DRAFT 8 January 2021

EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

(EXPH)

Opinion on

Public procurement in healthcare systems

The EXPH adopted this opinion at the .. plenary on … 2021
after public hearing on 3 February 2021

About the Expert Panel on effective ways of investing in Health (EXPH)

Sound and timely scientific advice is an essential requirement for the Commission to pursue modern, responsive and sustainable health systems. To this end, the Commission has set up a multidisciplinary and independent Expert Panel which provides advice on effective ways of investing in health (Commission Decision 2012/C 198/06).

The core element of the Expert Panel's mission is to provide the Commission with sound and independent advice in the form of opinions in response to questions (mandates) submitted by the Commission on matters related to health care modernisation, responsiveness, and sustainability. The advice does not bind the Commission.

The areas of competence of the Expert Panel include, and are not limited to, primary care, hospital care, pharmaceuticals, research and development, prevention and promotion, links with the social protection sector, cross-border issues, system financing, information systems and patient registers, health inequalities, etc.

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ACKNOWLEDGMENTS

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ABSTRACT

Every year, over 250,000 public authorities in the EU spend about 14% of GDP (about €2 trillion) on the purchase of services, works, and supplies. Many are in the health sector, a sector in which public authorities are the main buyers in many countries. When these purchases exceed certain thresholds, EU public procurement rules apply. In light of the rising healthcare costs in the EU as a whole, public procurement has increasingly been promoted as a tool for developing efficiency as well as contributing to better health outcomes. Public procurement Directives 2014/24/EU "on public procurement and repealing Directive 2004/18/EC" and 2014/23/EU "on the award of concession contracts" provide an EU framework for public procurement in the EU. Its core principles are transparency, equal treatment and non-discrimination.

In this situation, the Expert Panel has been asked to consider the challenges that arise with public procurement and any potential solutions to them within healthcare systems. We have examined the tendering of pharmaceuticals, health technology, and e-Health. In each case we identify a series of challenges relating to the complexity of the procurement process, imbalances in power on either side of transactions, and the role of procurement in promoting broader public policy objectives. We then make a series of recommendations designed to strengthen the procurement process, stressing the importance of using procurement to promote the goals of the health system, and specifically the interests of patients, to promote the wider goals of public policy in the social, economic, and environmental spheres, and building capacity within organisations engaged in public procurement to ensure that they have the necessary skills and expertise. A further three recommendations relate to particular topics, highlighting the need to strengthen action on corruption at all stages of procurement in the health sector, improve public procurement during emergencies, and take advantage of the opportunities offered by cross-border procurement.

Keywords: Expert Panel on effective ways of investing in Health, public procurement, pharmaceuticals, health technology, e-health

Opinion to be cited as:

Expert Panel on effective ways of investing in Health (EXPH), public procurement in healthcare systems, .. February 2021

ISSN 2315-1404
doi:xxxx

ISBN
ND-xxx

http://ec.europa.eu/health/expert_panel/index_en.htm

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EXECUTIVE SUMMARY

Background:

Every year, over 250,000 public authorities in the EU spend about 14% of GDP (about €2 trillion) on the purchase of services, works, and supplies. Many are in the health sector, a sector in which public authorities are the main buyers in many countries. When these purchases exceed certain thresholds, EU public procurement rules apply.

Public procurement Directives 2014/24/EU "on public procurement and repealing Directive 2004/18/EC" and 2014/23/EU "on the award of concession contracts" provide an EU framework for public procurement in the EU. In short, when a contracting authority concludes works, supply or services contract for a monetary value exceeding above EU financial thresholds, EU public procurement rules apply. The framework is based on the principles of transparency, equal treatment, and non-discrimination, and it is a mechanism to promote the Europe 2020 strategy, for smart, sustainable, and inclusive growth. The Directives apply the principle of Most Economically Advantageous Tender (MEAT). In order to compare the different offers, there are different types of award criteria that can be used either separately or in a combined manner: a) price, b) cost, c) the best price-quality ratio (BPQR). With this regard, the Directive contains a non-exhaustive enumeration of possible award criteria.

Against this background, the Expert Panel has been asked to consider the challenges that arise with public procurement and any potential solutions to them within healthcare systems, including a reflection on award criteria other than price or cost that could be used introduced to tenders for different medical supplies, and recommendations on what type of subject-matter are more apt for centralised procurement and how to support procurement of innovation.. Finally, it should consider what can be done at EU level to support public buyers in Member States in this endeavour.

Health sector specificities in relation to public procurement:

Procurement is "the process of finding and agreeing to terms, and acquiring goods, services, or works from an external source, often via a tendering or competitive bidding process" (Laffont and Tirole, 1993). The 2014 Directive describes it as "one of the ***market-based instruments*** to be used to achieve smart, sustainable and inclusive growth while ensuring the most efficient use of public funds [emphasis added". Note however that while the concept is based on market principles, public procurement can in principle still operate with limited or no competition. For example, if a public buyer wants to buy a patented medicine for which there are no distributors active on the market, it can make use of a negotiated procedure without prior call for competition, but still it has to publish a contract award notice in the Official Journal to ensure transparency.

While recognising that there are certain circumstances in which procurement can take place in the absence of competition, the principle that it is a means of selecting the most economically advantageous tender implies that there is economically choosing There are several key features of a competitive market that may not apply in the health sector. There may not be multiple firms offering goods to ensure that the market is competitive. In addition, health services can be complex, meaning that transaction costs may not be low. Transaction costs are influenced by uncertainty, frequency, and asset specificity.

In addition to the basic assumptions underlying the operation of markets, there is a series of issues that arise when purchasing capital (durable goods) and that have to be carefully considered in the preparation phase of the tender. The first is the need to consider costs that will accrue throughout the whole life of the product. Second, new technology increasingly comes in the form of bundled products, for example as combinations of medicines and monitoring systems, diagnostic equipment and operating contracts, or telemetry devices and remote monitoring. Third, there are major challenges because of the lack of interoperability of equipment, particularly that using information technology if there are no common standards. Fourth, unlike pharmaceuticals that are subject to rigorous evaluation before being placed on the market, many forms of technology (such as medical devices) do not go through the same process of evaluating their technical performance, other than to establish their safety. An area of particular concern is the growth of mHealth. All these issues pose a number of particular challenges when drafting the tender.

Finally, the strategic use of public procurement to boost innovation is closely connected to a government's power to shape and create market conditions. Public procurement is increasingly recognised as a potential strategic instrument and a policy lever for achieving government policy goals, such as innovation, the development of SMEs, sustainable green growth and social objectives like greater inclusiveness.

Health sector challenges:

Drawing on the preceding analysis, the challenges that apply to procurement across the different purchases that are made in the health sector can be placed in three broad categories, none of which are exclusive to the health sector but which have particular relevance to it. The first is the complexity of the transaction. The second is the imbalance of power between the procurer and the provider on each side of the transaction, especially where factors limit competition, on the provider side (barriers to entry, monopoly etc.) or the purchaser (small purchaser with limited technical skills). And the third relates to policy objectives that might be competing. The three challenges are looked at as they apply to pharmaceuticals, medical devices, and e-health solutions.

Better procurement:

There has been growing recognition that those undertaking public procurement require specialised skills and competencies. These include a detailed understanding of the organisation of health services, including the complex interrelationships between different groups of health workers, changing technology, and advances in models of care. The importance of recruiting, developing, and retaining such individuals is highlighted. Tools and methodologies to support professional procurement practice should be implemented, in particular e-procurement, with IT solutions that can enhance access to information, provide economies of scale, and promote standardisation and interoperability.

There is also a need to systematise the knowledge that already exists regarding public procurement in the health sector and the related purchasing tasks, such as sourcing (during the COVID crisis, public buyers in the health sector who directly awarded contracts to suppliers without any prior competition procedure, did not have any knowledge of the different suppliers on the market) and also on the entire supply chain (also where it went wrong in the crisis), and a need to push rigorous evaluation of existing and future procurement processes in the health sector.

Finally, it is important to put in place specific anti-corruption and governance tools focused on transparency, oversight, and accountability. Transparency, in particular, is one of the most important means for preventing corruption in the public sector, and it is even more important in times of emergency.

How can cross border procurement be used to increase efficiency and quality of the outcome?

Cross-border collaboration is one way for two or more public procurers in different Member States to acquire the advantages of economies of scale, first, lowering the transaction costs and, second, placing a higher quantity to be provided in the procedure. These gains can be passed on to the purchasers via fair prices, higher quality, or both. While there are, so far, few initiatives on cross-border collaboration on procurement in place in Europe, there is increasing interest in exploring their potential. Cross-border procurement is currently attracting particular attention in relation to pharmaceuticals.

Both within and across borders, successful joint procurement may depend on a number of essential pre-conditions, such as strong political commitment, trust between collaborating parties, price transparency, continuity through multi-year contracting to foster closer ties between participants that promotes asset-specific investment, and sharing of information and good practices, among others.

Cross-border collaboration could be especially useful in some cases: in small countries; when the products or services are homogeneous and adhere to clear standards; for high-

cost technologies; for low-volume products; where purchasers can share elements of the procurement process; for the procurement of very specific and specialised innovative solutions;

Recommendations:

This Opinion has highlighted the challenges of public procurement and, while its focus has been on the specific issues that arise in the health sector, many of them also apply, to varying degrees, in other sectors. This Opinion should not be viewed as meaning that public procurement should not be used (it is a legal requirement for public buyers to follow the EU procurement rules) but that the challenges must be acknowledged in the precise definition of each public procurement procedure.

In light of the issues explored, a series of recommendations have been outlined, including: ensuring that the interests of actual and potential patients are taken fully into account; those engaged in public procurement understand how the process can be used to promote wider social, economic, and environmental goals; those involved in public procurement should take measures that recognise the complexity of this process to consolidate knowledge and best practice, to professionalise procurement, and to recruit, retain, and continuously develop those with the necessary skills and expertise; there is repository of evidence, supported by a community of practice, on corruption in health sector procurement; comprehensive review of public procurement during the COVID-19 pandemic be undertaken; and cross border procurement be promoted in those circumstances where benefits outweigh costs.

1. BACKGROUND

Every year, over 250,000 public authorities in the EU spend about 14% of GDP (about €2 trillion) on the purchase of services, works, and supplies. Many are in the health sector, a sector in which public authorities are the main buyers in many countries. When these purchases exceed certain thresholds, EU public procurement rules apply. These rules are set out in public procurement Directives 2014/24/EU "on public procurement and repealing Directive 2004/18/EC" Directive 2014/25/EU on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC, and 2014/23/EU "on the award of concession contracts". There are also two remedies directives (89/665 and 92/13), subsequently amended in 2007 and 2014. Finally, there is Directive 2014/23/EU, on concessions contracts, which while having relevance to the health sector falls outside the scope of this Opinion.

The 2014 Directive applies where a contracting authority awards a public contract. The definition of a contracting authority in this context is set out in article 2 of the Directive as "the State, regional or local authorities, bodies governed by public law or associations formed by one or more such authorities or one or more such bodies governed by public law"

A 'body governed by public law' means any body with all of the following characteristics:
(a) they are established for the specific purpose of meeting needs in the general interest, not having an industrial or commercial character;

(b) they have legal personality; and

(c) they are financed, for the most part, by the State, regional or local authorities, or by other bodies governed by public law; or are subject to management supervision by those authorities or bodies; or have an administrative, managerial or supervisory board, more than half of whose members are appointed by the State, regional or local authorities, or by other bodies governed by public law.

We now turn to the objectives of the Directive. Drawing its legal basis from the Treaty on the Functioning of the European Union, the principles underlying public procurement are the free movement of goods, freedom of establishment, and the freedom to provide services, as well as the principles derived from them, including equal treatment, non-discrimination, mutual recognition, proportionality, and transparency. The Directives and subsequent legislation, as well as relevant case law, are designed to give practical effect to these principles. However, the 2014 Directive is also framed as a mechanism to promote the Europe 2020 strategy, for smart, sustainable, and inclusive growth as well as greater efficiency of public spending and the participation of small and medium-sized enterprises (SMEs). These are goals that might be achieved in other ways of allocating

funds by public decision makers, such as subsidies or direct award of contracts but, as the Directive states, overall, public procurement (OECD, 2009, European Commission, 2017b).

Following from these considerations, it is apparent that the merits of public procurement should be addressed from two different perspectives. Both take as a given the importance of fidelity to the processes, which should be transparent, open and accountable. This is of great importance as it respects the use of public money, but it should also be noted that a process can be transparent, in the sense that all procedures are verifiable and legal, and still deliver a price higher than it would be possible to achieve under different rules of procurement or under alternative purchasing mechanisms. Also, ensuring that a process is transparent, open and accountable, it does not necessarily follow that it will ensure that the product procured is of the optimal quality. However, beyond that, given the priority given to encouraging growth in the Directive, it implies that the award criteria can, in general, be designed in such a way that they reward the provider of the product with the greatest potential to contribute to economic growth, for example through innovation that will win export markets. The second relates to the importance of achieving value for money. This can be measured in different ways, depending, for example, on the perspective taken and the time scale over which it is measured. While these two perspectives are often aligned, it is important to consider what happens when they are not. In particular, a short term focus on value for money may not always reward the provider that is best placed to contribute to more sustained growth.

Before proceeding, it is important to note that EU public procurement rules do not say **what** a public entity "has to buy". The Directive contains a long list of areas that fall outside its scope, including the social security legislation of member states and liberalisation of services of general economic interest. Specifically, "nothing in this Directive obliges Member States to contract out or externalise the provision of services that they wish to provide themselves or to organise by means other than public contracts". However, although a detailed consideration is beyond the scope of this Opinion, it should be recognised that the application of these rules, while usually straightforward, can sometimes be complex. Thus, referring to the earlier Directive, in Hans and Christophorus Oymanns GbR v AOK Rheinland/Hamburg (Case C-300-07 of 11 June 2009), the CJEU held that a German sickness fund is a contracting authority for the purposes of the Directive. However, in Falck Rettungsdienste GmbH and Falck A/S v Stadt Solingen (Case C-465/17 of 27 June 2019) it held that ambulance services fall outside the scope of rules on public procurement, as public contracts for services relating to civil defence, civil protection and danger prevention, but subject to two conditions. These are that those services correspond to the Common Procurement Vocabulary codes

referred to in the provisions related to civil defence etc. and they are provided by non-profit organisations or associations, as well as being inextricably linked to the existence of an emergency service. It is to be noted though that the principles of equal treatment and non-discrimination still apply as the principles of the Treaty still apply to the award of such contracts.

The Directive does, instead, specify **how** it "has to buy" those works, supplies, and services that fall within its remit, i.e. which type of procedures can be used in which conditions and which rules must thereby be observed tender specifications (subject, selection, and award criteria), including the components of the contract notices and contract award notices that must be published in Tender Electronic Daily, a supplement to the Official Journal of the European Union.

Here, the key principle is that the "most economically advantageous tender" (MEAT) must be accepted, based on:

a) price, or

b) cost, using a cost effectiveness approach such as life cycle costing, or

c) the best price quality ratio (BPQR) to be assessed on the basis of award criteria linked to the subject matter of the contract.

At first sight, the MEAT criteria, and especially the first two, seem closely aligned with the goals of those responsible for delivering health services. Long faced with upward pressure on healthcare costs, in all member states, value for money is high among their priorities. Thus, public procurement has increasingly been promoted as a tool for combining efficient purchasing with achievement of better health outcomes (Kastanioti et al., 2013, Mudyarabikwa and Regmi, 2016).

Some of these considerations are recognised in the Directive. Thus, quality can, amongst others, include criteria related to:

- technical merit, aesthetic and functional characteristics, accessibility, design for all users, social, environmental and innovative characteristics and trading and its conditions;
- organisation, qualification and experience of staff assigned to performing the contract, where the quality of the staff assigned can have a significant impact on the level of performance of the contract;
- after-sales service and technical assistance, delivery conditions such as delivery date, delivery process and delivery period or period of completion.

The difficulty, for those engaged in procurement, is how to understand the need that it is intended to be addressed and what, among many possible trade-offs, is the best solution

While some challenges can be found in all sectors, they can be particularly problematic in the health sector.

The first relates to uncertainty, which in the health sector was first described by Nobel laureate Kenneth Arrow in 1963 (Arrow, 1963). Although his arguments emerged from an examination of the interaction between the patient and the health worker, or more specifically, the physician, and so are likely to be less in business-to-business interactions, many of them do have a wider resonance in relation to procurement in the health sector and may come in to play in certain circumstances. Although he was referring to health services, which on their own are excluded from the scope of this Opinion, they have some relevance as a growing number of procurements involve goods bundled with services, for example where a company sells a medicine linked to a system for monitoring its effects or a scanner linked to a contract to operate it.

Arrow argued that the health sector is different from many other products in five ways. First, an individual's need for healthcare is intrinsically unpredictable, unlike, for example, food or clothing, and in some cases the need is urgent. Thus, a contract to deliver a service for a defined group of people inevitably includes a degree of risk of over or under provision. Second, there are often barriers to entry to the market, for example where a new product requires regulatory approval or there are no health workers with appropriate skills. Third, trust is extremely important, given the inherent uncertainty of many aspects of medicine. Fourth, there is often an asymmetry of information, with those providing healthcare both better informed and in a position of power over those receiving it. Consequently, there is considerable scope for exploitation, gaming, and supplier induced demand.

Other issues relate to the specificity of goods or services being purchased. In our view, the attractiveness of procurement procedures, relative to alternative ways of contracting services, relies on the process being generally open to multiple potential providers that can offer different goods or services that can be substituted for one another. Thus, from a decision-maker's perspective the implication by public buyers of procurement rules should promote participation across providers in the tender procedure. Yet, in healthcare or in the purchase of medical supplies, this may not be the case. While for some common conditions, such as hypertension, there may be a range of drugs within a particular class that can be substituted, and within them, if the market is sufficiently large, there may be a range of manufacturers producing them once their patents have expired, this is not the case for many less widely used medicines. This can create problems. For example, where a single provider dominates the supply of essential medicines, they may exploit their position to obtain higher prices (as happened with the epilepsy drug Epanutin in the UK in 2016)(Hawkes, 2016).

There may also be a risk of interruption of supply if, for any reason, a manufacturer cease manufacturing something (Ventola, 2011). Complex equipment, a category that includes many types of medical technology, often requires training of staff and organising IT systems (with significant transaction costs should a healthcare provider change supplier, thereby limiting the ability to exit from a contract).[1] This issue is not specific to the use of public procurement procedures, and these concerns can be included explicitly in the contract awarded or in the award criteria. The critical element is whether, or not, these sort of considerations work against or in favour of public procurement versus other purchasing alternatives (long-term commissioning of services may facilitate investment in training by the supplier, for example, leading to a higher quality service relative to what would be achieved under public procurement with a shorter time contract period).

As noted above, these concerns are not unique to the health sector. Thus, they may equally apply to procurement of sophisticated defence equipment, where the threat may change markedly for geopolitical reasons, although this largely falls outside the scope of the 2014 Directive. In this respect, both health and defence contrast with, for example, procurement of major transport infrastructure. Thus, the procurement of a new road or bridge involves relatively little risk of a disruptive developments that will threaten their viability. For example, faced with the rapid demise of vehicles powered by fossil fuels, they require no major changes to convey vehicles powered by renewable energy.

As noted above, the 2014 Directive contains a long list of areas that fall outside the scope of public procurement, many with particular application in the health sector. For example, certain social, health, and education services are subject to a light touch regime (the "light regime") whereby the monetary threshold for using procurement rules is raised and the requirements are relaxed.

The Directive also recognises the potential to consider wider social and health considerations in assessing quality, for example "Measures aiming at the protection of health of the staff involved in the production process, the favouring of social integration of disadvantaged persons or members of vulnerable groups". In addition, in "certain services in the fields of health, social and cultural services [participation in the bidding process] could be reserved for organisations which are based on employee ownership or active employee participation in their governance, and for existing organisations such as cooperatives". On the other hand, and again demonstrating a recognition of the special nature of the health sector, although arguably surprising, while the Directive specifies a number of reasons why a potential provider must be excluded from the procurement process, such as involvement in fraud, money laundering, or child labour, public

[1] Transaction costs are used here in the sense of Williamson (1979) and are mainly related to asset specificity (investments in productive assets that have little value in alternative uses).

authorities can apply for derogations from these exclusions on grounds of public health (Art 57).

Given these considerations, the Expert Panel has been asked to consider the challenges that arise with public procurement and any potential solutions to them within healthcare systems. Specifically, it is asked to consider specificities of different health technologies. Its assessment should contribute to a reflection on award criteria that could be introduced to different tenders. It should also examine certain procurement initiatives being discussed to address some of the challenges that exist in the health sector, including examining for which subject-matters centralised procurement can be recommended and initiatives to favour procurement of innovation. Finally, it should consider what can be done at EU level to support Member States in this endeavour.

2. QUESTIONS FOR THE EXPERT PANEL

Taking into account the work done by the European Commission, OECD, WHO and other sources of reported examples /existing studies/analysis, the Expert Panel is requested to provide its analysis on the following points:

(a) To identify health sector specific challenges in relation to public procurement.

(b) To identify health technology specific challenges (medicines, equipment, medical devices, e-health, services, etc.) in relation to public procurement with a focus on what award criteria beyond "lowest price" should be introduced according to MEAT.

(c) To analyse to what extent centralised procurement (bringing together several procurers at subnational or national level or between Member States) can be applied to ensure maximum efficiency, also taken account of institutional features (such as the health system's organisation).

(d) To reflect what further EU cooperation can be developed.

3. OPINION

3.1. Public procurement

3.1.1. Public procurement: rationale and drawbacks

Public sector entities have a need for services and goods supplied by others. As public money is involved, a set of principles and rules is deemed desirable and should be observed in those transactions (value for money, non-discrimination, no corruption and transparency, among others). In line with these principles and rules the providers of those goods and services are selected in a competitive way (so that the selected provider is chosen on the basis of its merits and contribution).

A common benchmark is the functioning of purchasers in the private sector, where effective competition between suppliers exists. This benchmark is based on the theory of competitive markets, in which there are multiple purchasers and multiple providers, each with the information they need to make a rational choice, interacting in a process that has minimal transaction costs. Purchasers will obtain the goods and services that they want, in sufficient amounts, at the lowest possible cost commensurate with meeting their thresholds for quality.

From these considerations, it follows that there will be benefits from introducing or enhancing competition in the provision of goods and services to the public sector. Public procurement is an allocation process that awards a contract for provision of goods or services by means of tendering mechanism. Public purchases can also take other forms, like direct award of contracts, but these involve trading off (some of) the benefits from competition between providers, which may be justified when the goal is to promote specific investments by providers, or may be necessary when there are not enough providers or the characteristics of the product or service preclude competition in its provision.

As long as the process is appropriately designed it has the potential to achieve an optimal allocation of resources. The bidder with the economically most advantageous offer should win the contract and the public contracting authority will acquire the product or service at the lowest price for the desired quality, including a range of product or service characteristics, or at highest value for money, if quality differs across bids. In a homogenous product, lowest price is the objective. However, this requires that public procurement processes are transparent, in part to guarantee principles of non-discrimination and equal treatment, reduce the scope for corruption, and avoid a situation where hidden transactions lead to inferior goods and services being purchased, at higher prices, as those who could offer them more cheaply are excluded.

Procurement procedures involve several steps, each of which with its own challenges. The first step is an adequate definition of what is to be acquired, called 'subject-matter'. In this first step, the public procurer has to identify clearly the need to be satisfied. This must be done in a professional and transparent way. It normally requires involvement of stakeholders, a careful analysis of the market and the choice of the appropriate tender procedure that will be used. The second step is the publication at EU-level in the Supplement to the Official Journal, TED, of the contract notice, that should contain the following information (see Annexe V, part C of Directive 2014/24; amongst others information should be provided on the following: name and contact details of contracting authorities, type of contracting authority and activities exercised, whether or not it concerns a central purchasing body or is a joint procurement, CVP codes, whether or not contract is divided into lots, if applicable, location of execution of the contract, description of procurement nature, estimated order of magnitude, time frame for delivery and duration of the contract, conditions for participation, type of award procedure, reasons for an accelerated procedure (in open and restricted procedures and competitive procedures with negotiation), where appropriate, whether framework agreement, dynamic purchasing system or electronic auction is involved, in case of restricted procedure, whether the number of candidates will be restricted, in the case of negotiated procedures whether recourse is made to a staged procedure, whether performance is subject to particular conditions, the award criteria that will be used, time limit for receipt of tenders or requests to participate, languages in which tenders or requests must be drawn up; whether a project receives EU funds, name and address of review body, etc.), etc. This step is crucial is attracting attention from potential bidders. Its design also defines, to a certain extent, the barriers that may deter some potential bidders. The third step is the evaluation and award phase (although in the restricted procedure it may be preceded by a selection phase where those permitted to bid are selected). In this phase, participants submit their bids, according to the rules defined in the previous step. Exclusion criteria are applied and tenders are validated. Transparency is again a key element, usually involving public opening or disclosure of proposals (although the privacy of participants may be preserved, information on tenders must be public so that every interested party can verify that the rules were respected). The fourth step is the selection of the winner (or winners) of the procedure. The evaluation of tenders according to the specified award criteria results in the selection of the winning provider(s). After the award decision is communicated to all bidders, the contracting authority must respect a standstill period of ten days, in order to allow non-winning bidders to contest the decision timely. Only after the standstill period is expired, the contract can be signed at this stage. The final step is the execution of the contract, with payments and monitoring by the public purchaser.

Health products and services may have particular features that need to be taken into account in each of these steps in public procurement, as discussed in more detail below. These arise from specific features of the health sector.

Some issues relate to the extent to which the market in goods and services procured in the public sector involve multiple providers and low transaction costs. Thus, although the Directive contains several provisions that should facilitate participation by small and medium enterprises (SMEs), such as division into lots, and certain financial provisions, several studies have found that SMEs face constraints in their ability to engage in public procurement processes (Saastamoinen et al., 2018), with challenges that can be sector specific (Loader and Norton, 2015).

In writing the sections that follow, the Expert Panel recognises that this Opinion will have two audiences, each of which, in normal circumstances, has relatively little interaction with the other. They comprise those with expertise in procurement and those with expertise in delivering health services. Consequently, we recognise that each will already be familiar with much of what is written in some parts of the Opinion but, we believe, may not be with what is in other parts. However, we believe that there is value in bringing together the different parts within one document.

3.1.2. Public procurement: a brief overview of the 2014 EU Directive

The 2014 EU Directive on public procurement outlines different procedures for public procurement designed to ensure works, services and products of an appropriate quality are purchased at a fair price. These procedures vary depending on circumstances. We outline briefly key features of these procedures, and then discuss several issues that may be relevant in the health sector, such as the implications for quality and non-price dimensions. To align with terminology in the health sector, we use the term "provider" to refer to "economic operator" in the language of the Directive, and the term "purchases" as a shorthand for "supplies, works, or services". Although this section will be very familiar to those engaged in procurement, it is included for readers for whom it is not. The default approach is an "open procedure" that permits access to any provider willing to submit a tender, as long as it satisfies publicly known qualifying selection criteria. Ignoring transaction costs and possible collusion, this works well in principle for standardised products. It can also work for non-standard products or services if there has been a preliminary market consultation and where the contracting authority opts for a 'functional description, such as 'we wish to achieve cooler temperatures in patients' rooms'. But there may be challenges when quality or other non-price dimensions of the products are important. The main risk, especially if only one award criterion is specified, is that tenderers will offer a low price that reflects the lowest possible quality of the

product. This may mean that the overall cost to the purchaser is greater in the long term, for example where the product purchased means that health workers spend more time operating it or where it requires more frequent replacement. In this respect there is no difference between the private and public market. If purchasers have a clear idea of the quality dimensions that are required, the risk of poor quality can be addressed by purchasers adding a detailed specifications for any non-price aspect of the product in the tendering process or by adding award criteria other than price. This will however increase transaction costs. The change in the decision criterion from price alone to include other aspects seeks to ensure that value for money will be obtained, also in terms of quality address this risk, by valuing quality. "Quality" is the term used to encompass, in a very broad sense, the several notions of quality that may be applicable under the MEAT approach.

Quality can, amongst others, include criteria related to:

- technical merit, aesthetic and functional characteristics, accessibility, design for all users, social, environmental and innovative characteristics and trading and its conditions;
- organisation, qualification and experience of staff assigned to performing the contract, where the quality of the staff assigned can have a significant impact on the level of performance of the contract;
- after-sales service and technical assistance, delivery conditions such as delivery date, delivery process and delivery period or period of completion. (Art 67)

The non-price dimensions of quality can take the form of minimum technical requirements to be met by any supplier as of course all offers need to respect the technical qualifications of the subject matter or can form part of the award criteria for scoring the tender. However, the latter, especially where quality is multidimensional, requires some means of relating quality to price. Thus, a gain in technical performance may not of itself lead to a gain in lives saved, and even if there is an association, it may be non-linear or include threshold effects.

The 2014 Directive describes circumstances and requirements that must be met for contracting authorities to make recourse to a "restricted procedure". In general, there are two (usually) or more stages. In the first stage, a provider is selected on the basis that they can demonstrate that they are qualified to deliver the goods or services. In the second stage, only those providers invited to do so by the contracting authority following its assessment of the information provided may submit a tender. The different types of restricted procedures are as follows.

- Competitive procedure with negotiation

The first type of restricted procedure is the "competitive procedure with negotiation". In the first stage, the contracting authority has some idea of their needs and the characteristics of what they wish to purchase, as well as the criteria that will be used to assess the tenders. However, due to the complexity of the product or services, the contracting authority needs to improve or finetune the technical specifications following the negotiation with the economic operators.

The contracting authorities therefore engage in discussions with the participating economic operators who are invited to submit an offer. After negotiations, the tenderers are invited to submit a refined bid thus ensuring equal treatment of all tenderers. As with any of the forms of procurement, it is not permissible to provide information selectively to one that may give them an advantage in the tendering process.

This procedure can be used "without prior publication" in some exceptional circumstances, where only providers that are known to be able to meet the criteria can be invited. This may be when there is extreme urgency brought about by events unforeseeable for and not attributable to the contracting authority, for example when the Spanish government declared an "Estado de alarma" in response to the COVID-19 pandemic. However, in Commission v Italy (Case C-337/05 of 8 April 2008), which related to the purchase of helicopters to be used for military and civilian purposes by the Italian authorities, the court confirmed that the negotiated procedure without prior publication was only to be used in exceptional circumstances as set out in an exhaustive list. Member states cannot add new conditions to the cases set out in the directive simply to make procurement easier. The burden of proving that exceptional circumstances justify a derogation from the procurement rules lies with the contracting authority seeking to rely on those circumstances. In a similar case, also involving helicopters (Case C-157/06 Commission v Italy 2 October 2008), the court held that a need for confidentiality did not prevent the use of a competitive tendering procedure.

- Competitive dialogue

A second type of restricted procedure is the "competitive dialogue". Unlike the previous procedure, the contracting authority still has an idea of their needs but does not know what the best way (e.g. whether to buy a product or service) to address their needs is or the detailed characteristics of what is sought. A new solution is required, and this is the main justification for entering into a dialogue with the providers. In the first stage, providers submit a request to participate. The second stage involves a dialogue between the contracting authorities and selected participants to identify and define the means (solutions) best suited to satisfy the needs of the contracting authority. The dialogue can continue until one or more solutions has been identified.

Once the dialogue is complete, the contracting authorities ask the participants to submit their final tenders based on the solution(s) identified during the dialogue. Tenders are then evaluated based on the best price-quality ratio and the contract is awarded to the one that best meets the award criteria, conditional on also satisfying all selection criteria. Those providers engaging in the process can influence what is being asked for and, potentially, develop partnerships with other providers where each is contributing to one part of a complex product (though this feature is not specific to competitive dialogue only).

The Directive suggests that contracting authorities can use the competitive procedure with negotiation or the competitive dialogue in the following scenarios: i) the needs cannot be met with available solutions; ii) an innovative solution is required; iii) there are specific circumstances related to the nature, the complexity, or the legal and financial elements and related risks; iv) the technical specifications cannot be established with sufficient precision ex-ante. Compared with the 2004 Directives, the 2014 Directives have made recourse to negotiated procedures much easier.

If different tenderers offer solutions that differ in quality, then purchasers will award the contract based on the best price-quality ratio, in line with MEAT criteria, where quality is evaluated based on the award criteria in the published contract notice by which the tender procedure is launched. This means that purchasers can specify in the award criteria how quality will be evaluated and different aspects combined (e.g. by a weighting system), although this presents methodological challenges related to the development of suitable metrics, as noted above and which we discuss in more detail below.

- Innovation partnership

The third restricted procedure, innovation partnerships, are supposed to address even more challenging situations that relate specifically to the development of innovative products or services (e.g. a new pharmaceutical product, a vaccine, or a medical device) that are not available on the market. This should include the research and innovation process phase, the first production phase and subsequent purchase of the resulting supplies and services, provided they meet the performance standards and maximum costs agreed between contracting authorities and participants.

An innovation partnership is structured in successive phases, from research and development through to manufacturing. It will involve several partners, with numbers that can be reduced at each phase. As in the competitive procedures, contracting authorities negotiate with tenderers in initial and subsequent tenders to improve the proposals up to but not including the final one.

This form of contracting is much more complex and involves defining arrangements applicable to intellectual property rights, the structure of the partnership, the participants, and the duration and value of different phases. This must be clarified in the procurement documents produced by the contracting authorities. The structure of the partnership, including the duration and value of different phases, must reflect the degree of innovation of the proposed solution and the contribution of each stage in the research and innovation process. This is an area where the concept of life-cycle costing becomes useful, defined as calculating the total amount spent on an item 'from its conception and fabrication through its operation to the end of its useful life'(White and Ostwald, 1976). It seeks to 'optimise the cost of acquiring, owning and operating physical assets over their useful lives by attempting to identify and quantify all the significant costs involved in that life' (Woodward, 1997).

There are a set of initiatives related to "innovation partnerships" supported by DG RTD, DG CONNECT, and DG GROW. See Appendix 1.

- Specific instruments

There are several instruments mentioned in the Directive to facilitate public procurement. "Framework agreements" can be established between one or more contracting authorities and one or more providers to establish the terms of contracts, in particular in relation to price and quantities (Art 33). "Dynamic purchasing systems" are electronic processes that can be used for services available on the market (similar to electronic auctions and catalogues) (Art 34). "Centralised purchasing" allows contracting authorities to acquire services from a central purchasing body that can act as a wholesaler or an intermediary in awarding contracts, with the contract between the contracting authorities and the centralised purchasing body falling outside the scope of the Directive (Art. 37).

- Joint Public Procurement

Joint Public Procurement (JPP) is a means by which contracting authorities from different Member States may collaborate either to prepare a new tender and or to organise a joint tender to increase their purchasing power and increase the potential to obtain better conditions in contracts, reach important market thresholds, and have greater ability to orient the market (Art. 39). A JPP may be appropriate for the development and production and first purchase of innovative products or services and where the process meets several conditions, although these may not be known in advance: a) lower transaction costs; b) attracting a higher number of participants, with more competition delivering a better outcome for the public sector; c) achieving economies of scale and as such be able to purchase at fair prices and/or d) bring more transparency. The advantages have to be balanced against the disadvantages: a) greater complexity associated with the task of negotiating common procedures across countries; and, b) in

the case of multidimensional procurement procedures involving price and quality, different preferences/trade-offs across countries that may create suboptimal options for some of them. Member State initiatives on pricing of medicines and technologies, still at a preliminary stage, that are exploring approaches that may ultimately involve joint procurement , include the Valletta, and BeNeLuxA and Nordic Council co-operations, some of which were explored in the Expert Panel's opinion on innovative payment models (Expert Panel on Effective Ways of Investing in Health, 2018). Their aim is to strengthen the power of public authorities, reflecting concerns about the ability of small countries to negotiate with global corporations (Appendix 2, based on a consultation undertaken to inform this Opinion in Slovenia) considers issues facing small countries in more detail).

- Procurement in emergencies

During an emergency there are often concerns about the ability to obtain purchases at affordable prices while ensuring an equitable supply to all member states. Following the H1N1 pandemic influenza in 2009 the European Council requested the Commission to start preparing for joint procurement of vaccines in the event of a future pandemic. The relevant provisions for joint procurement of medical countermeasures are included in Article 5 of Decision 1082/2013/EU on serious cross-border threats to health. The Joint Procurement Agreement (JPA) was approved by the Commission on 10 April 2014, and as of March 2020 has been signed by 26 EU Member States, Norway, and the UK. The JPA sets out practical arrangements governing the mechanism; defines the decision-making process with regard to the choice of procedures; and organises the assessment of the tenders and the award of the contract. In case of extreme urgency brought about by unforeseeable events, the 2014 Directive allows some procedures to be used "without prior publication". This issue is discussed in detail later in the Opinion, drawing on experiences during the COVID-19 pandemic.

- Criteria for awarding the contract

The Directive specifies that contracting authorities should award public contracts to the provider with the most economically advantageous tender, on the basis of price or cost, using a cost-effectiveness approach, or the best price-quality ratio, which may include life-cycle costing.

A procurement procedure that makes recourse to both price and quality award criteria involves a multidimensional approach. The criterion of lower price is replaced by a scoring system to evaluate tenders and select the winner along more than one dimension. The design of that scoring function is not obvious, as it needs to balance the objectives of the public entity and the incentives to bid from the participants in the public procurement.

The Directive says that the price-quality ratio could be based on criteria including qualitative, environmental, and social aspects as long as these are linked to the subject matter of the contract. The first of these include quality, with a non-exhaustive list of its aspects including technical merit, functional characteristics, accessibility, design, innovative characteristics, organisation, qualification and experience of staff assigned to performing contract, and after-sales service and technical assistance. Although not compulsory, criteria can include life-cycle costing related to acquisition, use, maintenance, and end of life (such as collection and recycling costs). It can also include costs imputed to environmental externalities (e.g. emissions of greenhouse gases). Contracting authorities must describe the methods to be used in computing life-cycle costs.

Award criteria must be linked to the subject-matter and must be sufficiently detailed to enable the information provided by tenderers to be verified objectively by contracting authorities and must disclose the weighting of each criterion that will be applied.

The criteria used to make public procurement decisions should promote competition. This has two main elements: a) attracting participants in a transparent way; b) ensuring that the more efficient provider(s) emerge from the procedure. More efficient does not necessarily equate to lower cost, as other dimensions may need to be considered other than cost alone (from the perspective of the entity that initiated the tender procedure).

It can be challenging to organize a procurement procedure in which providers compete on both quality and price (both in the health sector and other sectors). The Directive refers explicitly to the use of the price-quality ratio. A more general approach, which does not necessarily involves a ratio, would specify a valuation V(pi, qi), where p is the price and q is quality of each tender i. The price-quality ratio implies V= pi/qi. A weighted sum of the different aspects would be represented by V =w0 qi – w1 pi, w0, w1>0 reflecting the importance of each factor (and of course one w can be normalized to 1 without loss of generality in the selection process). The critical point is that the weighted sum is not a particular case of the price-quality ratio, or vice-versa. Thus, the options laid out in the Directive already define a certain type of trade-off. Under the price-quality ratio criterion, it is possible to keep the ratio constant if the percentage increase in quality matches any percentage increase in price in the tender offer. In some cases, it may be possible for the procurement procedure to set a fixed price and let providers compete on quality only.

When contracting on quality, it also matters whether a final stage of negotiation can take place or not. The negotiation stage, if applying a condition of no price change from the initial tenders, means that the public contracting entity can use information on quality present in all previous bids of the procurement procedure to reach a final agreement with

the winner. Without the negotiation stage, the scoring function should put less weight on quality than is the case in the social valuation, to account for the incentive of firms to play strategically with quality. By putting less weight on quality, the public procurer induces firms to increase quality offered to obtain better prices in a winning tender. Increasing quality is less costly for the more efficient provider, implying that a more efficient firm incurs a lower cost by using higher quality to keep its price high. The existence of a negotiation stage, in an alternative format of the procurement procedure, makes it possible to recalibrate the quality demanded from the winner at that stage, using the information contained in all tenders submitted (recalling that all tenders comprise a price and a quality level). In this case, the initial scoring function can be the social value generated by the service.

This brief account illustrates how the design of the procurement procedure influences the evaluation criterion in a multidimensional situation (Che, 1993, Branco, 1997, Lorentziadis, 2020, Huang et al., 2019). The procurement rules allow for procedures that may include negotiations as part of the overall process of awarding a contract. Given that the dialogue involves several iterations that can be time consuming and costly for the providers, one issue is whether the purchasers should pay some amount to the participants of the dialogue who do not win the final bid. This payment induces greater willingness to enter into the procedure, increasing competition among participants, thus leading to a better outcome to the public entity. The next section considers issues that arise specifically with regard to procurement in the health sector.

3.2. Health sector specificities in relation to public procurement

3.2.1. Common challenges

Getting procurement right is especially important in the health sector as failure can cost lives. Details matter and small variations in rules may lead to substantially different results, potentially with quite distinct health outcomes (although these are rarely specified in procurement procedures). Specialist knowledge is required to ensure that appropriate rules and mechanisms are selected.

Those involved in procurement recognise the many challenges involved. A 2014 survey of suppliers operating in the UK identified the main barriers they face in procuring innovative products and services are a lack of interaction with procuring organisations, rigid specifications that do not take account of outcomes, low skills levels among procurers, and poor management of risk. The issue of risk has come to the fore in offers by some pharmaceutical companies to engage in risk-sharing agreements for the purchasers of their innovative and expensive products (Piatkiewicz et al., 2018). Whether

these agreements are able to protect the purchaser is, however, unclear and they can also be difficult to implement under existing procurement rules.

These issues are being addressed by a series of initiatives, including the development of a European Competency Framework for public procurers. However, many barriers are specific to different product types (Uyarra et al., 2014). A qualitative study of stakeholders from Mexico, Switzerland, Germany, and the UK undertaken in 2016 concluded that procurement practices for high-risk medical devices were often inadequate, for example with insufficient information on clinical outcomes, lack of follow-up of health technology assessments, and insufficient involvement of clinicians. However, the problems were much greater in Mexico than in Europe (Lingg et al., 2016).

3.2.2. Monopoly providers and high transaction costs

There are many situations in which the principles of transparency, non-discrimination, and equal treatment and in public procurement are either not met or are problematic in public contracts in the health and other sectors. One such assumption is that by creating transparency, equal treatment and non-discrimination between suppliers, the public procurer can achieve better contracts (i.e. higher quality, lower price, better quality per cost unit). Even when faced with a monopoly provider, the principle of transparency principle and provisions applies. Also it would not be possible to conclude a contract for an unlimited duration.

In this section we consider those that relate to the desirable features for a market to operate, the existence of many firms and low transaction costs.

The first desirable feature that may not hold in certain areas of the health sector is the existence of multiple firms or providers to ensure that the market is competitive. Many products that are purchased in the health sector are produced by monopoly providers, either because they hold the intellectual property rights involved, as with proprietary drugs, or because, for various reasons including market size and regulatory hurdles, others have declined to enter the market and may face substantial barriers in entering the market in the short term.

With some new forms of pharmaceuticals, the so-called biologicals, the intellectual property may reside as much in the method of manufacture as in the composition of the product. This may create insuperable barriers to market entry by competitors once the patent on the original product has expired. Similar considerations apply to the algorithms developed for certain technologies that employ artificial intelligence. Thus, attracting participants to the procurement procedure may fail. Without competition, some of the main expected benefits of procurement do not materialize.

A further problem can arise when potential providers decide not to bid. Typically, the public procurement procedure defines a reserve (or base) price, with tenders having to submit prices below it. A low base price caps the cost to the purchaser but also decreases attractiveness of the procedure to potential participants. Thus, the definition of the base price in a public procurement procedure must strike a balance between attracting participants and protecting the purchaser against high costs. A study of public procurement tenders in the health care sectors in the Czech Republic and Slovakia found that the average number of tenderers was only around two and in the Czech Republic for more than half of the tenders only one bid was submitted (Nemec et al., 2020). A procurement procedure may not need to attract many participants, for example when quality is well defined, easy to specify and to monitor. In such cases, competition may, in effect, take place prior to the tender process where firms decide that they cannot compete on price and so do not waste time preparing a tender. However, the public procurement procedure may fail if the base price is set too low. This has happened in public procurement of vaccines in Portugal, where the procurement procedure created a strong downward pressure on the base price for vaccines (Barros and Monteiro, 2019); as a consequence, after one year of very low prices, the next year the public procurement attracted no bids. Acquiring the vaccines outside the public procurement framework resulted in higher prices. The net effect was a higher cost to the public purchaser (Barros and Monteiro, 2019).

On the other hand, there is a problem where the paucity of bids reflects collusion or where there are products that only one or two providers can supply. Stable supplier collusion (collusive tendering or bid rigging) is always a concern (Jones and Kovacic, 2019). Collusion among bidding firms constitute one of the biggest obstacles to efficient public spending alongside political corruption and fraud (Messick, 2011).

The characteristics of collusive behaviour in public procurement markets is very similar to that of conventional markets: companies coordinate their behaviour regarding price, quantity, quality, or geographical presence in order to increase market prices. The essential long term determinants of the frequency of this kind of misconduct are 1) the ability to coordinate, 2) internal sustainability (credible punishment system, effective detection of cheating), and 3) external sustainability (ability to exclude new market entrants). Public procurement markets are more vulnerable to coordinated gaming given the above features than are traditional markets (Tóth et al., 2014). Transparency and strengthening of enforcement of competition law in the public procurement scene are crucial tools to avoid collusion. Some elements of the health sector may be especially susceptible to collusive behaviour where the number of potential market entrants is low, as with innovative products.

The second desirable feature for a market to work is low transaction costs. Critics of public procurement draw on the work of Nobel laureate Oliver Williamson (1975). Although writing about the decision that a firm would make to either purchase goods or services on the market or produce them itself, the issues he explored also apply, to some extent, to public procurement. In brief, where transaction costs are low, all else being equal, buying in the market is the preferred option.

Transaction costs are influenced by uncertainty, frequency, and asset specificity of the products involved. While all contracts involve a degree of uncertainty, for example whether the provider can deliver the goods or services contracted for, there are particular challenges where the nature of what is being purchased is difficult to specify in a verifiable way (that is, that can be observed by a third party). This is particularly problematic due to what is termed bounded rationality, whereby the purchaser is unable to anticipate all the possible factors that might impact on the delivery of the contract, and especially so where there is scope for opportunistic behaviour by the provider, defined as self-interest with guile. Even in the absence of opportunistic behaviour, it will often be impossible to write down all future contingencies and actions to be taken in each of them in a contract.

Another issue related to transaction costs is frequency, which relates to the extent to which a purchaser remains with a particular provider in subsequent contracting rounds or switches to an alternative. Public procurement has, implicit within it, the idea that open competition will encourage new market entrants, providing more innovative products at lower cost. However, switching to a new provider may involve setup costs, for example the transfer of patient records to a new data system, or information to patients telling them that they should obtain care from a different provider. Some of these costs are not specific to public procurement procedures and will be present in other purchasing mechanisms if it is not recognised that lock-in effects may be created (there will be change of supplier to save on these costs). These may need to be considered in the tendering process. Contracting with the same provider over a period of time may allow a degree of trust to develop, permitting less expensive contract monitoring processes, but may limit market entry by competitors.

Yet another issue with transaction costs is asset specificity. When a contract for a new purchase is let, the provider may have to commit considerable resources to invest in the means to deliver it. This may make them particularly dependent on the purchaser, as the assets produced might not be usable for a different purpose. On the other hand, the purchaser seeking an alternative provider must recognise that there will be additional costs involved if another firm has to make the same investment. A related issue is the challenge that arises when products and services that are incorporated into a broader

service or product that is delivered to the patient. Asset specificity may require long-term relationships to keep incentives for investment, which are incompatible with public procurement procedures, which rely on transparency, equal treatment and non-discrimination to obtain the best results for the purchaser.

Limited competition, high transaction costs, and asset specificity thus all have implications for public procurement in the health sector

These considerations point to several issues with public procurement that must be considered. The first is the administrative cost involved. In principle, the cost of writing the tender document, evaluating it, undertaking due diligence on any potential providers, negotiating a new contract, and monitoring its implementation should be outweighed by the savings incurred. Where any of these is complicated, this may not be the case. A related issue is the ability of the purchaser to specify in sufficient detail the quality of the good or service being purchased, while leaving sufficient flexibility for the provider to adapt to changing circumstances.

A second is the rapidity with which a contract can be let. There will be times, for example in a pandemic, when speed is of the essence (Vlček, 2018). The negotiated procedure without prior publication may be used where public procurement rules designed to build in adequate time for potential providers to respond maybe ill-suited. However there are trade-offs involved as hasty processes may lead to sub-optimal outcomes, including criminality. These risks should, in theory, be reduced by the obligation to publish the contracts subsequently. However, this does not always happen and a group of UK Members of Parliament has initiated judicial review to require the UK government to publish COVID-19 related contracts worth £3 billion (Plimmer, 2020).

Finally, while one of the objectives of public procurement is to reduce the opportunity for collusion or corruption, in practice it does not always succeed. Thus, those responsible for purchasing are in a position where they may be able to benefit from payments or other gifts by providers. While such gifts are generally illegal, they do exist and are typically concealed. Thus, it is important to have strong codes of practice to prevent this happening, including rigorous enforcement. However, it can be more difficult where the reward is in the future, for example when those responsible for purchasing decisions are led to understand that their decisions may influence their ability to obtain more lucrative employment with the provider at some point afterwards, the so-called revolving door phenomenon.

There are also some other considerations that may be relevant in the health sector (although not exclusively). The Directive includes a consideration of industrial policy, and especially encouragement of participation by Small and Medium Enterprises (SME). These can face serious obstacles. For example, the time to prepare bids in a procurement

procedure could be an entry barrier. The Directive allows adjustment of the time between the publication of the contract notice and the moment where the offers should be submitted, which may mitigate this effect. They may also face challenging requirements to demonstrate financial strength or product certifications. There is a need to ensure balance between having adequate due diligence and avoiding foreclosing the market by means of over-rigorous technical conditions, all the while ensuring that patients are protected from unsafe or ineffective health care services or products.

The Directive contains the principle that larger contracts shall be divided into lots. If not division is possible, it should be explained why no division into lots was possible. This should encourage participation by SMEs. This offers two different types of benefit: increased number of participants in the market, creating greater competition, and developing the local economy. This requires that the buyer knows the market and, specifically, the number of potential participants. Otherwise the decision to divide a tender into lots may actually decrease competition by fragmenting the market (for example, if only two providers have the ability to supply the service, with a single lot they must compete and the winning price will tend to be low; if dividing into two equal lots, each provider could compete only for one of the lots, e.g. where they have a comparative advantage, in the knowledge they will win and prices will be high; if instead smaller lots attract more participants, then prices will again tend to be lower). Whenever division into lots is used, one way to increase competitive pressure is to have asymmetric lots of different size and value, making competition work on price for the lot with larger size to have better offers from the point of view of the public sector while still allowing a larger number of firms to benefit from the public acquisition. Dividing large contracts into lots may also have disadvantages if it creates coordination problems across different services and providers (for example in the context of integrated care for patients with chronic conditions). In summary, when defining lots, several issues must be considered in the decision: competition effects, costs of executing the contract, and technical difficulty associated with splitting the contract into lots, all issues that may be important in health care.

Participation in cross-border procurement procedures for health-related purchases, whether as a purchaser or supplier, raises additional issues and can be relatively simple or very complex. Whenever the purchase is an intermediate input in the delivery of health care it may be relatively simple to use procurement procedures, as health technologies (in a broad sense) tend to be similar across geographies (countries, regions). Actually, EU regulations have brought a lot of standardization into the procurement of products. At the other extreme, and outside the scope of this Opinion except to the extent that services are bundled with goods, as described earlier, delivery of care to patients that relies on human contact and local culture creates demands on

providers that make it difficult for new entrants from other geographies and cultures to participate and tender a winning bid.

In summary, there are many situations in which the assumptions underlying public procurement do apply in the health sector, such as the purchase of many consumables and non-technical equipment, e.g. hospital beds. In these cases, the description of what is being purchased is straightforward, the quality can be assessed relatively easily, and there is little scope for opportunism (except in emergencies when urgency may lead to failures of due diligence, as discussed later). However, there are some in which the same assumptions do not apply, or apply with qualifications, pointing to a need for appropriate measures to overcome the problems that arise.

3.2.3. Life-cycle costing, bundles, interoperability, and technical performance

In addition to the basic assumptions underlying the operation of markets, there is a series of issues that arise when purchasing major capital.

The first is the need to consider costs that will accrue throughout the whole life of the product. Manufacturers in many areas, from razor blades to printer cartridges, have found ways of converting what was once a series of one-off purchases, in which the buyer could easily shift their allegiance to another manufacturer, into a long-term cash flow in which the purchaser is, in effect, trapped. Thus, reagents are packaged in containers that are unique to the manufacturer, for example. Although common standards and requirements have improved the situation in the Common Market area, this means that the procurement process must take full account of all of the costs involved throughout the life-cycle of the product. This may mean rejecting an offer in which the initial capital outlay is lower, but the long-term running costs are higher. Thus, it is important to ensure that the tender process includes a mechanism by which all of the future cost components can be quantified and, as appropriate, adjusted to take account of any costs associated with the financing of the purchase, including interest rates, with appropriate discounting. The use of lifetime approaches is common in economic evaluations in the health sector, which facilitates the use of "life-cycle costing" referred to in the Directive. Methodological guidelines for economic evaluation of health products and/or services often include a discussion of appropriate discount factors. However, it is important to recognise the inevitable uncertainty with estimating the long-term costs of technologies, given the scope for possible substitutions, productivity changes, and decreasing learning costs.

Second, new technology increasingly comes in the form of bundled products, for example as combinations of medicines and monitoring systems, diagnostic equipment and

operating contracts, or telemetry devices and remote monitoring. These pose particular challenges for those procuring them given the high degree of asset specificity.

Third, there are major challenges because of the lack of interoperability of equipment, particularly that using information technology if there are no common standards (Pronovost et al., 2018). This has led to a number of initiatives designed to promote interoperability but there are numerous barriers. These include a lack of agreement on requisite standards, divergent incentives and agendas among vendors, and disparate and inconsistent characteristics in purchasing strategies and practices. As a consequence, when procuring digital services for health and health care systems, interoperability is still very low on the agenda. This is in contrast to the situation in other sectors, where it is relatively highly developed, often out of necessity. Thus, it is essential that aircraft and air traffic control can communicate effectively with each other in real time. Similarly, the ability of mobile phones to move across different networks has demanded common standards to achieve high levels of interoperability. The same is true of the banking industry, allowing customers to obtain cash from different companies' ATMs. For this to happen in the health sector, however, will require leadership, bringing purchasers and providers together to commit to the achievement of interoperability, identifying goals and requirements, and developing mechanisms for collaboration on common standards and specifications. It will also be important to ensure that those providers committing to interoperability are rewarded, for example by including a requirement that systems be interoperable within tender documents.

Fourth, unlike pharmaceuticals that are subject to rigorous evaluation before being placed on the market, many forms of technology (such as medical devices) do not go through the same process of evaluating their technical performance, other than to establish their safety. An area of particular concern is the growth of mHealth. The number of mobile health applications on the market is increasing rapidly. While they offer many advantages, especially in terms of patient empowerment, few have been subject to any formal evaluation of their ability to produce health gain. One problem is the frequent failure to collect and analyse evidence on a product's performance over time, principally because data systems and information infrastructure do not support this. In this respect, there are opportunities for greater use of patient reported measures. To evaluate whether a device or procedure is worth paying for, and at what price, information about its impact on the user is required. Health information systems are good at collecting data on health care activity but lacking when it comes to collecting information on the outcomes of this activity. Some have begun to capture PROMs (outcomes), PREMs (experience) and PRIMs (clinical safety incidents) (De Rosis et al., 2020). The extent to which these measures have been adopted varies greatly among countries and, in many, will require investment of resources for meaningful integration into health information

systems. In the near future, the use of Real World Data with information coming from multiple and diverse sources could play a role in generating outcome measures (although this should not be instead of the rigorous evaluation required for approval of pharmaceuticals, for example)(Löblová et al., 2019). However, such data, along with evaluations of characteristics such as ease of use, accuracy, and acceptability to healthcare workers can inform procurement decisions (Huddy et al., 2019).

Given these issues, there are several particular challenges with application of the MEAT criteria. These include overcoming inertia. For procurement and finance professionals choosing the option that is the lowest cost in the short term has an instinctive appeal because it is seen as objective and less likely to be the subject of criticism or legal dispute. Legal disputes are feared by many purchaser organisations, since they may require a lot of resourcing from the purchaser side and they can also place the development plans of the purchaser organisation into a state of paralysis while the parties are waiting the final verdict.

There is also the issue of silo budgeting. This is probably the greatest barrier to MEAT, even if decision-makers are theoretically supportive of taking a value-based approach (Expert Panel on Effective Ways of Investing in Health, 2019). It is difficult to for procurement officials to spend more this year if the benefits show up on someone else's balance sheet now or at some point in the future. A mechanism to incentivise this broader way of measuring value, and a clear signal from hospital leaders or policymakers, would be required to encourage the adoption of MEAT. Finally, there are challenges in measuring value. Trying to monetise value and weigh long-term benefits or broader socio-economic factors is difficult. Even in some instances hospitals may actually have perverse incentives against reducing length-of-stay and readmission rates. The longer the time frame, the greater the uncertainty. In addition, political cycles tend to be short so there is no incentive for policymakers to take a long-term view. In some specific cases, a degree of risk-sharing between supplier and purchaser can mitigate the uncertainty.

3.2.4. Procurement for innovation

Governments seeking to foster innovation have traditionally directed their efforts to ensure that providers operate in an environment conducive to innovation, mainly removing barriers to firm entry, allowing potential entrepreneurs to enter the market with new or improved goods and services (based on innovation) and meet unmet or latent demand. In recent years, however, the role of so called "demand-side policies" to support innovation has gained in prominence and has been receiving growing interest from many countries (OECD, 2011), accompanied by a growing body of research (Izsak

and Edler, 2011). Demand-side innovation policies refer to the set of policies that support demand for innovation and include public procurement, regulation, setting and certifying standards, consumer policies and user-led innovation initiatives, to address market and system failures in areas in which social needs are pressing. Public procurement can stimulate innovation when certain conditions are met: (i) when it expresses a clear and consistent set of needs to be addressed by the innovative effort in a clear contract specification; (ii) when *quality* is placed at the centre of the tender, rather than merely *price*; (iii) when it provides an assured market for early products with uncertain commercial possibilities; and (iv) when it forces contractors to share information and encourages the entry of new competitors so that it stimulates technology diffusion (Geroski, 1990).

The idea behind public procurement for innovation is to ensure that new developments coincide with the needs of end users (Alessandrello and Maspons, 2018). Discussions on the positive impacts of such policies took place as far back as the 1970s (Mowery and Rosenberg, 1979, Rothwell and Zegveld, 1981). In 2004, three governments issued a position paper to the European Council calling for the use of public procurement across Europe to spur innovation (French German and UK Governments, 2004). This development was manifested in reports such as that by the Aho Group Report (Aho et al., 2006), which identified grand challenges, where policies that support demand for innovation could be used more: e-health, pharmaceuticals, energy, environment, transport and logistics, security and digital content.

Among demand-side innovation policies, public procurement is increasingly recognised as a potential strategic instrument and a policy lever for achieving government policy goals, such as innovation, the development of SMEs, sustainable green growth and social objectives like public health and greater inclusiveness (Edquist et al., 2015). All of these goals are in line with the aims specified in the 2030 Agenda for Sustainable Development and the related Sustainable Development (OECD, 2016).

The strategic use of public procurement to boost innovation is closely connected to a government's power to shape and create market conditions (Directorate-General for Enterprise and Industry, 2014). Given the scale of public procurement, governments, among other actors, can influence demand on national or sub-national levels, and can also create a signalling effect as lead user and influencing the diffusion of innovations more broadly. As a result, the role of the purchaser in the public sector is changing to include more elements of active risk and benefit management. In the same way, to reap the benefits of procurement for innovation, the envisioned policy changes have to be well planned. The implementation of strategic use of procurement for innovation requires strong political commitment, strategic management, capabilities to manage new

organisational processes and new ways of working across all levels of government (OECD, 2015). For public authorities to act as a lead customer, it requires defining long term needs, developing an innovation policy and a procurement strategy. This means a shift from a focus on the procurement process to a focus on the issues to be solved. For private enterprises, it requires to act as a cooperative partner, developing tailor made solutions and not pushing innovative solutions (van Putten, 2012).

The results from the OECD Survey on Strategic Procurement for innovation 2015, show that in many countries the use of procurement for innovation has been included in national or sub-national innovation strategies (OECD, 2017). Results also show that there is room for improvement in terms of the implementation of professional guidance, exchange of experiences and good practices, and the collection of reliable performance data. To fully exploit the potential of strategic procurement for innovation these activities should be part of the implementation process.

The EU's Horizon 2020 program has developed instruments to drive innovation public procurement and its implementation throughout Europe. The program's budget in 2018-2019 was 124 million euros and supported CPP and CPTI initiatives. Thanks to this kind of funding, since of 2012, 24 CPP projects and 15 CPTI projects have been co-financed by the EU (European wide Innovation Procurement in Health Care, 2020). Policies to support technological innovation is pursued by many European programs where coordination would be desirable among them.

3.2.5. Green public procurement

Green public procurement has been defined the European Commission as a "process whereby public authorities seek to produce goods, services, and works with a reduced environmental impact through their life cycle when compared to goods, services, and works with the primary function that would otherwise be procured (European Commission, 2008). It is seen as a mechanism to support progress to the Sustainable Development Goals and to demonstrate commitment to a number of international treaties and the Commission set a non-binding target of 50% of public tendering to be compliant with its sustainability requirements by 2010, to favour improvements in the environmental, energy and social performance of products and services.

These considerations can be incorporated into procurement through inclusion and technical specifications, award criteria, and contract performance conditions (Testa et al., 2016, Fuentes-Bargues et al., 2017, Fuentes-Bargues et al., 2019). However there may be technical challenges in including certain environmental criteria and, especially, in monitoring them during the execution of the project (Large and Thomsen, 2011). There have, however, been several innovations that support this process, including the use of

neural networks (Bendana et al., 2008) and application of weighted multi-criteria analysis (Moretti et al., 2017, Pastor-Ferrando et al., 2010). Most of the literature on green public procurement, however, focuses on works, such as construction projects, where it takes account of considerations such as energy efficiency, use of materials with recycled and reused content, and the environmental implications of construction, including transport of materials (Fuentes-Bargues et al., 2018). Life cycle costing, discussed earlier, is a key element, but surveys, albeit now somewhat dated, suggest that this has been slow to become established outside construction projects, and even there its uptake was slow (Renda et al., 2012). De Giacomo et al. (2019) have identified a series of barriers to its application (Table 1).

Table 1 Barriers to application of life cycle costing (LCC)

Type of barriers	Barrier description
Internal to the organization	Human resources
	Lack of awareness from practitioners
	Lack of familiarity with the concept of LCC itself
	Lack of staff skills
	Resistance to change
	Resistance to innovations
	Resource scarcity
External to the organization	Lack of clarity regarding LCC
	Lack of fiscal incentives
	Lack of reliable data to support LCC
	Lack of common methods to guide its adoption process
	Uncertainty regarding the benefits linked to LCC

Source: compilation by De Giacomo et al. (2019)

While these considerations apply to major capital projects in the health sector, such as hospitals, there is rather less literature on the use of green public procurement of other health-related products, such as pharmaceuticals, even though their manufacture may have considerable environmental consequences, such as the development of antimicrobial resistance as a result of disposal of waste products (Bloomer and McKee, 2018). A 2013 study concluded that the US healthcare system was responsible for an estimated 12% of the nation's acid rain, 10% of the nation's greenhouse gas emissions, 10% of the nation's smog formation, and 9% of the nation's respiratory disease from particulate matter (Eckelman and Sherman, 2016). There are, however, a few examples, such as a study that used life cycle costing to compare reusable and disposable laryngoscopes, taking account of a wide range of the costs, including cleaning the reusable versions (Sherman et al., 2018), and similar studies comparing disposable and reusable blood pressure cuffs (Sanchez et al., 2020) and anaesthetic equipment (McGain et al., 2017). There are also some published reports on the use of life cycle costing as a means of incorporating sustainability considerations in hospital design (Stevanovic et al., 2019, Kirkham et al., 2002a) and on methodological issues relating to this process (Kirkham et al., 2002b). There are also examples of European Commission guidance on Green Public Procurement of some items relevant to the health sector, such as imaging equipment (European Commission, 2020a) as well as training materials (European Commission, 2019).

A related, but separate issue is the use of "Innovative Public Procurement" to stimulate environmental innovation. A recent empirical analysis of the use of this approach in Europe, comparing firms matched on other characteristics but differing in their record of participating in tender processes that included innovation criteria, found that this was associated with greater use of sustainable processes (Ghisetti, 2017).

If society fails to protect the environment the health sector will have to deal with the consequences. Consequently, it is a matter of substantive and symbolic importance that it takes a lead. The concept of Green Public Procurement offers a means to do this. Yet the evidence available to the Expert Panel suggests that this approach is not yet widely used in the health sector, at least compared to other sectors such as construction of major infrastructure. There are several steps that could be taken. Thus, the current voluntary targets could be made mandatory, possibly in sector-specific Directives or Regulations. At national level, authorities could do more to encourage this approach, for example by including incentives, both monetary and otherwise, or regulations that promote adoption of "whole life value thinking" by public authorities, thereby creating values that permeate these organisations, supporting development and standardisation of methodologies and training in their use (recognising the need to avoid national measures that interfere with the operation of the single market). There is also scope for exploring ways in which savings that would otherwise accrue to other organisations, for example through reduced costs of disposal of toxic materials, can benefit the procuring authority.

3.2.6. Procurement as a tool for economic growth

The importance of encouraging small and medium enterprises as drivers of regional growth results from their role in job creation and introduction of new ideas. Most employment created every year is done in SMEs. They also have shorter life spans. Their role and intended higher participation in public procurement tenders is an explicit objective of the Directive 2014/24/EU. The health sector has a particular interest in promoting this goal. A stronger local economy, and with it greater employment and higher incomes, provided these are equitably distributed, can be expected to reduce the burden of disease that the health system must manage (Suhrcke et al., 2006a). Although it is not its primary objective, the health system does contribute substantially to economic development, by protecting and promoting the health of the population and thus their participation in the labour force, their productivity, their willingness to invest in their own education and skills, and their propensity to invest in local enterprises (Suhrcke et al., 2006b). One way in which the health sector contributes to economic development and growth is through public procurement. The role of public procurement in stimulating innovation and growth can take place at both the patient level and the intermediate

goods and services level (as part of the service or product delivered by a health care provider).

Given the specialized nature of health care, SMEs face many barriers to market entry in public procurement. Moreover, regional procurement markets will rarely be sufficient to sustain their growth so they must build a wider vision for their business, either national or international (with the latter almost mandatory for SMEs located in the smaller countries of the European Union). On the other hand, the health sector also procures non-specialist products and, as shown in a study from Spain, is especially well placed to contribute to regional development (Sánchez-Carreira et al., 2019).

These challenges call for partnerships to identify problems and solutions (such as among health care providers, producers, and universities in a region) that may later on be included in procurement procedures. Obviously, these cannot create a "market reserve" situation from which providers from outside are excluded but can facilitate the exchange of information to guide innovation efforts by suppliers in the market. Procurement is, however, only one element of industrial policy and there will be a need for complementary frameworks or economic and financial ecosystems to encourage regional development and the growth of SMEs. This is of course, not specific to procurement by health care providers.

In this context, health care providers will need to engage in two processes: dialogue about their options and the challenges faced on the one hand, and stability in those options, on the other hand, so that suppliers can adjust and innovate in their products and services. Thus, procurement procedures should be embedded in a more general framework of relationships. It is not that the criteria used in procurement mention other elements than price alone. If there is not enough advance information about the strategic options facing the health care provider, SMEs will not have the possibility of presenting their own innovative products and services. Their size, almost by definition, does not allow them to carry a portfolio of innovations from which they can pick what matters for a particular procurement procedure.

One approach to the linkage of public procurement and regional development, with a focus on small and medium enterprises, is the use of Regional Foresight exercises. While Foresight exercises are most often conducted at national level, there have been a number of regional exercises. While most were in other sectors, at least one included healthcare. This exercise, in Lombardy, identified three areas of innovation that could be met by local suppliers, automated equipment for moving beds and stretchers, ICT-based remote systems for control, monitoring and home assistance to disabled and chronically ill people, and robotic systems for blood sampling (Vecchiato and Roveda, 2014). This

experience suggests that Regional Development Authorities can play an important role in supporting public procurement processes.

The relationship between public procurement and innovation, and between public procurement and local development is not a simple or an obvious one. Innovation can take several forms, though the most commonly associated with health care is the development of new therapeutics or new medical devices. Innovation can also be directed to improved processes and to cost reduction (process innovation, as different from product or service innovation) or a combination of these. Procurement has often been used to lower costs, without concerns for innovation. Examples abound in the acquisition of many standardized products, from gloves to injectable liquids to pacemakers and orthopaedic devices, are in this typical class of products, all of them being part of what we may call the hospital supplies market. The challenge is how to use innovations from (local) suppliers and innovation developed with suppliers to improve efficiency and reduce costs, by the supplier, and improving processes, by the health care provider. The difficult element is how to incorporate in the procurement process the possibility of innovation and ideas brought by the (local) supplier that may both improve operations by the health care provider and remunerate the innovation effort by the supplier.

Under a price-only tender procurement this is hardly possible. This requires a broader strategy by health care providers, in which procurement becomes one of the instruments used. This strategy will also develop local suppliers, typically small and medium enterprises (SMEs). It should also be recognized that local (regional) procurement markets will not be large enough to sustain growth of SMEs. Suppliers will have to build a wider vision for their business, either national or international (almost mandatory for SMEs located in the smaller countries of the European Union). The strategy of health care providers will need to include two key elements: dialogue about their options and the challenges faced on the one hand, and stability in those options, on the other hand, so that (local) suppliers can adjust and innovate in their products and services. Thus, procurement procedures are to be imbedded in a more general framework of relationships. It is not enough for procurement criteria to mention other elements than price alone to foster the participation of SMEs. If there is not enough advance information about strategic options of the health care provider, SMEs will not have the possibility of presenting own innovative products and services. Their size, almost by definition, does not allow them to carry a portfolio of innovations, from which they can pick what matters for a particular procurement procedure. It also matters the type of innovation the health provider wants to get under the procurement procedure: innovation that improves a product or a service that already exists, innovation that appears by surprise to improve an existing product or service, innovation that disrupts a market. Regular procurement

procedures are more likely to produce innovations of the first type, continuous innovation that improves current health care delivery. These innovations are often neglected in their contribution to better health care and to local development of innovation by SMEs. Thus, procurement by health care providers alone is unlikely to contribute much to the development of local businesses of SMEs. Given the very specific nature of health care, there is the need for networks of partnerships, which will be mostly local in nature, to identify problems and solutions (say, partnerships between health care providers, companies and universities in a region) that may be later on be included in procurement procedures. The procurement procedure ensures that there is not "market reserve" for a particular supplier or set of suppliers. Note that procurement sets a fair procedure, allowing any supplier to participate, while the partnership gives information to guide innovation efforts by suppliers in the market. For the local development of SMEs, complementary frameworks or economic and financial ecosystems need to be present to bring to the wider market the innovations. This is of course outside the health sector and it is not specific to procurement by health care providers. The key takeaway is that for procurement to help develop innovation by local suppliers some conditions are necessary: a) have a process by which the health care providers transmits in a consistent manner its needs and objectives for future procurement procedures, b) health care providers must be open to ideas and innovations that suppliers may present (and thus have mechanisms for open, non-discriminatory, dialogue with potential suppliers, be it large, medium or small companies); c) ensure that procurement procedures are known, stable over time and clear, especially in the definition in which dimensions there is freedom for innovation to occur; d) let the relevant elements of the MEAT be known well in advance, at least in their general lines, so that (local) suppliers have time to direct innovation efforts (what has been termed "specific" investments elsewhere in the Opinion).

There is a clear potential for alignment between the goals of the health sector and regional development and industrial policies in promoting the economic development and thus the health and wellbeing of the population served by the health system. European Union policies and legislation encourage this but there is more that could be done. This is primarily a goal of industrial rather than health policy, but the European Union and national and regional authorities may consider taking additional steps to promote the use of public procurement to promote regional industrial development. Possible measures include mechanisms that enable engagement between health organisations and local producers, for example in regional Foresight exercises and other forms of dialogue.

3.3. Health sector challenges

This section seeks to identify health technology specific challenges (medicines, equipment, medical devices, e-health, services, etc.) in relation to public procurement with a focus on what award criteria beyond "lowest price" should be used within the MEAT concept. To recall, criteria can amongst others include:

a) quality, including technical merit, aesthetic and functional characteristics, accessibility, design for all users, social, environmental and innovative characteristics and trading and its conditions;

b) organisation, qualification and experience of staff assigned to performing the contract, where the quality of the staff assigned can have a significant impact on the level of performance of the contract; or

c) after-sales service and technical assistance, delivery conditions such as delivery date, delivery process and delivery period or period of completion.

Drawing on the preceding analysis, the challenges that apply to procurement across the different purchases that are made in the health sector can be placed in three broad categories.

The first is the complexity of the transaction. The "lowest price" approach has the advantage of simplicity, in that the purchaser does not need to make an assessment of the characteristics of the purchase that go beyond minimum criteria in the technical specification. This can be especially challenging in health care. Thus, while for some products, such as pharmaceuticals, the technical merits may be established (albeit conditionally, as unanticipated side effects can arise during post-marketing surveillance and medicines may be used beyond the indications for which they were approved), this is not the case for many types of technology or equipment, as illustrated by problems that have arisen previously with medical devices such as breast implants (Greco, 2015) and joint prostheses (Cohen, 2012). It is even less so for procurement of services, where the performance of the contract depends crucially on the ability to recruit and retain skilled, experienced, and motivated staff. A related issue relates to assessing the appropriateness of the purchase in a given setting. While a medicine is likely to function in the same way everywhere, a model of care may not as it should be consistent with local norms, values, and expectations.

The second, which again is not limited to the health sector, is the imbalance of power between the procurer and the provider on each side of the transaction, especially where factors limit competition, on the provider side (barriers to entry, monopoly etc) or the purchaser (small purchaser with limited technical skills). Thus, the "lowest price" may be inflated where there is a monopoly provider, as with the manufacturer of a medicine that

is under patent and there is no obvious substitute. This is becoming an ever greater problem with innovative medicines, and especially biologicals, that depend on precise molecular targeting (Expert Panel on Effective Ways of Investing in Health, 2018). A similar problem can arise even when other companies could legally enter the market but do not, for example where the barriers to market entry are high, for example where there is a requirement to create new, complex, and expensive manufacturing capacity, or where there is a need for rapidity, as in a pandemic, where there is insufficient time for others to enter the market, or where one company holds a large share of the available product or a critical component thereof. Another form of power imbalance arises where the design of a product combines some elements that are contestable but others that are not, for example where a disease management programme expands what once might have been procured in the form of a particular medicine to a package of services that include administration and monitoring, thereby increasing the relative power of the provider. Other types of power imbalance arise where the purchaser is small, for example a purchasing agency in a small member state, both because they will often have limited technical expertise in procurement and the specialised assessment of purchases and because they have limited purchasing power.

The third relates to policy objectives. The primary objective of a health system is to improve health, for example by encouraging innovation through the discovery and development of a new product or a new model of care. But it may also be to contribute to regional or other development policies. Therefore, there may be competing policy objectives and trade-offs between objectives.

We now look at each of these as they apply to pharmaceuticals, medical devices, and e-health solutions.

3.3.1. Pharmaceuticals

Complex transactions

Pharmaceuticals have several characteristics that make transactions complex. First, those involved in protecting and improving health (hospitals, primary care centres, health professionals etc.) require vastly larger numbers of product lines than producers of other things, such as manufactured goods. The number of unique medicines has increased dramatically and, while some can be substituted for others, increasing targeting of individual molecules means that ever greater numbers of drugs have a unique mode of action. To add to the problem, the demand for individual product lines can often be difficult to predict. Thus, faced with 10 patients who are ill, especially if they have multi-morbidity as is increasingly the case, the producer of health could easily require 50 or more different products, some in different dosages. Furthermore, as the condition of the

patients may change over time, for example with a deterioration in their condition or the onset of infection, their needs and expectations may vary (De Maeseneer and Boeckxstaens, 2012). In contrast, a producer of a manufactured good, such as a car, will be able to standardise the components, so that different models may share perhaps 80% of the parts. Moreover, the parts that are required for a particular car will only change when the manufacturer decides to introduce a new model.

Reports of shortages of medicines, even in advanced industrialised countries,(Goldsack et al., 2014, EAHP, 2018) demonstrate just how complex their procurement is, even without the need to consider distortions of the market, such as exploitation of a dominant position by manufacturers to increase prices or divert supplies to more lucrative purchasers, or even withdrawal entirely from the market. Unlike components in some other sectors, pharmaceuticals have a finite and, in some cases relatively short shelf life or may require expensive storage facilities, for example in refrigerated warehouses. Thus, the obvious solution, to increase stockpiles in anticipation of interruptions of supply is problematic. However, manufacturers may also face problems, for example when there is a surge in demand for their products, as in an epidemic, or where there are shortages of essential ingredients.

The issues that arise from this situation, and which need to be taken into account in the procurement process, include the need to agree contracts that have sufficient flexibility to allow demand and supply to match up, as well as the need to ensure the sustainability of the market, generating sufficient incentives for the providers to continue to make profits that are reasonable but not excessive. These issues also call for close communication between public procurers and competition authorities.

A second set of problems arises especially but not exclusively when procuring products that are new to the market. (Expert Panel on Effective Ways of Investing in Health, 2018) A new pharmaceutical must obtain regulatory approval before being placed on the market. However, those responsible for procuring pharmaceuticals for health systems must make an additional judgement, often based on considerations of cost effectiveness. There are now structures and processes in place in several member states to undertake these assessments, while others, especially small member states, may draw on assessments made elsewhere. However, there are a number of issues to be taken into account when interpreting the cost effectiveness data.

The first is how to proceed when clinical benefits in the population in question are uncertain. The clinical trials required for a new medicine to be approved are rarely undertaken in patients that are fully representative of the population that will ultimately receive it (Britton et al., 1999). For example, older people, or patients with comorbidities may be excluded from the trials. One solution is being proposed is the use of

performance-based managed entry agreements. These have the advantage of addressing financial risks, but not clinical uncertainty. However, there are concerns that they are opaque, even to the extent that they are not open to inspection by the Court of Auditors, and the expiry date of the patent is concealed, hampering the entry into the market of generic or biosimilar medicines. However, there is scope to improve the design of such agreements and harmonize them across countries, if confidentiality provisions in some countries, sometimes enshrined in legislation, can be addressed.

A second issue arises when a new product has multiple indications, providing varying degrees of benefit for each. One possible solution is indication-based pricing. This is thought to enhance innovation because companies capture a larger share of surplus generated. However, it is difficult to verify use by indication, is not acceptable to all countries, and each additional indication often leads to a price reduction, which de-incentivizes new uses of existing medicines. This raises issues that go beyond the scope of this Opinion, including the potential for delinkage of the costs of research and development on the one hand, and of production and sales on the other.

A third issue relates to the pricing of products used in combination with other treatments. One approach is to view such products as 'Add-on' therapy, additional to 'backbone' therapy, with payment based on the value of the combination therapy relative to a comparator, with payers determining their willingness to pay (WTP). However, if the two products are already marketed for other indications, the sum is well above the payer's WTP, causing lower price adjustments (e.g., confidential rebates on list prices) for one or both constituent therapies. If the therapies are sold by different companies, competition law may hinder individual product price negotiation. One possible response is to set the price in a way that reflects the respective contributions of the constituent medicines to the overall clinical benefit of treatment of this requires identification of a framework that makes it possible to determine these shares.

These issues pose major challenges because of the growing number of new therapies entering the market at high prices. Current solutions involve developing policies to contain pharmaceutical costs, including overall budget constraints or spending caps. However, this has had limited success and retail pharmaceutical expenditure as a proportion of gross domestic product has, on average, remained stable over the past decade (1.5%). Possible future directions involve earmarking funds for medicines used in particular settings (e.g. oncology) with caps beyond which companies selling products financed through these funds are required to pay rebates. In risk sharing agreements, the effective price or payment is conditional on the performance of the product. The drawback of this approach is that increasingly every actor is stimulated to participate in a "gambling" process: the pharmaceutical company, the patient, the clinician and the

reimbursement agency… This affects the reputation of the system negatively. Moreover, risk-sharing agreements and managed entry agreements do not address adequately the issue of high prices, and public procurement for products under patent will not generate competition (by definition of patent protection) (Expert Panel on Effective Ways of Investing in Health, 2018).

Market power imbalances

Public procurement can redress power imbalances between purchasers and providers by increasing competition. Even when a provider does not hold an actual monopoly of provision, they may be able to maintain monopoly status. This can happen when two or more providers exist, where they provide a homogenous product of known quantity, thereby eliminating search costs for the purchaser. Assuming the capacity of others in the market to supply a product is known and, overall, is less than the amount demanded, a provider can offer to provide the residual knowing that others cannot. Public procurement may lead to increased supply and lower prices than would be achieved through price negotiations with each one or simply allowing providers to announce their list prices. This has the effect of intensifying competition (Hay and Liu, 1997), delivering benefits that will be larger the greater the initial power imbalance.

There are, however, particular challenges with pharmaceuticals because the largest pharmaceutical companies have turnovers that far exceed the gross national income of many countries. This places the smaller member states at a particular disadvantage. One possible response is the development of joint procurement arrangements, whereby the demand from several countries (or purchasing entities) is combined to increase purchasing power. Companies have to submit their proposals under the uncertainty of what rivals do. Of course, the force of competition in joint procurement is reduced when innovative products, without close therapeutic substitutes, are being discussed, leaving aggregation of demand to be the most important advantage in negotiation.

Policy objectives

From a health policy perspective, the primary goal of pharmaceutical procurement is to enable patients to have access to the medicine they need. Despite claims by providers about the scale of their contribution to local economies that are often exaggerated, especially where they are able to use complex financial processes to avoid taxes, pharmaceutical pricing is high on the policy agenda because expenditure on medicines comprises a substantial share of health budgets and all industrialised countries. The corollary of this is that the pharmaceutical industry is an extremely important player in the economy.

Pharmaceutical pricing policies are also contested because of the often considerable amount of public subsidy involved, either through investment in the basic research necessary for a new chemical to take the first steps to being developed as a medicine or through other mechanisms such as incentives built into tax schemes to encourage innovation. A further problem arises when pricing mechanisms are set to encourage investment in the research and development necessary for innovation, yet the amount spent on these activities is far from transparent. For example, a recent study that used publicly available data from US Securities and Exchange Commission filings produced an estimate the cost of bringing a new medicine to market that was substantially lower than many previous ones based on industry data that have not been made publicly available (Wouters et al., 2020). Given the importance of the pharmaceutical industry, it is unsurprising that, where data are available, as in the USA, it is among the most active in lobbying legislators. (Wouters, 2020) Given these considerations in mind, it is clear that there is a tension between ensuring the sustainability of an industry that can reap the rewards of innovation while at the same time providing medicines that are affordable (OECD, 2020a).

Summary

In the vast majority of cases, procurement of pharmaceuticals is straightforward and there is clear guidance from the WHO on best practice (Box 1), with several elements already enshrined in EU procurement and other Single Market law, such as transparency, equal treatment, proportionality, and mutual recognition. A high proportion of medicines that are used have been on the market for many years, with many having lost their patented protection. Often, there will be a number of providers of a generic medicine and, even when patents have not yet expired, there may be scope for substitution of drugs within classes. Some manufacturers may, however, try to argue that their products are unique. On the other hand, some providers of generic drugs may just have the sales permission under their name and the production of the drug is completely outsourced to make their product as cheap as possible. Such companies are susceptible to various disturbances in the production chain which may result in shortages of the drug. In practice, it is quite difficult for the purchaser to ensure that there will not be problems in the availability of the purchased pharmaceutical product during the contract period (Ferner et al., 2019). Finally, even though, in theory, there are few barriers to the market entry that theory would predict would occur in the face of shortages of a product, the evidence of profiteering with generic medicines shows that this is a real problem.

Box 1 Features of successful procurement

- transparency – contract procedures must be transparent and contract opportunities should generally be publicized;
- equal treatment and non-discrimination – potential suppliers must be treated equally;
- proportionality – procurement procedures and decisions must be proportionate;
- mutual recognition – giving equal validity to qualifications and standards from other Member States, where appropriate.

Key elements that are expected to lead to a good procurement outcome

- reliable payment and good financial management;
- procurement by generic name (international non-proprietary name);
- procurement limited to essential medicines list or formulary list;
- formal supplier qualification and monitoring;
- competitive procurement;
- monopsony commitment;
- order quantities based on reliable estimates of actual need;
- transparency and written procedures;
- separation of key functions;
- a product quality assurance programme;
- annual financial audits with published results;
- regular reporting on procurement performance.

Source: (WHO EURO, 2016)

There are some situations that are more complicated. This most commonly is the case with innovative medicines, where there is a need for mechanisms to assess their efficacy and cost effectiveness and to prioritise among competing calls on expenditure. Problems can also arise where a manufacturer exploits their dominant position, for example by increasing prices at short notice, leaving insufficient time for others to enter the market. Finally, there are particular challenges facing small countries that may lack the capacity to evaluate new medicines or have limited purchasing power when negotiating with large multinational corporations.

It would be naive to believe that the complex issues involved in procurement and pricing of pharmaceuticals could be resolved in this Opinion. The Expert Panel recognises that there are many interests involved, in some cases with member states taking quite different approaches depending on whether they are predominantly producers or consumers of pharmaceuticals. Everyone has an interest in the development of innovative medicines, but to benefit Europe's population, they must be available at prices that are affordable. Similarly, the price paid must be a fair compensation of those

companies that invest in their development and manufacture. The existing system has many imperfections. Given the complexities involved, we do not make any specific recommendations for a way forward, not least because many of the issues are a matter of national competence and are dealt with in different ways. Instead, we note the need for much greater transparency, so that it is possible to ascertain accurately what is being paid for, not least because at least some proportion of the costs of developing innovative medicines are already borne by public authorities through their support for research and development. Ultimately, the Expert Panel can see many advantages in delinkage of research and manufacturing costs, as set out in its previous Opinion on innovative payment models, but recognises the political challenges in moving to such a policy.

3.3.2. Health technology

Complex transactions

Many of the same issues arising with pharmaceutical procurement apply to the purchase of health technology. However, there are some additional considerations and some of the issues are less problematic. For example, there are often many fewer product lines and the products themselves are often standardised. Thus, there is rarely the situation would arise where a pharmaceutical must be available in different dosages. Moreover, items of equipment, once purchased, will typically remain in use for a long time. This is not, however, the case for the many consumables that may be required to operate the equipment. A contemporary example is the dramatic increase in demand for glassware, transport media, and reagents for testing for the presence of coronavirus. In this case, many of the challenges involved in procuring pharmaceuticals are similar. There is an additional, although related, issue of interoperability, where consumables design for one piece of equipment may not work with another. This is an area where purchasers and providers have quite different interests but where the development of common standards would improve the functioning of the market. Unfortunately, previous experience is not encouraging. In 2009 the European Commission proposed that a single design should be used for mobile phone chargers within Europe. Manufacturers signed up to a voluntary agreement but this expired in 2014. Currently, there are three main models. Efforts to take this forward have continued through 2020 but progress remains limited.

A particular challenge with health technology is how to assess quality. The public procurer must know the product very well before designing the tender specifications and thus the award criteria. Then they will be able to test, for instance, the functionality. As noted previously, MEAT can include a wide range of criteria, including aesthetic and functional characteristics, consumer service, technical assistance, environmental sustainability, and disposal costs. However, operationalising these criteria and allocating

scores against them can be a very complex task, involving many difficult judgements. Purchasers may require time and effort to ensure the weights are appropriate to reflect the value of products. Each acquisition may have to develop its own set of weights and indicators, increasing transaction costs. Thus, how does one weigh aesthetic characteristics against cost of disposal? There are, however, a number of examples in the literature that can be drawn upon to show what is possible. Some of these are described in Table 1 (Gerecke et al., 2015).

Table 2 Public procurement processes that have applied wider MEAT criteria.

Institution, year	Technology	Quality criteria
Stockholm County Council, 2012	Wound care products	Total cost of treatment, and rate of complications avoided
Norway regional health authority, 2011	IV catheters	Low level of patient-reported pain, ease-of-use, and perceived safety in handling
Karolinska University Hospital, 2014	14-year tender for imaging services (including MRI, ultrasound, and CT scanners)	Maintenance of technical standards over the entire contract and details related to service, upgrades, and replacement scanners
Canadian provincial health authority, 2014	Pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization therapy devices over a 4-year period	Expected life span of the devices, including battery depletion
Hospital Clínic Barcelona, 2017	TAVI, diapers, and underpads	TAVI: incidence of complications Diapers, and underpads: not developed yet

Even where, at first sight, the technology is simple, concerns about quality may arise. In Medipac-Kazantzidis Medipac-Kazantzidis AE v Venizeleio-Pananeio (PE.S.Y. KRITIS) (Case C-6/05 of 14 June 2007) the Court considered whether a Greek hospital could reject a tender for the provision of sutures on the basis that it considered that they did not adequately protect public health, even though they bore a CE mark, meaning that they could lawfully be sold within all member states. The Medical Devices Directive 93/42 contains a "safeguard" procedure, whereby a contracting authority can reject a tender for medical devices bearing a CE mark if it judges that the product is technically inadequate. However, to do so, it must inform the relevant authorities in the member state concerned, which is responsible for invoking the safeguard procedure, and which must refer the matter to the Commission. The court held that the procurement procedure should be suspended pending the decision by the Commission, which is binding on the

contracting authority. However, the court also held that, if the suspension of the award procedure caused problems in running the hospital, it may be possible to invoke a public health derogation from provisions and free movement of goods or provisions relating to urgency of procurement, in each case transparently demonstrating why it is doing so.

Some commentators have addressed the requirement in Directive 2014/24/EU (subject to derogation in certain circumstances) to report the price-quality ratio. This could imply that each bid should be measured separately and then compared in terms of the incremental cost-effectiveness ratio (ICER), which is often used in the health sector. One study of procurement of health technology proposed using net monetary benefit rather than the ICER in competitive tenders that evaluate three or more devices in the same lot (Messori et al., 2020). However, it set out how the mathematical principles involved would have to be adapted to comply with the Directive.

Power imbalances

Many of the issues arising with pharmaceuticals also apply to health technology. The largest manufacturers, while typically smaller than the largest pharmaceutical companies, have market power. These issues are not specific to public procurement and apply to many forms of purchasing. However, it is important that they are not neglected. One way to redress the imbalance between purchasers and providers is to promote cooperation between member states, especially the smaller ones, by sharing information on emerging developments, (horizon scanning) and collaborating on health technology assessment standards. A potential hurdle is the different organization of health care systems across countries. Still, a common, or at least coordinated, approach to the evidence needed for reimbursement decisions and health technology assessment offers important benefits. In this respect, the European Commission initiative on strengthening existing EU cooperation on HTA, including support for joint horizon scanning and joint clinical assessments could be beneficial.

Policy objectives

As noted above, procurement using MEAT can take account of social and environmental considerations, in addition to health. As an example, the Swedish Government has committed itself to include these considerations in its public procurement (Streng, 2018). The procuring authority can decide which social and environmental considerations are relevant for the procurement at issue, subject to the provisions of the Procurement Directive.

The provisions of the directive as they relate to environmental sustainability have been examined in a series of rulings by the European Court of Justice. Thus, in Case C-368/10 of 10 May 2012 (the "Dutch Coffee" case) the court agreed that it was acceptable to refer

to aspects of the process of producing a product even when these do not form part of the material substance of the goods being purchased. In Evropaïki Dynamiki v European Environment Agency (Case T-331/06 of 8 July 2010), the court held that the EEA was entitled to award higher marks to a tenderer that had demonstrated its commitment to environmental management by obtaining third-party certification of its credentials. However, this case was decided under the Financial Regulation governing the award of EU agency contracts rather than the Procurement Directives, although the principles of the same.

The inclusion of environmental considerations however poses several challenges. First, this can reduce the number of tenders, limiting competition and the possibilities for successful procurement. Second, globalized production with complex supply chains can make it difficult to assess the environmental impact in ways that enable comparisons to be made in the procurement process. Third, it is necessary to take a life cycle perspective, from manufacture to disposal.

Social considerations can also be challenging to include. The public sector may encourage producers from the third sector and social enterprises to participate in competitive tendering and Directive permits tenders to be restricted to non-profit organizations or to certain operations that have social and vocational integration as a primary goal. However, few purchasers have the skills and expertise necessary to include these considerations in evaluation of the adequacy of suppliers.

Literature on procurement suggests that when officials are uncertain about the quality that is being delivered, they should employ appropriately complex weightings of criteria. Empirical studies have shown that the lowest price award criterion becomes increasingly disadvantageous with increased contract complexity and in oversupplied markets. Instead, weighting rules that consider both price and quality outperform first-price mechanisms, although they add complexity to the selection of supplier. There is a growing body of literature on the use of multi-criteria decision analysis in this process (Zozaya González et al., 2020). Weightings should preferably convert assessments of quality into monetary values in order to foster transparency of decisions (Bergman and Lundberg, 2013). Even with the most straightforward tenders, procurement officials should dispense with the lowest price rule because suppliers' solutions always differ in more dimensions than price. A combination of factors based on price, quality, delivery, and technology will incentivize more reputable suppliers (Rhode, 2019).

Summary

In many cases, procurement of health technology is straightforward. There are agreed technical specifications for many of the more commonly used items. Once purchased, running costs are relatively low as a proportion of the initial outlay. Maintenance is

straightforward. However, there are situations where this is not the case. Increasingly, complex health technology is bundled with services, or requires large volumes of consumables, giving the manufacturer a powerful incentive to limit the potential for substitution with cheaper versions. There may also be substantial running costs and costs of disposal when the equipment is replaced. An extreme example is where it contains radioactive material. For these reasons, it is important to employ life-cycle costing, while recognising that this involves considerable uncertainty, especially where the item is expected to be in use for a long period.

The simplest approach to procurement is to purchase the product that is on the market at the lowest price. However, there are a number of other considerations that can be taken into account and which are included in the MEAT criteria. The inclusion of quality or non-price dimensions is one of them, which involves purchasers defining appropriate weights that reflect their evaluation. However, tenders that allow for differing quality are appropriate for scenarios where the purchasers have no clear idea of the required product, which in turn may make challenging to specify the evaluation of quality through exact weights. Other considerations, such as acceptability to staff and patients, go beyond the usual technical assessments that are available to the purchasers. As a consequence, the transaction costs may increase, especially if this is the first time the product is being procured or if the purchaser is not drawing on experience of others that have been in this position. It will be necessary to make a judgement as to whether the benefits of the increased evaluation that is required outweigh the costs of undertaking it, recognising that a poor procurement may cost more in the long run, especially if it has to be repeated.

Beyond these criteria, it is possible to include social and environmental criteria. This adds a further level of complexity and, while there may be sound policy reasons for taking them into account, the cost of doing so will fall on the purchaser while the benefits accrue to society as a whole. For this reason, it is unlikely that they will be included unless there is a requirement, normally embedded in legislation or regulations, as in Sweden, to do so as otherwise there will be the risk of free riders.

To safeguard quality of procurement, there are a number of steps that can be taken. These might include development of clear and easily understood procurement strategies where these do not exist, with strengthened measures to enforce compliance if necessary, a strong political commitment to alignment between the strategy and its implementation, clear mandates for all those involved in procurement, and systems of performance indicators that can be monitored regularly. Although beyond the scope of procurement legislation, there would be benefits from a renewed drive for standardisation of equipment or components, confronting the way in which minor

differences in design can, in effect, act as a barrier to competition and hence achievement of optimal outcomes from the tendering process. There is also an environmental argument for standardisation, as the current situation leads to unnecessary waste when contracts are changed. Another is investment in developing and disseminating standard methodologies for life-cycle costing of health technology. A third is greater investment in health technology assessment, and in particular levelling of the inequalities in capacity among member states. Finally, procurement of health technology should engage from the outset with those who will use it and, where relevant, those on whom it will be used to ensure that it fully meets their requirements, including acceptability of use.

3.3.3. E-Health

Complex transactions

The challenges involved in procuring e-health solutions are much greater than with pharmaceuticals or health technology. The selection process needs to ensure that the clinical and technical needs are addressed while taking account of the corresponding regulatory and financing contexts (Mathews et al., 2019). Except in the most straightforward cases, purchasers are likely to require assistance from specialist procurement advisors.

Recent examples of such complexity can be found in accounts of purchasing electronic health records (EHR) systems. EHRs require complex systems and while their primary purposes are the documentation and coordination of care they also play a major role in ensuring efficiency, quality of care, staff satisfaction, and sustainability of organisational finances (Hertzum and Ellingsen, 2019). Hertzum et al. compared compare the experiences of implementing one system, Epic, in the UK and Denmark with the preparations for implementing it in Norway, highlighting the high level of complexity involved. In Norway, procurement required coordination among hospitals, primary care clinics, nursing homes, and home-care services in 84 municipalities.
One of the few published accounts of procurement of an EHR system for a major teaching hospital reports high the output-based specification included over 5000 criteria, of which 3400 were individually scored (Priestman et al., 2019). This was complemented by a series of visits to sites already using the products, including those in other countries. The authors proposed a series of lessons learned.

The first set of lessons relate to the overall process. There were major benefits from developing a stakeholder map that included key staff groups, prior to commencing the procurement process, as well as ensuring that their time was protected. This involved over 200 clinical and operational staff. As the authors noted, per staff inclusion has been

identified as a factor in unsuccessful implementations previously (Priestman et al., 2018). It was important to ensure that the overall vision for the project, including how it would change ways of working and the benefits that it would provide, were understood widely among staff. Finally, procurement staff benefited greatly from their visits to other sites where the product had been installed, allowing them to anticipate difficulties.

A second set of lessons related to the procurement process. Their experience highlighted the importance of a detailed understanding of clinical activities, which they obtained through workshops and focus groups. It was also important to identify and address any biases among those engaged in procurement, such as those resulting from their previous positive and negative experiences with other systems. In retrospect, the authors believed that their very complex scoring system could have been simplified because a large number of the criteria did not differentiate the providers. In this respect, they suggested that simplified checkboxes to indicate compliance with requirements may be more appropriate. They also suggested that products could possibly be differentiated more effectively by means of a focus on how they operated in practice. In this regard, they cautioned against aligning suppliers to design the demonstrations of their products, as this often allowed them to avoid identifying areas where they knew that weaknesses existed. Throughout this process, the authors highlighted the crucial importance of usability of the product and its acceptability by staff.

This report highlights the complexity involved in procurement of e-Health solutions, which goes well beyond what is required with pharmaceuticals and technology.

Market power imbalances

The development of e-health solutions is, in effect, a collaborative process involving the service provider, the purchaser, such as a health insurer or hospital, and the patient or user. Unlike the situation with medicines and most technology, the patient plays a key role by providing their data. Without it, solutions based on artificial intelligence cannot work. However, having provided their data, they lose ownership over it. The algorithms that are developed with these data can then be marketed by the provider. This raises important questions that are, thus far, largely unresolved about ownership of a product that is developed using freely supplied data from patients, and where the data they provide add much of the overall value of the product. There are also many complex and unresolved ethical considerations and issues of liability when clinicians are basing decisions on results generated by complex algorithms (Davenport and Kalakota, 2019).

Policy objectives

As noted, the identification, description, and mapping, in an interdisciplinary way, of the organizational complexity and care pathways of the hospital or care system will be key in

the process of procurement process of an e-health solution. This includes assessment of the compatibility of the e-health solution with the billing and regulatory policies of the care system or state where should be implemented. The fit of the vendors' approach with the organization and the potential for building a strong relationship with the vendor teams were evaluated (Snowdon et al., 2019).

It appears also very important to invite the multidisciplinary team involved in the procurement to collect or build scorecards to assess the different e-health / vendors solutions. The components of such scorecards can be based on the four domains of e-health, technical, clinical, usability and cost (Mathews et al., 2019).

The evaluation within the procurement phase should assess the ability and willingness of vendors to support stakeholders and meet their needs, stimulate new ideas, and adapt to changing environments and expanding systems (Huebner et al., 2020). It is also very important to include processes that allow for continued development of the product as experience with it accumulates. The contract should result in a successful partnership that enables co-design throughout the life of the system (Snowdon et al., 2019).

It is important to ensure that procurement of e-health innovations does not encourage policies and practices that widen inequalities (McKee and Stuckler, 2018). The most obvious is the potential for widening the so-called digital divide, whereby those with limited access to the Internet risks being excluded from access to services. However, there are many other threats. The most important is the way in which algorithms developed by artificial intelligence can entrench existing inequalities, for example by incorporating pre-existing but hidden bias. For example, an artificial intelligence application developed by a London medical school was later found to systematically discriminate against female candidates and those with non-European names (Gholipur, 2018). It replicated the human decision-making process that it replaced, but where the bias was concealed. Problems can also arise when algorithms are developed in one population, for example with few members of ethnic minority populations, but implemented in another, where the relationships encoded in the algorithms do not apply to the same degree.

The digital transition of the healthcare system now underway also offers scope for expansion of e-procurement that has the potential to increase transparency and accountability and combat corruption but this is still poorly developed. Mackey and Cuomo argue that future efforts should emphasise combining cost-saving measures with anti-corruption indicators, prioritizing regulatory harmonization for e-procurement systems, with standard setting and the latest anti-corruption measures (Mackey and Cuomo, 2020).

At the beginning of this Opinion, we noted that when considering whether public procurement is the most appropriate approach, to take a case-by-case approach, keeping

in mind that some characteristics of products and services will be more amenable to public procurement procedures, and that certain steps to achieve optimal public procurement must be taken. Some of the challenges that can be mentioned in relation to public procurement will also be present in alternative purchasing mechanisms. Their consideration in this Opinion should not be viewed as meaning that that public procurement should not be used (it may still be better than the alternatives) but that the challenges must be acknowledged in the precise definition of each public procurement procedure.

To take a few illustrative examples, when the service or product requires investment by the supplier to meet detailed specifications of the purchaser, and thus such specific investment calls for a longer-term relationship, then creation of a joint venture may be better than repeated procurement procedures, with regularly negotiated service level agreements, may be more appropriate.

When a public procurement procedure for which the market has one supplier, defining a reserve price may be critical, otherwise the supplier will naturally set a high price (this can easily be the case for a new patented pharmaceutical product). It may be more appropriate to use an alternative purchasing mechanism (which is the case in many countries, with negotiated prices and/or managed-entry agreements and/or specific contracts).

When a public procurement procedure of a product or service of pre-defined and easily verifiable quality with division into equal lots in a way that each supplier is guaranteed to win one lot, then price competition will be severely affected, while a different division of lots (or even no division) would keep price competition.

It is important to recognise that innovations in e-health create a range of novel challenges, going well beyond other forms of health technology. It is not clear that these are always fully understood. They include, to even greater degree than with many forms of health technology, the importance of ensuring that the products procured meet the needs of the users, something that may require very extensive consultation, piloting, and simulations. It is essential that users, and where appropriate, patients, are fully engaged in this process from the outset. Furthermore, the procurement exercise should include some means of adapting the product as circumstances change. Obviously, this involves a transfer of risk which will need to be priced into the procurement exercise. A second set of issues arises from the use of the data that are required, and, in some cases, from the algorithms that are delivered. Put simply, the value of these products often lies in the information that they gather up from those served by the organisation of has procured them. It is essential that all parties involved have a clear understanding of the intellectual property issues that are involved. There are a number of possible ways of

addressing this, including the creation of joint ventures, but the challenges are formidable, especially when the procurer is a small health organisation and the provider is a global corporation.

3.4. Cross cutting considerations

Beyond the recommendations made in relation to the three types of procurement, the Expert Panel proposes a cross cutting recommendation that recognises how improvement in health and responsiveness to the legitimate expectations of users are two of the fundamental goals of a health system. Public procurement is an obvious means to help to achieve these goals but this is only possible if patient outcomes and experiences are measured routinely. Consistent with this view, the perspectives of existing and potential patients, as appropriate, should be taken into account when procuring goods and systems that affect them. There are well-established mechanisms to do this, based on the concept of co-production, in which providers and users of health care work together to find solutions that address the needs and expectations of both groups (Fusco et al., 2020). Yet, as the examples of procurement failure described in our Opinion show, other interests are sometimes prioritised. To operationalise this recommendation, several measures are needed.

Improvement in health and responsiveness to the legitimate expectations of users are two of the fundamental goals of a health system. However, as the examples of procurement failure described in our Opinion show, other interests are sometimes prioritised. To operationalise this recommendation, several measures are needed.

- Entities providing health services cannot know if they are improving health if they do not measure it, and without such information it is not possible to develop criteria for procurement of products and systems whose goal is protecting or promoting health. Those responsible for procurement in the health sector should work with others to promote development and wider implementation of patient reported outcome and experiences measures (PROMs and PREMs), as far as possible promoting their routine and widespread use in clinical practice. National research bodies should support this process. The European Commission should continue to support cross-country collaborations to support this process;
- Those responsible for procuring in the health sector should work with patients (actual and potential) and frontline providers to increase the use of non-price measures of quality, as described in the Directives, that are relevant to those who use and benefit from what is being procured. This should draw on the principles of co-production, increasingly widely used in health research;

- The European Commission should support these activities, including the development of European guidelines, using as its legal basis Art. 168 of the Treaty: "The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation".

3.5. Better procurement

3.5.1. Professionalising procurement

This Opinion has highlighted the complexity of public procurement and, while its focus has been on the specific issues that arise in the health sector, many of them also apply, to varying degrees, in other sectors. There has been growing recognition that those undertaking public procurement require specialised skills and competencies (OECD, 2011). Yet many organisations have yet to make the necessary transition from processes that are little more that engaging in simple ordering functions, buying more of what was bought before or whatever is easiest to find, to developing a strategic approach that involves evaluating the organisation's needs, not just in the present but over the long term, including sufficient flexibility to adapt to changing circumstances. There are strong personal and organisational incentives to play safe. There is an old saying that "Nobody ever got fired for buying IBM" (Maycotte, 2014). The alternative is to invest in specialist expertise, both in procurement and in the products that are being procured, and in time, to understand the needs of the organisation, the products available to meet those needs, and in some cases, completely different ways of meeting the needs. This requires a cadre of professionals who possess a wide range of skills and competencies, including negotiation, project management and risk management skills, are necessary for successful delivery of strategic procurement initiatives (Edquist et al., 2015, OECD, 2019). There are several examples where public bodies have come together to pool expertise, in some cases with reports of efficiency gains (Hebert, 2011). It also requires a new approach to management, with an organisational culture that values initiative and risk-taking (OECD, 2017).

These considerations have informed the 2017 Commission Recommendation on the professionalisation of public procurement (European Commission, 2017a). The preamble emphasises the priority given to growth rather than cost containment, which has long been the priority for those responsible for health systems. The communication therefore identifies public procurement as an instrument to achieve smart, sustainable, and inclusive growth, contributing to the commission's agenda for growth, jobs, and cross-border trade. It does recognise that value for public money in ever constricting budgetary

environments is important, but presents this as a challenge, alongside the need to maximise accessibility and show accountability for minimising inefficiencies, waste, regularities, fraud, and corruption.

It sets out three complementary objectives. The first is to develop an appropriate policy architecture for professionalisation, with high-level political support and clear assignment of responsibilities to institutions nationally, supporting local, regional, and sectoral initiatives that endure across political cycles, with the institutional structures supporting specialisation and sharing of knowledge.

The second focuses on human resources, with improved training and career progression of procurement practitioners. In this it includes those involved in the procurement of goods, services and works, as well as those responsible for oversight of public procurement, such as auditors. It highlights the importance of recruiting, developing, and retaining such individuals, recognising the importance of making their positions attractive in a competitive market.

The third involves attention to systems that can provide tools and methodologies to support professional procurement practice, and in particular e-procurement, with IT solutions that can enhance access to information, provide economies of scale, and promote standardisation and interoperability. The systems should also promote integrity, by implementing mechanisms to ensure compliance and transparency.

Understandably, as one of the first attempts to set out the necessary steps in professionalising public procurement, the Commission Recommendation does not address the specific challenges in the health sector, as set out in this opinion. However, moving forward, we believe that it is essential that those involved in health sector procurement do have a detailed understanding of the specificities involved, including the complex nature of delivering healthcare, involving multidisciplinary teams, sometimes working across organisational boundaries, in a situation where knowledge is often changing rapidly and where advances in technology offer new opportunities for working. In this sense, while those involved in procurement must have the appropriate mix of specialist skills and knowledge in procurement, they will also require additional skills and knowledge of the specific characteristics of health sectors.

Public procurement is most likely to succeed in an organisation that encourages innovation. Although beyond the scope of this Opinion, it is important to note that there is a literature on leadership for innovation, including in the health sector (Weintraub and McKee, 2019). It recognises the importance of many of the approaches already described in this Opinion, such as drawing on specialist expertise, engagement with stakeholders, and managing complex partnerships. It also involves supporting those who are willing to

take risk, recognising that there are strong incentives for individuals to avoid it, especially where there is a culture of punishment of failure.

3.5.2. Building a knowledge base for health procurement

Professionalisation of any field requires the accumulation of a body of specialised knowledge. In developing this opinion, we have become aware that there is relatively little in the academic literature on procurement in the health sector *per se*, and while there are many accounts of procurement processes available, they are frequently prepared by those involved in the process, using the descriptions as a means of their own activities. While this is entirely reasonable, it does mean that there is relatively little rigorous evaluation of procurement processes in the health sector. Consequently, there is a need to systematise the knowledge that already exists.

There is also a body of evidence on innovation procurement, including Public Procurement of Innovative solutions (PPI), for when challenges can be addressed by innovative solutions that are nearly or already in small quantity in the market and do not need new Research & Development, Pre-Commercial Procurement (PCP), for when no near-to-the-market solutions exist and new research and development are needed. PCP offers a means to compare the advantages and disadvantages of alternative approaches, thereby identifying the most promising innovations through the stages of solution design, prototyping, development and first product testing (European Commission, 2020e). Those engaged in procurement may benefit from the European Assistance For Innovation Procurement initiative, which provides free technical and legal assistance to individual procurers to implement PCPs and PPIs (European Assistance For Innovation, 2020). Potential partners may be able to benefit from InnovFin, or EU Finance for Innovators, support from the European Investment Bank (European Investment, 2020). There is also guidance on how to avoid common errors and adopt best practices in public procurement of projects funded by the European Structural and Investment Funds (ESIF) (European Commission, 2020c).

Except in the simplest of cases, public procurement requires considerable expertise. Those leading organisations that engage in public procurement must ensure that they have sufficient expertise to undertake it well. This requires a combination of generic expertise in public procurement, including the ability to take full advantage of the opportunities offered by the Directive, as well as expertise in their sector, in this case health. This will include the skills necessary to engage effectively with stakeholders, and especially those who will use and benefit from what is being procured. It will also require the ability to use methods and evidence from health technology assessment and health services research to take account of costs across the entire life-cycle and arising from the

operation of equipment or from the implementation of new models of care. This process should inform the development of quality criteria for assessing the different bids and comparing the price of each bidder against the quality of the services. Specifically:

- We endorse the recommendation by the European Commission to promote the professionalisation of public procurement;
- While noting the emergence of Europe-wide initiatives to convene those involved in health sector procurement to exchange experience, we encourage other pan-European organisations involved in the exchange of information on health management and health systems to place health sector procurement on their agendas;
- Noting that there is much information on procurement available, but in many different places, we recommend that the European Commission, taking as its legal base Art. 168, examine how it could support a "community of practice", drawing together a wide range of disciplinary perspectives and examples of best practice, and making full use of the various EU programmes, such as ERASMUS+ to facilitate interchange of staff between public purchasing agencies.

3.5.3. Reducing scope for corruption

The regulation of public procurement must balance discretion in determining the extent to which criteria have been met with processes to minimise the scope for inappropriate influence to be brought to bear on those decisions. Corruption, , defined by Transparency International as the "misuse of public trust for private gains"(Willett, 2009), has long been a concern in the health sector (Jain et al., 2014), with surveys by Transparency International consistently identifying it as one of the most corrupt sectors in many countries (Transparency International, 2013). By promoting transparency, public procurement should reduce the scope for corrupt decision making. There are, however, limits to what can be achieved. First, by their nature, corrupt actions are concealed. In many countries, regulators are under resourced and may themselves become corrupted, as may the politicians to whom they report, illustrated by a series of ongoing scandals in some Member States. Thus, it is often only by the painstaking efforts of courageous investigative journalists, some of whom have been murdered (Bjørnskov and Freytag, 2016), that such activities are revealed. Second, the procedures adopted for public procurement must balance the ability for those deciding on bids to have sufficient discretion to assess different offers, especially where the criteria being assessed are not amenable to quantification, with rules to prevent that discretion being subject to inappropriate influence (McCue et al., 2015). This can be helped by implementation of other methods to strengthen governance, simplify procedures, and potentially greater use of computerised tools.

In the mist of the current COVID-19 pandemic, and when faced with diminishing global stocks of essential products, some public authorities have suspended the usual procedures for public procurement, invoking emergency ones. Given that one of the purposes of the usual procedures is to increase transparency and reduce the risk of corruption, it would be expected that their suspension would pose a risk. (Group of States against corruption (GRECO), 2020). This concern seems to have been justified by experience. Bribery has emerged even in countries where this was very uncommon. In the health care sector, bribery makes medical services more expensive and of a lower quality, leading to unequal access to medical care and undermining patients' trust in the health services. In addition, it distorts competition and has serious financial consequences for public health care insurers, and thus for the state budget.

It is therefore important to put in place specific anti-corruption and governance tools focused on transparency, oversight, and accountability. These have been described in a recent review published in association with WHO (Kohler and Dimancesco, 2020). Transparency is one of the most important means for preventing corruption in the public sector, and it is even more important in times of emergency. This requires increased capacity and public accountability of State institutions entrusted with regulatory and control functions in relation to the management of public resources, by implementing measures to strengthen integrity and the management of conflicts of interest with respect to persons entrusted with key decision making roles, including through responsive monitoring and compliance mechanisms.

As emergency legislation shifts power towards the executive, the oversight role of the other branches of power (legislative, judiciary), institutions (ombudsman, anticorruption agencies and other specialised bodies dealing with corruption) and civil society (e.g. community-based responses, information sharing and tracking measures systems, establishment of hotlines for public reporting, whistleblowers, etc.) becomes key. The media have a particular role to play in this process. The Organized Crime and Corruption Reporting Project is a very valuable resource, bringing together reports by investigative journalists and has collated a portfolio of accounts of corruption during the pandemic (OCCRP, 2020). So do civil society organisations, with Transparency International's Open Contracting for Health (OC4H) offering useful information and resources to assist organisations engaged in monitoring corruption in procurement (Transparency International, 2020).

Although there is a growing body of evidence on the scale and nature of corruption in the health sector (Hutchinson et al., 2019, Vian, 2019), there is still relatively little empirical research on how to tackle it (Gaitonde et al., 2016). This must be a priority for future research and synthesis of existing experiences. Researchers have pointed to the potential

offered by digital technology in pharmaceutical procurement but have noted that this is still some way off providing workable solutions (Mackey and Cuomo, 2020).

The first step in tackling corruption in public procurement is to recognise that it exists and that those who are engaged in procurement can face incentives to act in a corrupt manner. Many of the remedies go far beyond the scope of this opinion and involve upholding the rule of law. We also recognise that there is a trade-off between ex ante approaches, such as establishing extensive procedural checks and balances, although at the expense of flexibility and often involving considerable costs of compliance, and ex post approaches, based on rapid identification and strong sanctions against transgressions. Moreover, controls should not have the effect of deterring innovation, a fundamental role for public procurement. Consequently, the precise measures to be taken will have to take account of the situation in individual Member States, while underpinned by the essential requirement for transparency.

Moving forward, the European Commission should support a process whereby evidence and experience in tackling corruption in the health sector is collated and synthesised to feed into the community of practice in health sector procurement. The European Union and national governments should intensify efforts to develop digital tools to facilitate action against corruption in the health sector, and especially in relation to pharmaceuticals and medical technology.

3.5.4. Procurement in emergency situations

The 2014 Directive envisages that there may be circumstances in which some of the rules of procurement are set aside because there is an urgent need for, for example, "vaccines or emergency equipment". The Commission has set out guidance on a range of models that may be adopted (European Commission, 2020b). These include the scope to substantially reduce deadlines in restricted procedures, or to even make recourse to a negotiated procedure without prior publication, to make a direct award to a preselected provider, provided they are the only one able to deliver what is required, or even to consider alternative solutions for engaging with the market, although once the contract is awarded, a contract award notice must be published. These measures should, however, only be used "insofar as is strictly necessary where, for reasons of extreme urgency brought about by events unforeseeable by the contracting authority, the time limits for the open or restricted procedures or competitive procedures with negotiation cannot be complied with."

The extent to which governments have used these measures varies considerably, as revealed in a report by They Buy For You and the Spend Network (2020). The number of

direct awards increased in most countries but not all, and in some it increased very markedly (Table 3).

Table 3 Change in ratio of direct awards to all awards (direct plus competitive) 2019-2020

Country	2019	2020	Percentage point increase	Ratio 2020:2019
Latvia	3.12%	0.72%	-2.40%	0.23
Slovakia	11.67%	5.53%	-6.10%	0.47
Sweden	1.77%	1.41%	-0.40%	0.80
Estonia	4.96%	4.33%	-0.60%	0.87
Hungary	4.20%	3.80%	-0.40%	0.90
Croatia	2.57%	2.56%	0.00%	1.00
Italy	5.03%	5.17%	0.10%	1.03
France	9.92%	10.64%	0.70%	1.07
Czechia	3.40%	3.95%	0.60%	1.16
Bulgaria	12.33%	14.60%	2.30%	1.18
Poland	2.11%	2.71%	0.60%	1.28
Norway	6.47%	8.73%	2.30%	1.35
Denmark	6.77%	9.95%	3.20%	1.47
Netherlands	6.68%	10.20%	3.50%	1.53
Belgium	1.78%	2.72%	0.90%	1.53
Germany	5.00%	7.90%	2.90%	1.58
Finland	6.65%	11.51%	4.90%	1.73
Slovenia	1.57%	2.80%	1.20%	1.78
United Kingdom	6.89%	12.68%	5.80%	1.84
Lithuania	2.63%	5.68%	3.10%	2.16
Spain	6.06%	16.58%	10.50%	2.74
Austria	4.41%	17.36%	12.90%	3.94
Greece	0.19%	0.77%	0.60%	4.05
Portugal	1.75%	13.20%	11.50%	7.54

Source: They Buy For You and the Spend Network (2020)

While recognising the extreme urgency of procurement during the COVID-19 pandemic, in which public authorities faced a global shortage of critical life-saving supplies, experience has shown that there are considerable risks involved (Box 2).

Box 2 Examples of procurement failures during the COVID-19 pandemic

- Faced with a severe shortage of ventilators at the onset of the pandemic, the UK Prime Minister issued a "ventilator challenge". This attracted interest by a number of companies that had never previously manufactured ventilators and who had yet to design products and obtain regulatory approval. The process had been heavily criticised as the specification was deemed too basic and it would involve companies designing products from scratch. A panel of external experts wrote to the medical device regulator saying that what was being asked for "will result in the need for more ventilators, more oxygen, more drugs, more ventilator days, more staff and almost certainly worse patient outcomes" (Foster, 2020). Although health professionals stressed that patients would require the machines for several, and possibly more, days, the tender document stated that they would only be used for "a few hours", while many critical requirements were dropped. An initial draft of the specification linked to a YouTube video in which the presenter described a ventilator designed in 1961 and stated that it had "been confined to the history books" (Foster and Pooler, 2020). Although the exercise generated good publicity for one of the companies involved, which is better known for its vacuum cleaners, the new products did not make it into production (Pooler, 2020).
- The UK government was offered 2 million Coronavirus antibody tests by Chinese companies at a price of €18 million (Kirkpatrick and Bradley, 2020). The money had to be paid in advance and the UK government would have to arrange their collection. The Prime Minister described them as "as simple as a pregnancy test" and promised they would be a "game changer". However, when they arrived it was found that they did not work.
- A criminal investigation was launched after an order for face masks placed by the Belgian federal government with a Luxembourg provider was delivered late, with products that were sub-standard and with expired certification (Bauldry, 2020). It was later discovered that the provider had filed accounts only once, in 2017, reporting a cash balance of €574.50.
- An investigation in Denmark revealed that protective equipment, to an estimated value of DKR200 million, was unsafe. It exposed large scale forgery of certificates as well as abuses by some authorised testing facilities within the EU (Hecklen et al., 2020).
- Faced with public pressure from hospitals over shortages of personal protective equipment (PPE), a UK minister announced that supplies would be arriving imminently after the government placed an order with a Turkish firm for 400,000 items (Rawlinson, 2020). After several days of delays, the equipment was brought to the UK on a British military flight, although it was then discovered that only 10% of

the order had been fulfilled. When tested, all the items failed to meet the required standards.

- An official in Palermo appointed to procure materials for the COVID-19 response was arrested in an investigation into a "5 percent gang", involved in deals amounting to €600 million worth of supplies and services (Cavallaro, 2020)
- Portuguese authorities used the negotiated procedure without prior publication procedure in a tender for protective equipment that ran for 9 months, in to 2021. This did not meet the criterion for using this procedure of extreme urgency (Telles, 2020).
- A French pharmaceutical company was defrauded of €6.4 million in a purchase of face masks and sanitisers by an individual based in Singapore, with the items never delivered (Europol, 2020).
- A German government order of several million face masks from Kenya was never delivered (Deutsche Welle, 2020a).
- An accountancy firm awarded a contract to source PPE for the UK provided a service described as "useless", with manufacturers finding ways to circumvent its system and negotiate directly with hospitals when their calls to the firm went unanswered (Geoghegan and Hoskins, 2020).
- The UK Department of Health and Social Care contracted with a financial services company to acquire £252 million worth of PPE, in a deal brokered by an individual who was advising both the company and the government. However, large quantities of what was delivered failed to meet basic safety requirements rendering it unusable. It has been estimated that £156 million was wasted (Kinder, 2020).
- The UK government agreed a contract to research public opinion for £840,000, without prior publication, to a firm with close links to a senior minister and the Prime Minister's special adviser and whose staff had been involved in the pro-Brexit campaign, justifying it by the emergency created by COVID. However, government documents suggested that part of it related to communicating the government's Brexit messages (Conn and Geoghegan, 2020).
- 600,000 of a consignment of face masks bought from China by the Dutch government failed quality tests and the entire consignment had to be rejected (Deutsche Welle, 2020b).
- Concerns have been raised about a series of procurements in Slovenia with companies that have no track record in producing or sourcing the products being sought (Delić and Zwitter, 2020). The recipients include an individual whose main activity is in gambling.
- Concerns were exacerbated when it was discovered that one of the companies had been involved in previous scandals in a government contracts. In one, it cost a government agency £30 million to resolve the problems caused. In the other, its call

centre workers were found to have referred to fraud victims as "morons", "psychos" and "screwballs". The then-civil service chief executive officials would "make sure" that it was not awarded further government work "unless they could persuade us that they had got better" (Johnston, 2020).

The OECD has proposed a series of short term measures to minimise the risk of procurement failures in an emergency (Boxes 1 & 2) (OECD, 2020b). These are designed to ensure transparency while recognising the urgency to obtain the necessary goods and services. It was beyond the scope of this Opinion to review the emergency preparedness plans of Member States and it appears that only a few have undertaken major exercises in the management of pandemics that might report the issues that have been examined. However, one that is in the public domain, Exercise Cygnus, undertaken in England in 2016, does not mention procurement (Public Health England, 2017).

Box 3 Short term measures to reduce risks with procurement in an emergency

- Maintaining and retaining documentation of procurement processes
- Developing detailed guidelines on procurement strategies under a crisis.
- Putting further emphasis on contract management, so that established procedures are applied to reinforce accountability and transparency.
- Favouring existing collaborative procurement instruments such as framework agreements
- Ensuring maximum openness of information, including open data
- Setting up a central price and supplier tracking system for key products and services
- Subjecting all emergency procurement processes to audit and oversight.
- Adapting audit and oversight strategies, as well as analyses of potential corrupt patterns in relation to the COVID-19 situation, where bargaining powers of the public and the private sectors are drastically reversed, including effects on competition.
- Respecting sunset clauses in place for the emergency procurement rules and extending only after applicable approvals (e.g. parliamentary oversight)

Source: (OECD, 2020b)

Box 4 Long term measures to reduce risks with procurement in an emergency

- Reviewing existing emergency procurement legislation to ensure that it is relevant for future global health emergencies
- Using or expanding existing e-procurement platforms to record transactional information on the procurement of emergency items
- Allowing remote access by auditors and oversight bodies to all procurement records
- Ensuring an appropriate cadre of trained public officials who have the skills to carry out an emergency procurement procedure.
- Preparing mechanisms to address future supply-chain disruptions for critical goods or services
- Creating digital and easily accessible tools to allow the public to track all emergency purchases

Source: (OECD, 2020b)

Unfortunately, as the examples in Box 2 show, there are many examples from the current pandemic that point to abuse by officials and politicians in some countries. In these circumstances, civil society organisations can play an important role in holding public authorities to account. An example is the work of the Good Law Project in England that has initiated a judicial review of a number of procurement decisions by UK authorities during the COVID-19 pandemic (Good Law Project, 2020).

The current pandemic will not be the last. The European Commission should undertake a comprehensive review of public procurement during the COVID-19 pandemic. There have been many procurement failures, costing money and lives. While some mistakes were inevitable given the urgency at the onset of the crisis, many could have been avoided and there is prima facie evidence of misuse of the emergency provisions in the Directive and of political abuses or corruption. We endorse the advice from the OECD to put in place a series of short and long term measures to improve transparency of procurement in a crisis. This should form a core element of emergency preparedness going forward. A detailed review will offer an opportunity to learn from mistakes and identify ways to strengthen safeguards against errors and fraud.

How can cross border procurement be used to increase efficiency?

Cross-border collaboration is one way for two or more public procurers in different Member States to acquire the advantages of economies of scale (Espín et al., 2016b). These arise in two ways. First, by working together, the purchasers bundle their efforts, expertise and knowledge and thus lower the transaction costs that they must bear as the cost accruing to each procurer decreases as the number of public procurers increases (at least until the point in which the complexity of managing the partnership brings in extra costs, creating diseconomies of scale when too many are involved). The second source of gains due to scale results from placing a higher quantity to be provided in the procedure. This allows suppliers to accrue economies of scale in providing the product or service, which can be passed on to the purchasers via fair prices, higher quality, or both. A 2012 review identified eight potential benefits (Box 5) (Huff-Rousselle, 2012).

Box 5 Potential benefits of cross border pharmaceutical procurement

1) reductions in unit purchase prices;

2) improved quality assurance;

3) reduction or elimination of procurement corruption;

4) rationalized choice through better-informed selection and standardization;

5) reduction of operating costs and administrative burden;

6) increased equity between members;

7) augmented practical utility in the role of the host institutions (regional or international) administering the system;

8) increased access to essential medical products within each participating country.

Source: Huff-Rousselle (2012)

The benefits of specifically cross-border collaboration primarily derive from the increased size effect and efficiency of procurement planning, rather than from the cross-border aspect itself. Indeed, collaboration may be more successful – all else things equal – if the entities involved in procurement are in the same country than if they are in different ones because the benefits of collaboration may be offset by the costs of coordinating activities of partner organizations (Espín et al., 2016a). However, many of these costs have been reduced by single market rules within the EU which have, to some extent, overcome barriers created by different regulations and legislation, but not necessarily language and culture.

Currently, cross-border procurement is attracting particular attention in relation to pharmaceuticals, where there are specific issues because of national differences in approaches, some reflecting differences in ability or willingness to pay, although it is also being explored in relation to technology. However, there are many barriers to doing so. First, countries that believe they are able to achieve lower prices and privileged conditions of supply under confidential price agreements might not want to risk their privileged position by adopting a procurement approach that could lead to a single price, which might be higher than the one they were paying individually (large, high-income countries by exerting monopoly power in the negotiations; or small, low-income countries by benefiting from humanitarian or responsible corporate policies).

Second, pharmaceutical companies are likely to be reluctant to engage in this approach because public procurement leaves less room for them to price discriminate across countries. Price discrimination according to valuation of the product can be total welfare enhancing, although with the distribution of value tilted in the direction of the companies.

In addition, it undermines the widespread "hiding" of discounts to the list price to avoid the consequences of international reference pricing. The visibility of prices under public procurement decreases the attractiveness of bidding low prices by companies if they face international reference prices that use the results from public procurement in some countries to set prices in other countries. Join procurement may reduce this incentive to keep prices high if the procurement procedure replaces administrative prices through international referencing.

Third, if one of the countries is a potential parallel exporter, suppliers are likely not to grant the low price they otherwise would have charged to others for fear that the first country might divert products to higher-priced countries.

Both within and across borders, successful joint procurement depends on a number of essential pre-conditions: strong political commitment; trust between collaborating parties; low transaction costs in reconciling interests of multiple public purchasers; good governance to curb opportunistic tendencies; price transparency; effective communication between internal and external stakeholders; continuity through multi-year contracting to foster closer ties between participants; clarity on management responsibilities for the joint procurement process and their remuneration; and, finally, sharing of information and good practices. Also, learning from experience in the COVID-19 pandemic, it is unhelpful if Member States engage in parallel procurement exercises so the various parties are, in effect, bidding against each other and raising the price, thereby undermining the objective of joint procurement.

Cross-border collaboration could be especially useful in the following situations:

- In small countries or where there are purchasers, that cannot afford the fixed costs or do not have the necessary specialist expertise required to undertake the necessary market and health assessments;
- When the products or services are homogeneous and adhere to clear standards and are, or can be, easily authorized and marketed in any country. In the EU, this condition is normally met for medicines by virtue of the European Medicines Agency's centralized procedure for market authorization. Standardization remains a very real problem for other technologies such as medical devices, as the requirements for marketing authorization are considerably less strict and may vary across EU Member States.
- With high-cost technologies, e.g. new products that are on-patent or subject to other forms of market exclusivity that give the provider a monopoly, joint procurement offers scope for price reductions from pooling the volumes sought by multiple small purchasers;

- Low-volume products, especially if they are essential for health, as a way to minimize the risk of supply discontinuities and stock-outs or where products have an uncertain but potentially high demand, such as medicines required for epidemic outbreaks;
- Where purchasers can share elements of the procurement process, thereby reducing costs and improve performance, with many procurement and procurement-related activities – collection and elaboration of information, contracting, negotiating, purchasing, logistics, etc. –likely to offer economies of scale in setting up the procurement procedure.
- For the procurement of very specific and specialised innovative solutions that are not yet on the market by way of an Innovation Partnership so that several Member States can together with economic operators share the investment costs.

While there are, so far, few initiatives on cross-border collaboration on procurement in place in Europe, there is increasing interest in exploring their potential and an increasing body of work to support them, especially in smaller countries that face particular challenges – discussed in Appendix 2. However, the evidence about their effectiveness is still very limited, making it difficult to identify good practices. This is due, in part, to the relative novelty of many of these initiatives but also because evidence can be highly context-specific and not necessarily applicable to other settings (Ferrario et al., 2016).

Cross-border procurement should be a means to an end rather than an end in itself. By increasing the number of actors involved on the purchasing side of the procurement process it will inevitably add complexity and, as a consequence, transaction costs, at least the first time that this is done (although this may reduce in subsequent rounds) . This may generate a trade-off between the number of providers participating in the procurement, and the time required to complete the procurement of the service. However, these may be mitigated by the ability to share the work involved in specifying what is to be procured, especially where the needs of the member states are similar but the items to be procured involve complex specifications. Cross-border procurement will be especially attractive to smaller member states with limited purchasing power. However, given the complex nature of the pharmaceutical market within Europe, there are a number of potential unintended consequences to be considered. As a result, each case must be decided on its merits. Regardless of the decision made in any particular case, we support existing initiatives and encourage those involved to look beyond their individual actions to exploring whether they can develop common templates, procedures, and standards that can be used more widely. Depending on the particular good or service being procured, the balance may sometimes favour moving faster with fewer participants, while in others a broader participation may be more important than a speedier process. However, once a voluntary decision to join a joint procurement process

is made, Member States should avoid engaging in parallel processes of procurement for the reasons set out above.

3.6. What further EU cooperation can be developed?

The competence of the European Union in the field of health is limited. However, Art 168 states that "The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation". We take this as the legal basis for our recommendations, which appear throughout our Opinion and are brought together in the next section.

We have identified four areas where there is potential to achieve European added value in relation to procurement in the health sector. The first follows from the principle that procurement should focus on the needs of those who use health services. This will require sustained investment in measuring their experiences and outcomes when interacting with the health system. Successive EU research programs have supported work in this area and they should continue to do so, but it is also necessary for those who are providing health services and those who are paying for them to ensure that these measures are implemented widely, so that it is possible to make an informed judgement on ways in which procurement can promote better health and experiences when seeking healthcare.

The Directive provides many opportunities to take account of the quality of healthcare that will be delivered by whatever is being procured. While noting that considerable progress has been made in many Member States in building capacity and applying health technology assessment, there is more that could be done. Moreover, there is a need to develop a common European understanding of how to incorporate wider measures of quality into the procurement process. This is important not only because it will improve the quality of care but it will also avoid the risk of local definitions and understandings undermining the operation of the Single Market.

Our Opinion makes clear that public procurement is complex, and is particularly so in the health sector where there are many specific considerations to take account. There is a clear need for greater professionalisation of procurement. There is considerable scope for the European Commission to support the development of the "community of practice", including encouraging those involved to take full advantage of existing instruments, such as ERASMUS+.

Given the sums of money involved, there is an ever -present risk of corruption in any form of public procurement, although the health sector has long been recognised as

particularly vulnerable. There are opportunities for concerted European action to bring together knowledge and expertise to help to combat this.

The Directive contains provisions for procurement in the event of an emergency, provisions that have been used extensively in the COVID-19 pandemic. However, as we reported in the Opinion, there have been too many examples of procurement failures, some involving organised crime. As Europe looks to the recovery from the pandemic, it is timely to undertake a comprehensive assessment of the lessons that can be learned from this process.

There are already a number of initiatives whereby those seeking to procure goods collaborate across national frontiers. This has some obvious advantages but also some drawbacks, in particular the added transaction costs involved. There is clearly scope for expansion of this concept but those involved can make an important contribution by systematising the knowledge that they obtain in the process and looking at how to develop instruments and processes that can be applied by others.

4. Recommendations

Recommendation 1: Member States together with public buyers and decision-makers should develop purchasing strategies in the health sector in order to achieve a more innovative, efficient and sustainable health system, including digital technologies.

There is a clear potential for alignment between the goals of the health sector and regional development and industrial policies in promoting the economic development and thus the health and wellbeing of the population served by the health system. European Union policies and legislation encourage this but there is more that could be done. This is primarily a goal of industrial rather than health policy, but the European Union and national and regional authorities may consider taking additional steps to promote the use of public procurement to promote regional industrial development. Possible measures include mechanisms that enable engagement between health organisations and local producers, for example in regional foresight exercises and other forms of dialogue.

1.1 **The European Union and national governments should take steps to increase the quality of procurement of health technology**

To safeguard quality of procurement, there are a number of steps that can be taken. These might include development of clear and easily understood procurement strategies where these do not exist, with strengthened measures to enforce compliance if necessary, a strong political commitment to alignment between the strategy and its implementation, clear mandates for all those involved in procurement, and systems of performance indicators that can be monitored regularly. Although beyond the scope of procurement legislation, there would be benefits from a renewed drive for standardisation of equipment or components, confronting the way in which minor differences in design can, in effect, act as a barrier to competition and hence achievement of optimal outcomes from the tendering process. There is also an environmental argument for standardisation, as the current situation leads to unnecessary waste when contracts are changed. Another is investment in developing and disseminating standard methodologies for life-cycle costing of health technology. A third is greater investment in health technology assessment, and in particular levelling of the inequalities in capacity among member states. Finally, procurement of health technology should engage from the outset with those who will use it and, where relevant, those on whom it will be used to ensure that it fully meets their requirements, including acceptability of use.

1.2 **The European Union and national governments should take steps to synthesise the specificities that arise in the procurement of e-health products and develop appropriate responses.**

It is important to recognise that innovations in e-health create a range of novel challenges, going well beyond other forms of health technology. It is not clear that these are always fully understood. They include, to even greater degree than with many forms of health technology, the importance of ensuring that the products procured meet the needs of the users, something that may require very extensive consultation, piloting, and simulations. It is essential that users, and where appropriate, patients, are fully engaged in this process from the outset. Furthermore, the procurement exercise should include some means of adapting the product as circumstances change. Obviously, this involves a transfer of risk which will need to be priced into the procurement exercise. A second set of issues arises from the use of the data that are required, and, in some cases, from the algorithms that are delivered. Put simply, the value of these products often lies in the information that they gather up from those served by the organisation of has procured them. It is essential that all parties involved have a clear understanding of the intellectual property issues that are involved. There are a number of possible ways of addressing this, including the creation of joint ventures, but the challenges are formidable, especially when the procurer is a small health organisation and the provider is a global corporation.

1.3 ***Those responsible for health policy and its implementation should recognise explicitly that public procurement is a means to achieve the goals of the sector, including improvement in health and responding to the legitimate expectations of those who use it***.

Improvement in health and responsiveness to the legitimate expectations of users are two of the fundamental goals of a health system. However, as the examples of procurement failure described in our Opinion show, other interests are sometimes prioritised. To operationalise this recommendation, several measures are needed.

- *Entities providing health services cannot know if they are improving health if they do not measure it, and without such information it is not possible to develop criteria for procurement of products and systems whose goal is protecting or promoting health. Those responsible for procurement in the health sector should work with others to promote development and wider implementation of patient reported outcome and experiences measures (PROMs and PREMs), as far as possible promoting their routine and widespread use in clinical practice. National research bodies should support this process. The European Commission should continue to support cross-country collaborations to support this process;*
- *Those responsible for procuring in the health sector should work with patients (actual and potential) and frontline providers to increase the use*

of non-price measures of quality, as described in the Directives, that are relevant to those who use and benefit from what is being procured. This should draw on the principles of co-production, increasingly widely used in health research;

- *The European Commission should support these activities, including the development of European guidelines, using as its legal basis Art. 168 of the Treaty: "The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation".*

Recommendation 2: Member States and the European Union should take steps to increase the use of Green Public Procurement in the health sector

If society fails to protect the environment the health sector will have to deal with the consequences. Consequently, it is a matter of substantive and symbolic importance that it takes a lead. The concept of Green Public Procurement offers a means to do this. Yet the evidence available to the Expert Panel suggests that this approach is not yet widely used in the health sector, at least compared to other sectors such as construction of major infrastructure. There are several steps that could be taken. Thus, the current voluntary targets could be made mandatory, possibly in sector-specific Directives or Regulations. At national level, authorities could do more to encourage this approach, for example by including incentives, both monetary and otherwise, or regulations that promote adoption of "whole life value thinking" by public authorities, thereby creating values that permeate these organisations, supporting development and standardisation of methodologies and training in their use (recognising the need to avoid national measures that interfere with the operation of the single market). There is also scope for exploring ways in which savings that would otherwise accrue to other organisations, for example through reduced costs of disposal of toxic materials, can benefit the procuring authority.

Recommendation 3: Member States should take measures to professionalise procurement, and to recruit, retain, and continuously develop the necessary skills and expertise

Except in the simplest of cases, public procurement requires considerable expertise. Those leading organisations that engage in public procurement must ensure that they have sufficient expertise to undertake it well. This requires a combination of generic expertise in public procurement, including the ability to take full advantage of the opportunities offered by the Directive, as well as expertise in their sector, in this case

health. This will include the skills necessary to engage effectively with stakeholders, and especially those who will use and benefit from what is being procured. It will also require the ability to use methods and evidence from health technology assessment and health services research to take account of costs across the entire life-cycle and arising from the operation of equipment or from the implementation of new models of care. This process should inform the development of quality criteria for assessing the different bids and comparing the price of each bidder against the quality of the services. Specifically:

- *We endorse the recommendation by the European Commission to promote the professionalisation of public procurement;*
- *While noting the emergence of Europe-wide initiatives to convene those involved in health sector procurement to exchange experience, we encourage other pan-European organisations involved in the exchange of information on health management and health systems to place health sector procurement on their agendas;*
- *Noting that there is much information on procurement available, but in many different places, we recommend that the European Commission, taking as its legal base Art. 168, examine how it could support a "community of practice", drawing together a wide range of disciplinary perspectives and examples of best practice, and making full use of the various EU programmes, such as ERASMUS+ to facilitate interchange of staff between public purchasing agencies.*

Recommendation 4: Cooperative procurement, including joint procurement, should be encouraged at the appropriate level (regional, national, EU) whenever there is good evidence of its potential benefits

Cross-border procurement should be a means to an end rather than an end in itself. By increasing the number of actors involved on the purchasing side of the procurement process it will inevitably add complexity and, as a consequence, transaction costs, at least the first time that this is done (although this may reduce in subsequent rounds) . This may generate a trade-off between the number of providers participating in the procurement, and the time required to complete the procurement of the service. However, these may be mitigated by the ability to share the work involved in specifying what is to be procured, especially where the needs of the member states are similar but the items to be procured involve complex specifications. Cross-border procurement will be especially attractive to smaller member states with limited purchasing power. However, given the complex nature of the pharmaceutical market within Europe, there are a number of potential unintended consequences to be considered. As a result, each case must be decided on its merits. Regardless of the decision made in any particular case, we support existing initiatives and encourage those involved to look beyond their

individual actions to exploring whether they can develop common templates, procedures, and standards that can be used more widely. Depending on the particular good or service being procured, the balance may sometimes favour moving faster with fewer participants, while in others a broader participation may be more important than a speedier process. However, once a voluntary decision to join a joint procurement process is made, Member States should avoid engaging in parallel processes of procurement for the reasons set out above.

Recommendation 5: The European Commission should undertake a comprehensive review of public procurement during the COVID-19 pandemic

The current pandemic will not be the last. As we have catalogued in our Opinion, there have been many procurement failures, costing money and lives. While some mistakes were inevitable given the urgency at the onset of the crisis, many could have been avoided and there is prima facie evidence of misuse of the emergency provisions in the Directive and of political abuses or corruption. We endorse the advice from the OECD to put in place a series of short and long term measures to improve transparency of procurement in a crisis. This should form a core element of emergency preparedness going forward. A detailed review will offer an opportunity to learn from mistakes and identify ways to strengthen safeguards against errors and fraud.

Recommendation 6: Member States should ensure that there is repository of evidence, supported by a community of practice, on corruption in health sector procurement

a) *The European Commission should support a process whereby evidence and experience in tackling corruption in the health sector is collated and synthesised to feed into the community of practice in health sector procurement;*

b) *The European Union and national governments should intensify efforts to develop digital tools to facilitate action against corruption in the health sector, and especially in relation to pharmaceuticals and medical technology.*

Appendix 1 European initiatives related to procurement in health

- Internal Market, Industry, Entrepreneurship and SMEs (https://ec.europa.eu/info/departments/internal-market-industry-entrepreneurship-and-smes_en)
- Responsibilities previously covered by the Directorate-General for Internal Market (DG MARKT) and the Directorate-General for Enterprise and Industry (DG ENTR)
- Develops and carries out the Commission's policies on: Business and industry & Single market
- One of their main tasks is to:
    - Identify key issues that affect the competitiveness of the European healthcare industries and propose solutions in cooperation with stakeholders.
    - Focus on the contribution of the healthcare industries to the European economy and the interactions between policies affecting research and development, market access, intellectual property, competition, and international trade.
- Specific information on their healthcare industry sector is available, but publications are not recent (e.g., 2013, 2014) (more info at: https://ec.europa.eu/growth/sectors/healthcare_en).
    - For instance, documentation from the "Pharmaceutical forum – Pricing and Reimbursement" are from 2008 and can be found here: http://ec.europa.eu/DocsRoom/documents?locale=en&tags=Working%20Group%20on%20Pricing%20and%20Reimbursements
    - Medical Devices is its own sector within the healthcare industry (https://ec.europa.eu/growth/sectors/medical-devices_en)

Existing EC Innovation Procurement Initiatives (https://ec.europa.eu/digital-single-market/en/innovation-procurement)

- Two complementary solutions are being encouraged by the EC; they can be applied to all sectors
    - Public Procurement of Innovative solutions (PPI): Used when challenges can be addressed by innovative solutions that are nearly or already in small quantity in the market and don't need new Research & Development (R&D). (https://ec.europa.eu/digital-single-market/en/public-procurement-innovative-solutions). The steps are:
        - Form a critical mass of purchasing power on the demand side
        - Make an early announcement of the innovation needs (with the required functionality/performance and possibly also price requirements).
        - The actual public procurement of the innovative solutions
    - Pre-Commercial Procurement (PCP): Used when there are no near-to-the-market solutions yet and new R&D is needed. Compares the pros and cons of alternative competing solutions approaches. Enables to de-risk the most promising innovations step-by-step via solution design, prototyping, development and first product testing. (https://ec.europa.eu/digital-single-market/en/pre-commercial-procurement). It involves:
        - Competitive development in phases
        - Risk-benefit sharing under market conditions
        - Separation from the deployment of commercial volumes of end-products / services
        - Encouraging the creation of growth and jobs in Europe
        - Noted limitation of PCP: Does not cover large scale commercialization because R&D cannot include quantity production
- How is the EC supporting PCP and PPI?

    - Through FP7 and H2020 calls for public procurers to prepare and undertake PCPs (calls available at: https://ec.europa.eu/digital-single-market/en/news/calls-eu-funding-opportunities-pre-commercial-procurement-and-public-procurement-innovative)
        - Upcoming DG CONNECT calls related to COVID and beyond. The health-related areas are below. (https://ec.europa.eu/digital-single-market/en/news/get-ready-submit-proposals-innovation-procurements-health-field)
            - PCP
                - Digital Health and Care
                - Integrated Care
            - PPI
                - Diagnostics
        - Health related funded projects (https://ec.europa.eu/digital-single-market/en/eu-funded-projects)
        - Joint transnational PCP projects in ICT domain:
- eCare - Consortium of health procurers that focuses on innovative digital solutions supporting continuum of care for frailty prevention in old adults
- HSMonitor - Consortium of health procurers that is looking for innovative ICT-enabled monitoring solutions to improve health status and optimise hypertension care
- MAGIC - Consortium of health care providers that aims to improve care delivery systems that empower patients in optimising their recovery from a stroke together with healthcare professionals.
- RELIEF - Consortium of healthcare procurers that aims to get new innovative solutions developed for recovering life wellbeing through ICT based pain self-management techniques.
- anti-SUPERbugs - Consortium of healthcare procurers that is looking for smart ICT solutions to detect the presence of resistant microorganisms. The aim is to give real-time feedback to the user and share the information with the healthcare provider's electronic record systems linking the infection with the place of detection.
- NIGHTINGALE - Consortium of healthcare procurers that aims for robust monitoring and communication systems that connect patients and carers. They should provide early warning of acute deterioration of patients' health condition in and out of hospital, and learn and adapt to different individuals in different situations. An approach based on wearable sensors, self-learning adaptive algorithms and big data analysis will be used.
- PROEMPOWER - Consortium of healthcare procurers that aims to get a disease self-management solution developed to help meet the imminent threat of a type 2 diabetes epidemic. Proempower will make person-centred care a reality – giving the patient the steering wheel – for optimal health outcomes.
- STARS - Consortium of healthcare procurers that aim for smart solutions that provide patients with individualized avoidance and reduction of unnecessary healthcare related stress factors, across the preclinical, hospitalisation and aftercare periods. Technical challenges to overcome for suppliers relate to vital signs measuring, wireless real-time transfer of large data amounts and big data analysis and decision making.
- LIVE INCITE - Consortium of healthcare procurers that are looking for smart ICT solutions that enable lifestyle interventions in the perioperative process. The aim is to influence patients in a personalised way to take the necessary actions both prior and after surgery in their life style to optimise the health care outcome.
- NYMPHA-MD (completed) – Consortium of mental care hospitals that completed a PCP on next generation services for mental health treatment focusing on bipolar disorder. One of the phase 3 solutions is already deployed. Other is working on commercialisation.

- THALEA (completed) – Consortium of hospitals that obtained a highly interoperable telemedicine platform that detects increased risk ICU-patients. Wider deployment in the THALEA II PPI will enable earlier diagnosis and improved efficiency, reducing sepsis mortality by 25% and the length of hospital stay by 20-50%.

- DECIPHER (completed) – Consortium of public health providers that acquired innovative solutions that enables more efficient and safer medical care for patients with chronic diseases, such as Type-2 Diabetes, that are on the move across Europe and can generate up to 24% of cost savings (over € 8M) for the procuring regions.

▪ **Joint transnational PPI projects in ICT domain**

- THALEA II - Consortium of hospitals that is preparing a PPI after the THALEA PCP to deploy highly interoperable telemedicine-platforms that detect increased risk ICU-patients.

- RITMOCORE - Consortium of hospitals that is preparing a PPI to procure innovative solutions for the treatment of elderly patients with arrhythmias, pursuing wider deployment of such solutions following the success of the STOP AND GO PPI. This includes a support centre for remote monitoring of pacemakers, delivering pre-defined information sets to all stakeholders in the care path, integration and quality labelling of vital signs home monitoring devices and wearables and support for patient activation.

- STOP AND GO (completed) - Consortium that procured innovative ICT based telecare services for elderly that suffer from multiple conditions such as heart failure, diabetes, etc. In Barcelona for example newly procured implantable cardioverter defibrillators led to a 9.8% reduction in hospital visits, reduced the risk of death by 29% and the implants were .successful in 98,12% cases, compared to 90% under the old approach.

▪ **EU co-financed coordination and networking projects related to PCP and PPI**

- PIPPI - Network of European university hospitals that is identifying shared needs for new innovative digital healthcare solutions in preparation of launching new PCPs and PPIs in this field in the future

- Procure2Innovate - Network that is creating an EU wide network of national competence centres on innovation procurement. The network is spearheaded by five countries that are reinforcing existing national competence centers (Germany, Austria, Netherlands, Spain, Sweden) and five countries that are setting up new competence centers (Portugal, Greece, Ireland, Estonia, Italy). Together they invite others to join.

- PRO4VIP (completed) - Network of healthcare procurers that developed an innovation procurement roadmap for novel cost-effective ICT-based assistive technologies for visually impaired people and clinical tools that help physicians with the early detection of such conditions.

- EPP-eHEALTH (completed) - Group of healthcare providers created an EU wide network or e-health procurers that published unmet needs and developed joint procurement roadmaps for more sustainable e-health solutions. EPP eHealth procurers have already engaged in a number of new innovation procurements (e.g. STARS, RELIEF).

- SAEPP (completed) - Network of ambulance procurers and users that prepared the ground for the procurement of an ICT-equipped ambulance of the future that enables a shift to more on-the-spot treatment. This can avoid unnecessary hospital admissions and reduce the associated patient distress.

- INSPIRE (completed) - Network of contracting authorities that fostered demand for innovative ICTs in eHealth, active aging and independent living: INSPIRE procurers have engaged in several PCP and PPI procurements nationally and at EU level (e.g. STOPANDGO, THALEA, RELIEF, ANTISUPERBugs, EMPATTICS).

- Through the European Structural and Investment Funds (ESIF), to financially support individual procurers to prepare and undertake PCPs, to support them to participate in Horizon 2020 funded PCPs (https://ec.europa.eu/information_society/newsroom/image/document/2016-37/synergies_innovation_procurement_updatewp2017_16968.pdf)
- The Horizon 2020 Access to Risk Finance work programme, which provides, in cooperation with EIB and EIF, loans for individual or groups of public procurers to start PCPs (Innovfin large projects) and helps companies that are involved in PCPs to gain easier access to loans, guarantees, counter-guarantees, hybrid, mezzanine and equity finance to grow their business in view of wider commercialisation of solutions (Innovfin for innovators). (https://www.eib.org/en/products/blending/innovfin/products/legacy-products.htm)
- The European Assistance For Innovation Procurement Initiative provides free of charge technical and legal assistance to individual procurers to implement PCPs and PPIs. (https://eafip.eu/)

Appendix 2 Public procurement in small countries

This appendix summarises the findings of a consultation undertaken in Slovenia

Small countries face constraints when engaging in large and complex procurement exercises as a consequence of the small number of expert staff available to them as well as their limited purchasing power on the market. As a consequence, there is a particular interest in the opportunities provided by cross-border collaborations. However there are also concerns that the existing EU mechanisms may not fully take account of the specific factors facing small countries.

The challenges can be seen by considering pharmaceuticals. Small countries offer limited prospects for pharmaceutical suppliers and, as a consequence, prices may be higher or access may be less. Although the centralised procedure for drug approvals exist, there are no obligations for producers to provide their products to all EU countries; the pricing of the drugs is not regulated and is left to the economic logic of the drug industry. The opportunities provided by joint procurement can be seen in the case of vaccines, presenting an example of a EU response against serious cross-border threats to health (Article 5 of Decision 1082/2013/EU). Based on that experience, it is possible to identify further steps that may be taken in other areas such as:

- Drugs - to prevent drug shortages (there is a single market for registration of the drug, but at the same time there is no process to ensure equal access to medicines; small markets are especially vulnerable to shortages of rarely used drugs; drugs for rare diseases; very expensive drugs; old and cheap (but essential) drugs (vitamin K, old antibiotics, antibiotic syrups); drugs that are off patent; experimental COVID 19 drugs; essential drugs used in intensive care units; new medicines registered by the central procedure but with low expected number of patients (oncology drugs for certain subtypes of cancer); and Advanced Technologies for Novel Therapeutics;
- Medical devices – there are considerable obstacles to effective public procurement in this area, since there is no central (EU) registration in place, they are subject to the free market, quality issues are mostly addressed post festum (pacemaker recalls). Stockpiles would be needed (pandemics, natural or man disasters);
- Complex services - to reduce the inequalities in care for rare diseases or diseases of low frequency but with complex management (e.g. heart surgery for children), a joint procurement for "joint treatment facilities" could be a solution (with **uniformly defined** European competencies for healthcare professionals, unified basis for terms of payment, responsibilities, quality, legal issues etc);
- Digital solutions – there are problems with **data standardisation** (e.g. it is difficult to reach agreement across countries for essential data on prescriptions). In telemedicine, for example, developers are striving for standardisation.

The Slovenian experience (based on 9 joint public procurements involving all 26 hospitals, where the Ministry of Government Administration runs the procedure and the Ministry of Health provided the content led to final agreements in only four) concluded that joint procurement puts a great organisational burden on those involved, **ownership** by hospitals was missing (the potential savings would not go to their budget, causing problems in forming **expert groups**), **standards and expectations among hospitals were very different** (even for gloves those eventually chosen were of very low quality, technical specifications among hospitals were different (e.g. 9000 different needles), and the economic benefit was small. It would be easier to run joint public procurement for drugs, since there is product standardisation, the maximum resale price is defined and regulation exists. There was considerable pressure to prepare procurement with other countries, but no other country was interested at the time, or the legal barriers were too complex. Public pressure was present to a great extent. Public procurement, as it is now, is also a **very time consuming process** and not suitable for urgent needs (such as the COVID 19 pandemic).

It was felt, based on the experience of joint procurement for vaccines, that the process of the joint EU procurement has to become more efficient, for example:

- Broaden the EU tenders outside medical countermeasures, **beyond health threats;**
- An **EU list of essential drugs** could be defined;
- **Better regulation of medical devices** is needed, as a prerequisite for efficient (EU and other) public procurements;
- **Greater co-ordination of HTA, supported by EU legislation, is needed**; small countries have few people who can conduct HTA and conflict of interest is problematic;
- EU joint procurement could become **institutionalised**, with dedicated (human) resources; that body would **lead the procurement process** but countries would join on a voluntary basis.;
- A European procurement agency would have great **negotiating power** with industry, providing on the one hand a large EU market, and on the other hand contribute to a **fair price**, taking into account not only the number of inhabitants in the country, but also measures of wealth (not only GDP, but rather minimum wage and poverty line in the country), resulting in differential pricing system;
- Such an agency may represent **a point of reference** for countries to obtain reliable information such as of the real prices of the drugs/devices across countries, characteristics of the producers/supplier;
- The **centrally defined rules/characteristics** of the mechanism should be ready in advance in more detail, clear and specific as much as possible, please see the suggestions of fast EU joint procurement mechanism
- **Overcome "winner takes it all"** approach, such as 3 preferred product (health professionals still may have a choice, and the other producers can stand in for the company in the potential production deficit; it does not stop the development of the market, potential quality issues are less prominent) (3 preferred products); secure supply chain without stock-outs should be a prerequisite; differential pricing system should be more acceptable if more companies are involved;
- regional initiatives for joint procurements for drugs do exist, but legal basis across the countries varies a lot and presents a major obstacle; the obstacles are even bigger when clinical care centres should be exchanging patents and care; a **unified common EU legal basis** could overcome this.
- EU for example could not guarantee to the countries as much of the vaccines as ordered by countries, the negotiations with producers were described to be very hard; **adjustment of the negotiations protocol is needed** to assure the delivery agreed **amount** of the ordered product; at the end, only half of the amount was available, and EC could not tell, what will happen to the other orders; this is very cumbersome for a health ministry, since the resources had to be held in the state budget and the situation was unpredictable. **The rules should assure greater predictability.**
- **Fast EU joint procurement mechanism** should be developed, where decisions/agreements at EU level have to be defined in advance, including professional view (such as specifications), legal basis and procedural steps and including how the procurement will end (with an agreement how the material will be shared among countries). Countries need to be well informed during the procurement process itself. Such fast EU joint procurement mechanism could/should be **prepared in advance for a few key scenarios.**
- For emergencies, it seems that it would be wise to have some stockpiles at EU level and EU joint procurement may be a mechanism to buy the goods.
- For joint procurement of drugs, the EMA plays a key supportive role with expert groups that developed joint procurement specifications. For other goods, **establishment of strong expert groups with a broader system view** to prepare specifications is essential for effective procurement;

- EU joint procurement mechanisms could be used for **any goods or services**, where Member States show an interest.
- **Joint public procurement joining small countries only** would be a benefit also for industry; however, their concerns regarding pricing need to be taken into account.

In summary, joint public procurement at EU level could offer a mechanism to improve access by EU citizens to high quality healthcare, establish solidarity among EU countries and help to reduce inequalities in health across EU. At least in some small countries, there are growing concerns that seeing health systems as a primarily national competency is a barrier to successful actions to assure good health and wellbeing. There is a need to better prepare for challenges in the future. Small countries have their specifics and in the current approaches these are not adequately taken into account.

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