REQUIREMENTS AND PROBLEMS TOWARDS PUBLIC PROCUREMENT PROCESS

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### CONTACT DETAILS

- Entity Name:
- Country:
- Region:
- Department/Unit:
- Main contact point:
- Type of entity:

Public healthcare service provider

Private healthcare service provider

Municipality

Regional authority

Policy maker

Patient Association

Other:

## PUBLIC PROCUREMENT PREPARATION SURVEY

**1. Which purchase or procurement model(s) does organization follow? What is their frequency?**Open tender<sup>1</sup>Direct Purchase<sup>2</sup>

Frequency:

Frequency:

Negotiated purchase<sup>3</sup>Accelerated public tender<sup>4</sup>

Frequency:

Frequency:

Pre-Commercial Procurement<sup>5</sup>Public Procurement of Innovation<sup>6</sup>

Frequency:

Frequency:

Other:

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(\*Frequency: number of contracting models prepared per year – i.e. 2 tenders/year)

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**2. Within your organization, who is the prescriber of solutions to be purchased?**

Regional authorities

Hospital manager

Chief Medical Officer/Chief Nursing Officer

Economy director

Chief Information Officer

Innovation Units

Head of department

Other:

**Brief explanation:****3. Within your organization, which stakeholders are involved in the development of the healthcare services and equipment investment plan?**

Regional authorities

Hospital manager

Chief Medical Officer/Chief Nursing Officer

Economy director

Chief Information Officer

Innovation Units

Head of department

Other:

**Brief explanation:**



**4. Within your organization, which stakeholders approve in the development of the healthcare services and equipment investment plan?**

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Hospital manager

Chief Medical Officer/Chief Nursing Officer

Economy director

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**Brief explanation:****5. Within your organization, which stakeholders execute healthcare services and equipment investment plan?**

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Innovation Units

Head of department

Other:

**Brief explanation:**

6. Within your organization, is there any health technology assessment group for the acquisition of new products or services?

Yes

No

7. Within your organization, are stakeholders involved in the investment of goods and equipment aware of the Innovative Public Procurement process?

Regional authorities

Hospital manager

Chief Medical Officer/Chief Nursing Officer

Economy director

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Innovation Units

Head of department

Other:

**Brief explanation:**

8. Does your organization have its own legal services?

Yes

No

- 8.1. If yes, do they provide their advice on the Innovative Public Procurement process?

**Brief explanation**

- 9. Based on your experience in participating in PPI/PCP, please list the points of success you would highlight:**

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Brief explanation:

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Yes

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Brief explanation



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- ☐ Other:



## PUBLIC PROCUREMENT PREPARATION SURVEY

## 1. Which purchase or procurement model(s) does organization follow? What is their frequency?

☒ Open tender<sup>1</sup>Frequency: ☒ Direct Purchase<sup>2</sup>Frequency: ☐ Negotiated purchase<sup>3</sup>Frequency: ☐ Accelerated public tender<sup>4</sup>Frequency: ☐ Pre-Commercial Procurement<sup>5</sup>Frequency: ☒ Public Procurement of Innovation<sup>6</sup>Frequency: ☒ Other: Frequency: 

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The request starts usually from clinicians and then go to their hierarchies. In parallel, all request are validated by finance.

**3. Within your organization, which stakeholders are involved in the development of the healthcare services and equipment investment plan?**☒ Regional authorities☒ Hospital manager☒ Chief Medical Officer/Chief Nursing Officer☒ Economy director☒ Chief Information Officer☒ Innovation Units☒ Head of department☒ Other: **Brief explanation:**

Clinicians, the Medical Devices Group, Finance, the Surgical Medical Testing Lab, Information Management Technology

**4. Within your organization, which stakeholders approve in the development of the healthcare services and equipment investment plan?**☐ Regional authorities☐ Hospital manager☐ Chief Medical Officer/Chief Nursing Officer☒ Economy director☐ Chief Information Officer☐ Innovation Units☐ Head of department☒ Other: **Brief explanation:**

It depends on the budget threshold. It could be Finance director up to the Wales Government

**5. Within your organization, which stakeholders execute healthcare services and equipment investment plan?**☒ Regional authorities☒ Hospital manager☒ Chief Medical Officer/Chief Nursing Officer☒ Economy director☒ Chief Information Officer☒ Innovation Units☒ Head of department☐ Other: **Brief explanation:**

The implementation team can include representative of all stakeholders ranging from clinical staff to information security and finance.

6. Within your organization, is there any health technology assessment group for the acquisition of new products or services?

☒ Yes

☐ No

7. Within your organization, are stakeholders involved in the investment of goods and equipment aware of the Innovative Public Procurement process?

☐ Regional authorities

☐ Hospital manager

☐ Chief Medical Officer/Chief Nursing Officer

☐ Economy director

☐ Chief Information Officer

☐ Innovation Units

☐ Head of department

☒ Other:

**Brief explanation:**

UK is outside the EU and therefore this does not apply. However, the procurement does not have a specific pathway for innovation procurement: this is actually an issue for scaling up from a pilot to a contract.

8. Does your organization have its own legal services?

☒ Yes

☐ No

8.1. If yes, do they provide their advice on the Innovative Public Procurement process?

**Brief explanation**

The assessment from the legal team is carried out in parallel with the finance assessment.

- 9. Based on your experience in participating in PPI/PCP, please list the points of success you would highlight:**

- 10. Based on your experience in participating in PPI/PCP, list the pain points detected:**

PPI is handled as regular procurement. This results in a lack of flexibility and not having a specific pathway for innovation. The usual process involves a pilot but then there is not a preferential way for setting up a procurement. What happens is that there is an analysis of the specs and requirement based to shape a public tender. However, there is not an easy distinction between when something is considered a pilot or requiring a tender.

- 11. Other interesting observations and/or comments:**