

Public Procurement of healthcare innovation in the ScanBalt area



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I. Demand-driven innovation in healthcare

The health market represents in most OECD countries around 10% of national gross domestic products (GDP), making Estonia one of the exceptions with a health market corresponding to around 6% of GDP. In addition contributes the public sector in most countries with 70-80 % of the spending in the health sector¹. Public health authorities are therefore important actors in the innovation system, not only as adopters of health innovation taking place among suppliers but also potentially as “intelligent” public procurers formulating demand for innovative solutions. The BSHR HealthPort project focuses on the interactions between healthcare service providers and SMEs with the aim of enhancing innovation, reduce health care costs and promote Small and Medium-sized Enterprises’ (SMEs) access to the Baltic Sea Region healthcare market.

Innovation emerges in general from interaction between suppliers, buyers and or other actors. As most healthcare service providers in the Baltic Sea Region are public organisations, this means that new products and services are developed many times as the result of interaction between public and private actors. There exists certain terms and notions that in different ways captures this interaction. One notion popularised in the Danish context is ‘public-private innovation’, which refers to different innovation generating interactions that may take place between a public agency and supplier(s) and/ or other organisations. To some extent it overlaps with the notion Public Innovation Partnerships understood as “a mutual cooperative arrangement between public and private organisations with the overall objective of innovating and developing public welfare solutions”². Talking about public private innovation is useful as it emphasises the importance of interaction between the private sector and e.g. health authorities. The starting point in the analysis are many times suppliers’ potentially useful innovations, and the ambition to provide opportunities for interactive learning by giving suppliers access to e.g. hospital wards where new solutions can be tested. Even if such opportunities are useful for the development of innovative solutions, public private innovation projects have a tendency to remain in the pre-commercial stage. The actual procurement phase is typically not an integrated part of those projects.

In the efforts to support public-private innovation of products and services in hospitals and the healthcare sector in general, a focus on the demand side is also important. This perspective emphasizes the role public agencies can play to formulate demand for supplier-side innovation, i.e. a complementary perspective to the public private innovation concept. Public demand-side innovation manifests in three main different ways;

¹ OECD Health Data (2012). <http://www.oecd.org/els/health-systems/OECDHealthData2012FrequentlyRequestedData> Accessed 16 April, 2013

² Weihe G et al. (2011) Strategic use of public-private cooperation in the Nordic region. TemaNord, 2011:510. Nordic Council of Ministers, Copenhagen. P. 14.

1. As public procurement projects, where e.g. a health authority sets up contracts for innovative solutions that requires some innovative effort from the supplier in order to meet the need defined.
2. Long term signalling, expressed e.g. as long-term (master) plans outlining more strategic political ambitions formulated by a public authority. Examples seen are the goals set on different levels to become CO2 neutral within a defined deadline or the currently undergoing development in Denmark towards building a set of “super hospitals”. Even if these activities lack any formal incentives for suppliers in the way concrete tender calls do, these kinds of signals may affect firm’s strategic decisions on where to direct their innovation activities, to be able to meet public needs in the future.
3. Standards and regulations, finally, may help both to remove depreciated and inefficient products from the market, but also induce innovation among firms currently not able to meet the standards and regulations. These pulling effects may be realised to the extent that the standards as well as regulations remain updated.

The demand side perspective underscores the importance of that e.g. hospital managers and procurers, has to place demand for, procure and adopt new products and services widely for innovations to take effect. Dissemination of novel solutions in the healthcare sector hinges on them being procured and implemented in more than just isolated test sites, which is sometimes not an entirely problem-free task. Also, even if procurers are able to include an innovative product in a hospital’s electronic order-system, it may not be diffused and used within the organisation anyway. Organised scepticism among physicians, lack of technology champions, silo budgeting, problems related to establishing the value of the innovation, and issues concerning de-spending and already made contract commitments may inhibit or slow down adoption of innovation³.

Associated with the demand-side is also the knowledge that prevails of the practice in which innovations are to be integrated. This knowledge prevails among health staff. Other interesting knowledge holders are patients and their next of kin. Given that this knowledge is utilised in procurement projects, the procurer may be thought of as an expert of the problem that needs to be solved, but not typically on the exact details of the solution. The supplier, on the other hand, may have in possession knowledge, skills and resources to come up with a solution, but lack specific knowledge about the specific need. The ultimate goal of the procurement process is in that sense to find a supplier that compensated with a certain amount of money will satisfy that need by applying its tools and skills to solve a particular problem. The knowledge prevailing in practice may work as sources of

³ Rolfstam M., Phillips, W., Bakker, E. (2011). Public Procurement of Innovations, Diffusion and Endogenous Institutions. *International Journal of Public Sector Management*, Vol. 24 No. 5. Pp. 452-468.

innovation, either by defining in rather open terms a problem that needs to be solved, or more specific suggestions on concrete devices that should be developed. Ultimately, the demand-side approach corresponds with the user-driven perspective of innovation which is a well-known mechanism leading to new solutions⁴.

Finally, private companies are dependent on securing return of investments in innovation, i.e. they need to sell their products or services. In particular in the health-tech sector where public customers play such an important role, a well-functioning public demand-system is critical. This requires considerations regarding all phases from creating possibilities for testing working prototypes to actually selling a solution.

Procurement by hospitals and doctors of products and services has traditionally been driven by economic considerations and for better patient treatment and care. Only recently, public procurement of healthcare solutions has been conceptualised as a means of driving regional economic development. Therefore, the conditions and possibilities of making that link is still investigated and experimented on. This paper contributes to these efforts by investigating framework conditions for public procurement of innovative solutions and recent developments in innovation policies and procurement practice in the Baltic Sea Region.

The issue has in the course of this project been described in “BSHR Health Port Task Part 2 of the State of The Region: Procurement as major source of boosting innovation in the region” by Christoffer Hermansson and Boo Edgar, where the importance of public procurement is stressed. This paper explores the identified barrier of the current procurement legislation. However, it should also be noted that many times are the legal issues per se not so problematic. Public procurement of innovation requires a range of skills, including legal skills, management skills and allocation of adequate resources. Of importance are also prevailing attitudes and norms. If a culture is natured that accepts public procurement as a too cumbersome process not useful for innovation, the chances for successful application is low. The interpretation of the meaning of the Directives may also play a role. Denmark for instance, appears in an international comparison as a country that applies a relatively strict interpretation of the rules. The successful application of public procurement as a means to stimulate innovation requires probably also therefore interventions aiming at developing a more innovation-friendly interpretation of the rules, which includes also pinpointing already available possibilities within the existing legal framework.

⁴ von Hippel, E. (1976). The dominant role of users in the scientific instrument innovation process. *Research Policy*, 5, pp. 212-239.

II. Public procurement of innovative products and solutions

In the European Union, the procurement of products and services by public authorities is regulated to ensure a fair and equal competition for private companies through two EU Directives on public procurement, the Utilities Directive 2004/17 and the Directive for the classic or public sector, Directive 2004/18. Other Directives that may apply are the 2205/28 Directive that specifies principles and guidelines for good clinical practice for investigational products; or the 93/42 Directives concerning medical devices and the rules for CE-marking later amended in the 2007/47 Directive.

In the following the regulation is described with a special view on procurement of innovative solutions⁵.

Procurement of innovative solutions seen from the public sector.

Public authorities must, in most situations follow detailed procedural rules when purchasing goods, services or construction works. The procedural rules are established to promote competition and ensure that public authorities buy the best and cheapest solutions. The rules of procedure arise from both national and EU legislation where the relationship between the two follows the subsidiarity principle. This means that all EU Member states should implement the Directives in national law. The EC procurement Directives apply when the price of the procured item exceeds certain threshold values. In addition to the rules provided in the EC Procurement Directives Member states may for instance regulate procurement under the threshold values. This means that the specific rules applied below the threshold values might vary between EU Member states.

Procurement law in e.g. Denmark consists mainly of the Tender Act, which regulates the procurement of works, goods and services up to the so-called "threshold values", and above that the EU Public Procurement Directive and EU Utilities Directive. Procurement of goods and services may fall into one of four categories. If the value of the purchase exceeds the threshold, the Public Procurement Directive, procedural rules are followed. If the value is lower than the threshold, but above DKK 500.000 the Tender Act rules on advertising duty use, while procurement with a value lower than DKK 500.000 as a starting point is not governed by the Public Procurement Directive or Tender Act. Finally, the purchased service can be directly excluded Procurement Directive, and thus not subject to either supply or advertising requirement. In these cases it is not the value that determines which set of rules applies, but instead the subject of the purchase.

Some types of purchases are more expensive to implement than others. This is important to be aware of when the purchase form is selected. Most costly for the public entity is the

⁵ Based on "Offentligt indkøb af innovation", North Denmark Region, 2011.

pre-commercial procurement (PCP) procedure while traditional public tender is the least costly. Other forms like competitive dialogue range in between.

The costs of procurement is however relative to the degree of complexity and uncertainty in the specific project. The application of more costly procedures such as the competitive dialogue may prove to be cheaper to use for the contracting authority than a traditional tender if the requirements specifications are very complicated to prepare. For instance, with competitive dialogue it is to some extent possible to allow contractors to contribute to the specification of requirements during the dialogue phase. This flexibility may help procurers to reach a more useful solution than would have been rendered with the application of the open procedure. Thus, although more costly, these “advanced” forms of procurement, may be better off to find a solution in an initially complex and uncertain situation.

PCP will often be the most expensive procurement form due to the fact that several suppliers develop product/services in parallel, and that this development to some extent is paid by the public authority. On the other hand, several different ideas are tested, and the authority has a greater chance of getting the best innovative solution. In some cases, it may be possible to put much of the development cost on the suppliers, in which case the PCP is not going to cost more than other forms of procurement. PCP is more likely to provide innovative solutions than traditional tenders. The differences phases in PCP also reduces the risks for involved stakeholders, as suggested ideas that turns out to be less useful can be abandoned before the commercial procurement takes place.

One of the biggest challenges in public private innovation projects as seen in Denmark concerns subsequent procurement of innovations emerging in development projects. One potential legal problem a contracting authority faces after development is that it might be difficult to buy on a commercial scale the product developed. If a contracting authority, for example, has an injection robot for use on the authority's hospitals developed, it is possible to buy a prototype and possibly also a small test series of this robot. A "test set" should not necessarily consist of a small number of copies, but may consist of the number of copies, which is necessary in order to ensure a sufficient quality of testing. However, if transparency and competition are maintained, procurement should be feasible. In order for the Authority to procure the robot on a commercial basis, a formal tender call needs to be published.

The challenge of being able to make a subsequent commercial procurement is that the commercial procurement must be made in compliance with procurement rules, and that the object of the commercial procurement (the product to be developed) often is very difficult to describe at the time of purchase of the R & D performance. The supplier and the contracting authority must of course first through R & D efforts to develop the product to be procured. The usual solution to this problem is that several tender calls are issued, where each tender call represents different phases. One tender call could aim at procuring a feasibility study, another a pilot study, etc. Another technique seen is the application of

functional specification, i.e. what happens when the specification is based on the intended outcome or function, not the specific technical details of the solution.

In a competition perspective, the particular challenge is to define the conditions under which the contracting authority subsequently wish to purchase the product developed, at the time of supply of R & D performance. These conditions include, among other things, the price, quantity and warranty obligations for the supplier.

A possible solution of this problem may be - in advance - to develop pricing models based on the development costs plus a margin for the supplier. It is important here to note that such pricing models must be based on objectively verifiable assumptions, thus creating transparency on the value of the subsequent procurement. The possibility of developing such procurement models is facilitated to the extent that the contracting authority has the opportunity to engage in a dialogue with the suppliers or even to negotiate with suppliers on a price model. It is also possible for a procurer to state a maximum price that will be paid.

Often however, the contracting authority does not have prior knowledge of the work and the expenditure of the development work, while the interested suppliers will often have better conditions than the contracting authority to draft the required pricing models. For this reason, a wide range of R & D services and a subsequent procurement on a commercial scale, is often best done using either a competitive dialogue or similar procedures.

As far as the contracting authority's interest in being able to procure the product developed, this will often be dependent on the outcome of the development project. Can the product be used at all, or is the price so high that the procurer does not want to buy the product? The purchasing authority will often have an interest in formulating this as an option, then the authority has the right but not the obligation, to buy a quantity of goods on the agreed terms, in some cases combined with a commitment to purchase a guaranteed amount.

In the case of PCP, the Commission in its recommendations set out guidelines under which the procurer does not have the obligation or the right to purchase the solution or otherwise to let the developed product be part of the contract. The supplier must therefore still compete for any contract with the authority concerned to delivery of the developed solution. In the case of PCP, the Commission has not made final recommendations on the issue that the development of a single solution could result in a monopoly situation. The Commission sets out several options, where one of them is to have at least two suppliers complete the development of a solution so that authority is not bound, but has the option, to purchase from either developers. On the other hand should not a monopolistic situation occur, if the procurement is carried in compliance with the regulations. One Danish example is the procurement of the Patient Briefcase, a communication device that enables remote interaction between health staff and patients. The contract was given to the only supplier that could deliver the system, after the market was given a chance to object to this intention.

Another option is to give all suppliers the rights (IPR) of the developed solution. This may, e.g. be done by reserving the right to let other suppliers produce the solution, maybe conditioned by paying a license fee to the supplier, who participated in the development. Such an approach will in most cases be able to create competition for the contract, which (all else being equal) results in a lower price. However, the developer still has an advantage, since he did not have to pay licensing fees to produce the product, and to ensure open competition this must be addressed in the following tender.

Six models of procurement in alignment with the Procurement Directive.

Public procurement projects may be set up in different ways, applying different tender procedures as described in the Directives and different delivery forms. This section gives a brief presentation of the most common forms. The presentation provides an overview and an introduction to some of the key terms used.

1. The default tender procedure according to the Public Procurement Directives

A public procurer can, according to the Procurement Directives, choose between two different types of tender procedures: the open and the restricted procedure. The open tender allows all interested suppliers to submit a bid, while the restricted procedure gives authority the possibility to select a limited number of suppliers to bid, typically based on a form of evaluation of qualifications. The latter is typically applied in contexts where the procurer wants to avoid the administration costs associated with handling unnecessarily many bids. Public procurement is typically performed using either the open or restricted procedure.

At a open tender, the authority advertises in the electronic portal Tenders4 Electronic Daily (TED) that it wishes to make a purchase, and all potential suppliers are invited to submit a tender. The public authority must then send the tender conditions and any additional documents to anyone who requests it, or make information freely available, for example, the authority's website. The Authority must include a date for final bidding, and all tenders must be evaluated. The evaluation must be based on some already published award criteria that can be either "lowest price" or "most economically advantageous tender". The supplier that best meets the chosen award criteria must be awarded the contract.

An open tender may result in many bids, which can make evaluation effort prohibitive. This can be avoided by using the method of restricted tendering procedure, which is divided into two phases. The first phase is called "pre-qualification" where suppliers can apply to tender, where typically their financial capacity and technical skills are presented. It is the authority that determines how the financial capacity and technical skills must be documented and evaluation in this phase relate only to determine candidates. The Authority will select objectively the best candidates who subsequently progress to the next stage and will be invited to tender (the "bidders"). The second phase is called the tender

phase and is identical to the process in a public offering with the exception that only the pre-qualified suppliers may submit a tender, and that the tenderers' qualifications are not evaluated again.

2. Procurement of Research & Development Services without competition (Article 16f-exception)

The exemption of R&D service contracts from the Procurement Directive is used widely today in basic research. The exploitation, however, is not limited to basic research, but can be used for the purchase of all kinds of R & D benefits granted that the service has "research level". This means that there is effective research or development. An example of this might be the purchase of new product development, which can improve the Authority's service and does not exist on the market in advance. However, the development of new functionalities or interfaces to e.g. existing IT systems generally is not considered be an R & D performance.

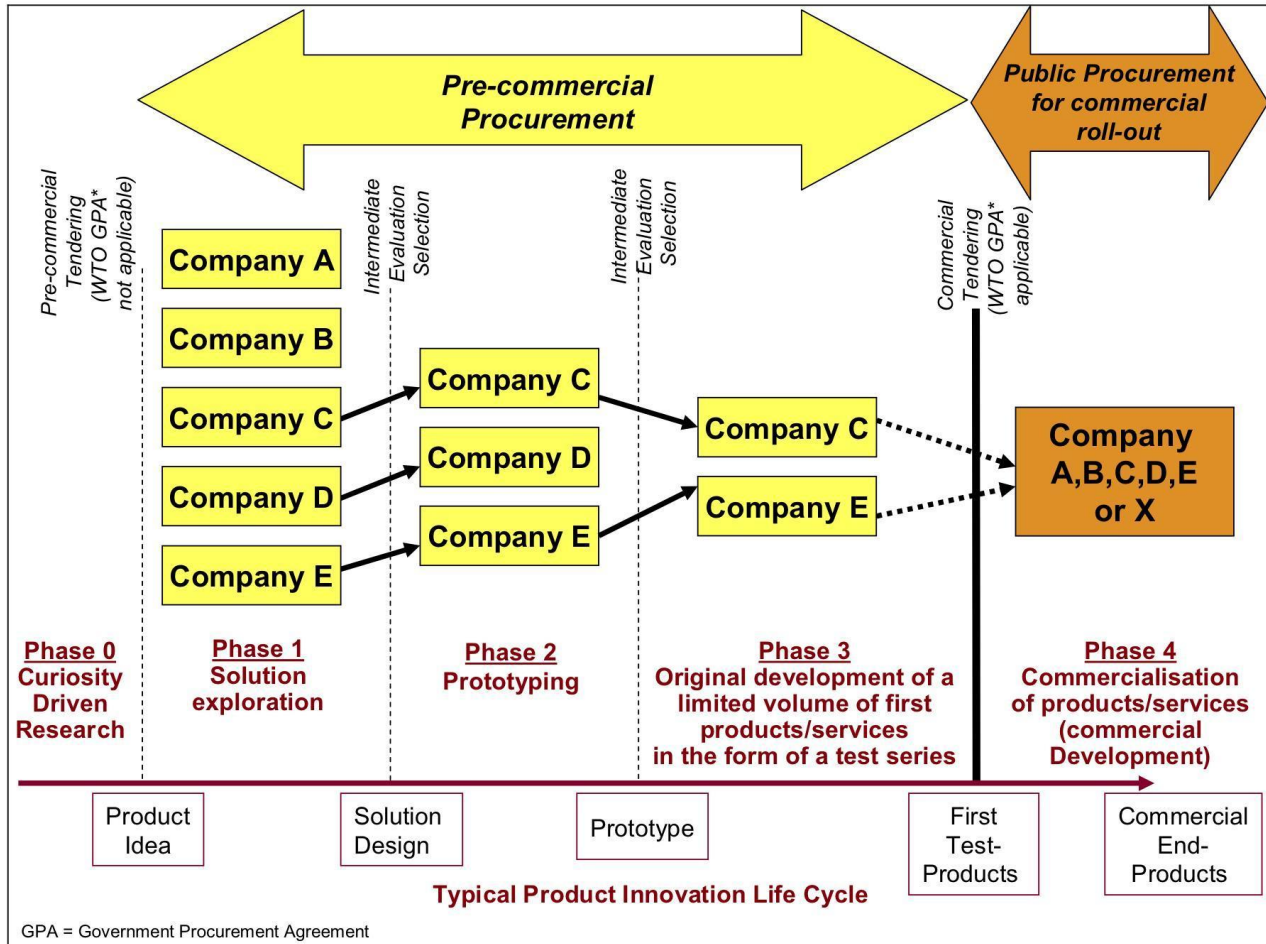
Since the procurement of R & D services are exempt from the Procurement Directive, such procurement is not following the complex procedural rules in the Procurement Directive or the general principles of EU law. A contract may be awarded directly to the desired partners without having to be sent out to tender. After having drawn up a contract with a partner, the development of the desired product is started.

There is no requirement that the contract may not be changed continuously, and authorities can conduct a dialogue with the private partner throughout the development and change the product specifications along the way, as needs arise or change. If the R & D contract concerns development of a product (a commodity), the contracting authority also has the possibility of buying a prototype or a small test series of product directly from the developer / manufacturer through negotiation and without a public tender. A subsequent commercial supply of the developed product is not exempt from the Procurement Directive.

An R & D contract can be referred to only cover the actual development of the product and possibly a prototype or some samples of the product to be used to test the functionality. After the functionality is demonstrated, and the product is ready for commercial production (mass production), the authority must use one of the other procurement forms for buying the product.

If a research and/or development is 100% financed by the contracting authority, it is a requirement that all rights for development results (the so-called Intellectual Property Rights - abbreviated IPR) do not become the property of the contracting authority alone. This can be done by reporting results publicly, or by awarding the partner company the IPR in whole or in part.

3. Pre-commercial procurement (PCP)



PCP is a method of procurement of research and development services, which is based on the above Article 16f-exception where the authority does not keep all rights to research results or the developed solution. The PCP method covers the Commission's recommendations and guidelines on how to implement the Article 16f-exception to ensure that the authorities get the best possible research services. The PCP model also complies with the EU Treaty in the sense that it maintains competition throughout the process.

PCP is different from the procurement of research and development services, as described above, primarily because the PCP focuses on competition and equal treatment in the selection of R & D partners, in the sense that the choice of partner is via tender and the award of the contract is based on objective, factual and non-discriminatory criteria.

The PCP process involves more than one company on the supply side. Instead of working with one company several companies work in parallel development, ensuring competition, since the authority will be able to choose between different vendors' solutions / products

after development. Similarly, this process enhances the authority's chances of developing a solution that meets its requirements when several different solutions are developed.

Since it is very costly to have more than one company to develop a solution – typically paid by the contracting authority – PCP operates as a starting point with a continuous selection of suppliers. The process is divided into phases, as determined by the public authority. At the end of each phase the authority evaluate the solutions and choose which suppliers can proceed to the next phase. In this manner, the continued development involves only the most promising solutions. The Commission recommends that the contracting authority, if possible, leave at least two companies carry out the whole process by which the public authority does not end up being tied to a single vendor solution in a subsequent procurement.

As described, PCP is mainly suited for development projects with a high social and economic value, where gains are comparable with the cost of development for both the contracting authority and the participating suppliers.

Rights to development results (IPR) must not become the property of the public authority alone, but must be shared with the private company developing the solution. In practice, this means that the company can then sell the newly developed product to other customers for commercial purposes.

4. Procurement of innovative solutions through framework agreements

A framework agreement is an agreement setting out the terms of future contracts between one or more authorities and one or more suppliers. Subsequent agreements are made on the basis of the terms set out in the framework agreement, as long as it runs.

It is only the framework agreement that need to be offered under the ordinary rules of procurement. The following contracts awarded under the framework agreement will not have to go through a tendering process again. The Authority can in this way make a single agreement instead of having to award contracts, each time the specified product or service is procured.

Services to be procured on the basis of a framework agreement need not be precisely described. It may, e.g. be sufficient to describe the services as "Engineering consultancy in hospital refurbishing".

In a framework agreement for innovative services, these services therefore need not be described down to the smallest detail. This gives the authority greater freedom to modify the requirements during the period of the framework agreement, and may even use the same supplier to develop solutions for various demands.

Framework agreements for consultancy services can in this way for example be suitable for procurement of R & D services in areas where over a period multiple projects are expected to start, and where the individual projects at the time of tendering is not yet fully defined.

If the authority concludes parallel framework agreements with several suppliers, the individual contracts under framework agreements must be awarded by predetermined conditions or as a result of so-called "mini-tender" where competition is reopened, e.g. for the price for the specific task.

5. The Design contest

The design contest is a procedure, where the authority wishes to give participants (suppliers) great freedom to develop an innovative solution. The procedure used in particular for spatial planning, urban planning, architectural and engineering work and new development of IT systems, but can also be used where the task calls for innovation, idea generation and creativity.

In practice, the procedure has most importance in architectural competitions. The main idea behind the contest is that one of several submitted solutions will be selected by a jury. The evaluation of the solutions must be in accordance with predetermined award criteria and composition of the jury must reflect the academic requirements for participants in the contest.

The design contest can be implemented as an open or restricted tender, and the procedure allows, without additional tender or advertising, to sign a contract with the winner of the competition for the purchase of the solution. When signing the contract for the purchase of the solution, the authority also has the possibility to procure an implementation of the solution (for example, an IT system) without tendering, as long as there is a direct functional relationship with the developed solution. If the purchase of the solution also requires the procurement of goods (e.g. hardware), it is possible without further tendering if the value of the services exceeds the value of the goods. It is also possible to set up a design competition as the initial procurement project, followed by a tender call aiming at realising the proposed design.

6. The Competitive dialogue

The competitive dialogue is a procedure, which was introduced in response to many authorities' wish to expand dialogue with bidders in order to find the optimal solution.

Actual negotiation is still not allowed, but with the competitive dialogue it is possible for the authorities to conduct a dialogue with the candidates on legal, economic or technical aspects of the purchase. Dialogue is conducted prior to final submission, after which the

authority is precluded from further dialogue / negotiation with bidders. Competitive dialogue should be used only in the case of particularly complex contracts, but are often very useful in relation to the purchase of innovative solutions. By "particularly complex contracts" means that the authority can not specify in detail the desired technical solution or that the legal and/or financial conditions applicable to the contract cannot be specified.

The contracting authority can thus draw upon the participating suppliers' experience and expertise to specify the requirements for the desired solution, makes tender form particularly suitable for procurement of innovation. The requirements cannot be changed after the contract is signed, but the competitive dialogue is still considerably more flexible than the open and restricted procedures as the authority has significantly better chance of describing the solution adequately.

Public Procurement of innovation

Public procurement of innovation has been defined as as "*purchasing activities carried out by public agencies that lead to innovation*"⁶. From the above descriptions it follows that there are no single format for procuring healthcare innovation. It depends on the actual situation e.g. the size of the contract, the complexity of the solution and the expected level of innovation. Generally, innovative solutions can be developed and procured when a fair and equal competition is ensured. Especially, the IPR of a given solution cannot be the sole property of the public authority, and the private part must not get any competitive advantage by engaging in the innovation project.

Innovation cooperation between public and private entities has been present in healthcare for long, but has been accentuated in the recent decades. The relationship is characterized by the partners being engaged in a co-creation process towards solutions to common defined problems. Therefore, it is not a traditional procurement of known solutions, nor a cooperation partnership focused more on effective operations rather that development of innovation and knowledge sharing.

A tentative and general model of procurement of innovative solutions and technology can be constructed as:

- I. Pre-procurement process:
Prior to a tender there is a process of preparing that includes among other considerations: exploration of need, budgetary considerations, defining of tender criteria, preparations of procurement process etc.
- II. Procurement process:

⁶ E.g. Rolfstam, M. 2012. An Institutional Approach to Research on Public Procurement of Innovation. Innovation The European Journal of Social Science Research. 25 (3), pp. 303-321.

The procurement process itself contains steps like formulating a tender, conducting the procurement and selecting a provider.

- III. Post-procurement process:
Establish cooperation between provider and procurer, negotiating contract specifics, et cetera. And, in some instances, engage in post-sale services agreements.

In each process, innovative elements can be developed within the legal boundaries. E.g. in the pre-procurement process, research and development activities can be employed to investigate the future envisioned practice and user perspectives, as well as creating a business case for subsequent procurement.

During the procurement phase, some of the models described earlier can be employed, e.g. the model for pre-commercial procurement.

Finally, during the post-procurement process, a window of innovation can be exploited by securing cooperation and synergy between provider and procurer – within the conditions of the tender. For product innovation, diffusion of the procured innovation within the organisation may be an important component.

Obviously, the room for innovation is higher earlier in the overall process, and the different innovation drivers can more easily be exploited in the early process. Insights from research may provide novel products and systems, and special emphasis on user needs and alignment with existing systems and frameworks may provide a basis for effects during implementation.

Procurement practice

Given the complexity of the regulation of procurement of innovative solutions, the actual practice of procuring vary in the different countries and institutions.

A trend in the Nordic countries over the last 30 years has pointed towards a change, where healthcare professionals increasingly accept that productivity/efficiency are terms that are legitimate in healthcare systems⁷.

To some extent professional administrators have permeated the hospitals in the same period, and introduced business logics, e.g. in procurement practice⁸.

In a recent study (Simon-Kucher), the change in procurement practice is described as:

⁷ Lehto, J. et.al. 2012. The Impact of Macro-economic Crises on Nordic Health Systems Policies, European Health Policy Group.

⁸ "Sundhedsvæsen, sundhedsteknologi og medico", Fremkom, NDR, 2012

- Increasing power of purchasing departments as well as an increasing degree of purchasing centralization.
- Centralized procurement is largely associated with decreasing price levels, a reduced innovation adoption and supplier lockout.⁹

The centralization of healthcare procurement is expected to decrease the adoption of innovative solutions by focusing on price and scale. Centralized procurement may also reduce the possibilities to utilize knowledge and needs identified by health staff and patients.

Sometimes claims are made concerning the administrative burden associated with bidding on public tenders, and that the bureaucracy should inhibit public procurement of innovation projects. This is especially important for SMEs as they are heavily burdened by such pre-procurement costs. It is obviously necessary to take into account these kinds of complaints. The general claim that the law inhibits innovation remains however unsupported in research. If one actually looks at why public procurement of innovation goes wrong, or fails entirely, the reasons found prevail typically on other levels than formal law. Less successful attempts to procure innovation can many times be explained by poor management, lack of legal competence, lack of the resources required to conduct public procurement of innovation projects. Sometimes the reasons for the negative perceptions can be found in poor training and awareness, both among suppliers as well as public procurers. What needs to be taken into account is also that the public procurement rules play an important role to prevent fraud, maintain competition and thereby lower the prices public procurers have to pay. Public procurement is a commercial activity aiming at finding the most economically advantageous bid. This means also, like in any business situation, companies must learn to loose.

There is a need for public politics to actively support innovation efforts, and the establishing of a new partnership between public authorities and private companies, especially SMEs. There are several ways of doing this and to some extent the issue becomes one about diffusion information about these options rather than try to develop anything which is not already applied. Public procurers may to larger extent than what is done today unbundle projects, and allow bids from consortia. They may also allow submissions addressing subsets of elements specified in a tender call. One should also take into account that SMEs may also participate in public procurement of innovation as sub-suppliers to large companies. This is very common in the construction sector. Even if the contract with the procuring agency is typically held by a large contractor, it is dependent on an array of sub-contractors to deliver the procured solution. By engaging in such projects, SME's would be able to focus on its core activities, while project management and administration would be carried by the large company. For some SMEs, in particular start-ups within pharmacological sector, the intention might even be never to reach the market themselves. Instead, when a certain maturity stage has been reached, it

⁹ " Centralized Public Procurement, Decision Makers, Tenders and Innovation", Simon-Kucher, Stuttgart, 2012.

expects to be bought up by a multinational company that in turn will manage the commercialisation stage.

In the following section, recent developments in the Baltic Sea Region are summarised to illustrate how public policy answers the need for innovation support.

III. Regional differences in policies and practice of public innovation and procurement

In the following a status on innovation policies in seven of the region's countries is summarized, with a special focus on healthcare innovation¹⁰.

Lithuania:

Innovative public procurement. In 2009, the Law on Public Procurement in Lithuania implemented provisions of EC Public Procurement directives allowing contracting authorities to procure innovative products, services or works through competitive dialogue procedure; to describe wanted product through functional specification, desired performance; to offer possibility of alternative proposals, preliminary contracts, thus, supporting innovation through public procurement (as mentioned in the Innotrend Country Report Lithuania, 2009). In the LIS Action Plan for 2007-2013 the Ministry of Economy sets an objective to promote the adoption of innovative procurement. First it intends to carry out a feasibility study during 2011-2013 on the adoption of innovative procurement practices in Lithuania, based on the experience of other countries

So far, the Lithuanian innovation policy has focused on the supply-side and has paid little attention to the demand-side for innovation. Nevertheless, there are weak signs of the emerging awareness on the demand-side policies.

According to Pro-Inno Europe there are no new demand-side innovation policy measures introduced since 2009. The discussion on the introduction of such measures is only starting to emerge at the policy design level in Lithuania. Moreover, this debate only concerns 'soft' measures – like awareness raising – not fully realising the potential of demand-side policies.

Denmark:

In the Danish policy debate the concept of public procurement has not been used as much as in the European context. In Denmark concepts like public-private innovation and public-private partnership are more commonly used.

Recently Denmark has implemented policy initiatives related to public procurement of innovations related to new hospitals and refurbishing of old hospitals. Furthermore, procurement of innovative solutions has been stated by the government as a means of growth.

¹⁰ Based on Mini Country Reports from Pro-Inno Europe.

Estonia:

The innovation system in Estonia was mainly set up in the beginning of 2000's when not only the legislation and institutions related to R&D and innovation but the whole public functional system was built up and made functioning.

The idea of e-health and electronic health record already emerged in 2002. The purpose was to develop a nationwide framework (database) to facilitate the exchange of digital medical documents and diffuse health information available so far only in local databases and information systems that were not able to communicate with each other. E-health gathers all patients' information in one database, doctors send digi-prescriptions directly to the pharmacy via e-health database and patients can have the medicine in any pharmacy all over Estonia.

There is a new measures launched since 2009: "National programme for health and R&D: sub-programme: Development of capacity of Health Science 2010-2015", which aims to develop Estonian healthcare sector.

Estonian innovation policy framework has remained unchanged since 2007 and does not include any public demand-side measure. So far, the demand-side measures have not been under discussion neither there are no ideas what could be possible demand-side measures. There are recent developments in e-services initiated by the Government, as examples of demand-side innovation as there are nothing alternative to present.

Finland:

The role of public sector as a customer is also emphasized, especially in the development of demand and user driven innovations. However, in general the main role of the public sector is seen to be in ensuring existence of a well-functioning, fair and competitive marketplace for the companies to operate on.

The Framework and Action Plan for Demand and User-driven Innovation Policy¹⁴ was published in 2010 by the Ministry of Employment and the Economy.

The action plan running through the years 2010 - 2013 covers the action points that promote policy implementation in the private and public sectors.

The Ministry of Employment and the Economy is implementing the action plan in cooperation with several other ministries and a broad range of stakeholders, such as Tekes, VTT, the National Consumer Research Centre and Forum Virium Helsinki¹¹. The Action Plan identifies several policy priorities for innovation policy activities to support demand-side innovation between 2010 and 2013.

¹¹ Ministry of Employment and the Economy 15/2011

These include:

- Promoting innovation friendly regulation;
- Development of standardisation to provide more effective support to innovation;
- Promoting the emergence of lead markets;
- Development of funding models for the introduction of investment-intensive innovations.

Germany:

Germany has strong focus on early interaction between potential users of new technology and those actors that develop technology. Public procurement has received increasing attention, though there is an ongoing debate over the effectiveness of the state as a lead user.

Demand-side innovation policy in Germany received a new stimulus by the High-tech Strategy 2020 of the German Government presented in 2010. One area is health and nutrition.

Also, the BioPharma programme is a particularly interesting activity from a demand-side policy view. Started in 2007, its main goal is to link different actors like researchers, hospitals, biotechnology and pharmaceutical companies, agencies and health insurances along the supply chain in order to develop and commercialise new biopharmaceuticals. Co-operation between the different partners is expected to lead to strategic optimisation, accelerated innovation processes and less failure of new biopharmaceuticals in approval and market introduction stages.

Public procurement is another important element of demand-side innovation policy in Germany. An important step was an amendment to the Law against Restraints on Competition that now allows public authorities to impose additional demands on contractors to foster innovative solutions.

In the German policy debate, public procurement is sometimes seen rather sceptical as an effective tool for stimulating innovation. First, innovations should stand the test in the market, particularly in international markets. Secondly, public procurement needs to follow strict cost-efficiency rules which limit the possibility of public entities to demand innovations that are more expensive than standard products and cannot clearly prove superior performance.

Latvia:

In 2006, the Parliament of Latvia passed new Public Procurement Law. The Law relates to the procurement made by state or municipal institutions, and to companies fully or partly owned or financed by such institutions. The law is an implementation of the EU Public Procurement Directive, and Latvia is therefore aligned with the European regulation.

Latvia does not pursue a demand-side innovation policy, and at present, to our knowledge no study or training is taking place in the field of innovation procurement. There is information on some special procurement used for innovation in Latvia, but those are not public measures and are used by a particular company or institute for its own needs.

Nevertheless, a national research program is under implementation with the aim to create new personalised medical technologies and treatment, and means for the improvement of public health.

Poland:

The origins of the public innovation policies, especially public procurement of innovation date back to April 2008, when a jointly prepared document on New approaches to public procurement by the Ministry of Economy in cooperation with the Public Procurement Office was adopted by the Council of Minister.

With regard to SMEs and public procurement, the document formulated a series of recommendations which were around the aspects of undertaking the assessments of barriers hampering access of the SMEs to public procurement, facilitating the access to advisory services and trainings, development of the Public Procurement Office portal, and ensure the provision of information about the public procurement in the existing business intermediary organisations. Similar type of recommendations were put forward as regards the role of public procurement in support of innovation activities (Ministry of Economy, 2008).

Recently, the Public Procurement Office has prepared a number of guides on public procurement, e.g. *Public procurement conducive to innovation*.

Whilst in general there are no specific lead-market type of initiatives, the programmes and project supported by the National R&D Centre (NCBiR) are the closest to the characteristics of this type of support instruments because the Centre is tasked to manage and implement strategic scientific research and development programmes, that translate directly into innovation development.

The use of public procurement as a tool in supporting innovation is limited. The situation has been slowly changing and certainly a strategic project commissioned by the Polish Agency for Enterprises Development (PARP) plays an important role, because it is precisely a programme to step up the knowledge, but also raise awareness of existing possibilities to use new approaches to public procurement more effectively.

IV. Entrepreneurial activities

This section examines the entrepreneurial activities associated with healthcare innovations, and construct a model for categorising different processes for entrepreneurs. The results builds partly on the survey data derived in the BSHR HealthPort WP3 on “Regional capabilities and existing practices survey”, 2012. The data from the survey points towards the importance of the entrepreneurs’ organisation, commercialisation initiatives, and adoption of innovations for future growth.

In the following the entrepreneurial activities are described in three sections: demand or procurement of products, business development and support structures. Also, three archetypical start-ups are used to illustrate different characteristics and conditions regarding product and development process.

Demand and procurement

Most entrepreneurs in healthcare are potential suppliers for the public healthcare sector, which poses a range of obstacles.

For pharmaceutical start-ups the innovation is typically based on research, and the process from theoretical and laboratory results to clinical evidence is long. The link between research results and clinical needs is therefore to a large extent uncertain.

For medico-technical start-ups the sales horizon is not as long, and the need for clinical insight is therefore higher. The medico-technical companies are typically more reliant on a direct interaction with clinicians, and have a strong focus on providing value for doctors and hospital administrators.

For ICT based start-ups, the envelope is even faster, and typical customer is not the public healthcare provider in the first place. Rather the healthcare start-up focuses on the consumer market or joins with an established healthcare solution provider.

Especially companies with a short time-to-market seem to have a more conservative approach to collaboration with the customers and view their relationship as mainly sale. For start-ups with a longer time-to-market the relationship with potential customers are more often characterised as innovation collaboration.

Business Development

Start-ups in the healthcare area seem to follow entrepreneurs in other fields with regards to business development. This need for business skills in the management team is apparently a general trait in all of the three types of start-ups. Apart from the cases where business competencies were present from the initial construction of the company or added

early in the development phase, the entrepreneurs were more driven by functionality and technical aspect of the start-up.

The hypothesis that research-based entrepreneurs would be underrepresented with business skills were not found, perhaps due to the capital demands in most pharmaceutical companies and the following need for including business competencies.

Support structures

The survey found that collaboration with support structures such as incubators were common.

Also, enrolment in entrepreneurship programmes is generally used by start-ups in the healthcare sector.

The distribution, however, seem to vary between the three groups of start-ups.

The group of companies with a strong focus on research and a long time-to-market are seen to be more integrated in incubators – especially connected to universities.

The groups oriented towards medico technical products generally move quicker into business centres or establish own production sites, and drawn on a broader variety of business support like experts in e.g. logistics, IPR, human resource etc.

The group characterised by mainly being software developers are seldom seen in incubators closely related to universities, and do not draw on experts in the same degree as medico technical companies. Rather, the ICT oriented start-ups are oriented towards the marketing aspects and collaboration with other software start-ups, e.g. in business centres.

A process map of entrepreneurs

The characteristic needs for the entrepreneurs are summed up in the table below.

	<i>Pharma and research-based start-ups</i>	<i>Medico technical start-ups</i>	<i>ICT oriented start-ups</i>
<i>Demand and Procurement</i>	Creation of needs in procuring organisations	Collaboration with professionals and decision makers.	Marketing and partnering with solution providers.
<i>Business Development</i>	Business skills, especially financing.	Business skills, especially project management.	Business skills, especially in marketing and partnering.
<i>Support structures</i>	Typically close connected with universities or research organisations.	Diverse field of expert advice, and access to production and test facilities.	Professional sparring and access to sales channels.

V. Final remarks

This report has focussed on public procurement of innovative products and services in the healthcare sector.

It has shown that there is an increasing ambition for seeking synergy between innovation in healthcare and regional economic development.

The formal conditions for public procurement (above the threshold values) are regulated throughout the European Union by the national implementations of the Procurement Directive.

The regulations provides for innovative measures before procurement, e.g. regarding research on technical innovations and user needs. Models of procurement, e.g. “pre-commercial procurement” can be employed to increase the innovation level during the procurement phase.

Some countries in the Baltic Sea Region have adopted strategies to utilise the healthcare expenditure to support development of the private sector, but few have succeeded in creating publicly driven programmes or initiatives where the innovative level of public procurement has provided the expected effects.

The study points towards a number of recommendations to support public procurement of healthcare innovations.

Both public and private actors need to be more competent in designing procurement processes and providing corresponding offers, where focus is on supplying effective healthcare solutions within the legal framework.

For entrepreneurs, different approaches to support and development must be employed as the field of start-ups in the healthcare sector is very diverse.

Supporting public actions to increase innovation in the different procurement processes are needed to fully exploit the innovative potentials, especially in the pre-procurement process.

Across the Baltic Sea Region there appears to be a wide spread of focus and experience regarding public support policies and initiatives. This leads to a need for harmonising procurement practises and models before the Baltic Sea Region healthcare market can become a common innovation platform in the healthcare sector.