Supplier challenges in health tech innovation

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Supplier challenges in health tech innovation: Evidence from the HealthPort project

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Abstract

Suppliers, in particular small innovative firms, is an important contributor not only for innovation in health-tech, but also a component to consider in the light of the emerging policy interest for using public procurement as a means to stimulate innovation. Research on barriers preventing these firms from providing innovations to public health authorities is therefore easily justified. Although substantive knowledge already prevails on the topic, it appears to be a lack in the literature concerning small innovative firms. To help to overcome this gap the paper discusses preliminary case study findings collected in the context of the Baltic Sea Health Region HealthPort project. The overall aim with the project was to facilitate 'business acceleration' by providing support, training and bridging innovative SMEs and health care organisations ultimately to strengthen the Baltic Sea Region health economy.

Keywords: SME involvement, public procurement, innovation

1. Introduction

The health market represents in most OECD countries around 10% of national gross domestic products (GDP). In most countries the public sector contributes with 70-80 % of the total spending in the health sector (OECD, 2013). Public health authorities are therefore important actors in the health innovation system, not only as adopters of supplier side innovation but also potentially as "intelligent" public procurers formulating demand for innovative health solutions. There is also a strategic dimension underscoring the role of healthcare innovation as a means to generate competitive advantages, growth and employment which connect to the general policy interest developed the last decade emphasising the role of public procurement as a means to stimulate innovation (Edler and Georghiou, 2007; Rolfstam, 2013). What could be seen as a sub-topic in this general innovation policy discourse is small and medium-sized firms (SMEs) and their role as suppliers to public health authorities. In particular small start-up research-based firms might lack managerial resources for negotiating barriers necessary to reach the commercial stage. The purpose with this working paper is therefore to explore barriers encountered by small innovative firms prone to become suppliers of health-tech innovations.

2. Literature

Many countries have recent years developed a policy interest for SME's and also stated a concern for involvement of SME's in public procurement (Zheng, Walker and Harland, 2006; Loader, 2013). Recently the British government gave the following view of the role of SME's. "SMEs are a crucial engine for growth: 99.9% of the UK's 4.8 million businesses are SMEs; they are responsible for over 14 million private sector jobs, and account for almost half of the

net growth over that period in jobs. There are also many good examples of small suppliers delivering significant benefits to the public sector through their greater innovation and at a comparatively lower cost base than large, incumbent government contractors. (Gov.uk, 2013, p. 2.)" The Danish Competition and Consumer agency makes similar remarks for Denmark; As 97 % of Danish firms are SME's and therefore a central category it is mandatory that there prevails a good working relationship between public agencies and this type of firms (Konkurrence- og Forbrugerstyrelsen, 2013).

The issue regarding SME involvement in public procurement consist of a set of sub-questions that needs to be taken into account. One initial question is what kind of involvement is envisaged and what effects are measures (see Loader, 2013 for a review of British surveys). It appears that the use of the involvement notion many times are used as a synonym for being a contract owner, i.e. that the entity counted as 'involved' is also the contract owner, while involvement regulated through sub-contracting is disregarded. Awarding a contract to a large firm may still have positive effects on SME's sub-contracted by the big firm that wins the contract. In other words, even if the contractor is a major player, this may not necessary exclude participation of SME's, if SME's are included as sub-contractors. For tender calls published in TED the proportion of SME's directly awarded a contract was 60% (years 2006-2008) which is similar to estimates for 2005 (61%) (Vincze, et al., 2010). Figures provided by the Danish Competition and Consumer Agency on SME participation in Denmark suggest a similar level. Danish SME's participates in 2/3 of Danish tender calls and win half of the tender calls. This should be compared with the private turnover, where SME's contributes with 1/3 of the total turnover (Konkurrence- og Forbrugerstyrelsen, 2013). If SME involvement through sub-contracting is also taken into account, SME involvement appears quite significant.

Concerning the extent to which SME's are more innovative that large firms, the evidence, in spite of what is sometimes claimed, rather inconclusive. Symeonidis summarizes hypotheses proposed in the literature as to why larger firms would be more innovative: R&D typically involve large fixed costs, which can only be covered if sales are sufficiently large; There are scale and scope economies in the production of innovations; Large diversified firms are in a better position to exploit unforeseen innovations; Large firms can undertake many projects at any one time and hence spread R&D risks; Large firms have better access to external finance; Firms with greater market power are better able to finance R&D from own inputs; Firms with greater market power can more easily appropriate the returns from innovation and hence have better incentives to innovate (Symeonidis, 1996). The same author also summarizes counterarguments, i.e. why larger firms would be less efficient innovators. Less managerial control and bureaucracy associated with larger firms would decrease returns of scale; the absence of competition, i.e. in monopolistic situations, may lead to innovation inertia (ibid, 1996). In comparison, it is well established that incumbent firms typically tend to be less innovative in situations where there is a technology shift (e.g. Christensen and Bower, 1996). In that sense appears size to be related to innovation inertia at some point. However, firm size per se appears not a central explanation variable in these situations. The underlying nature of the problems faced by incumbent firms in relation to technology shifts appears not to be that they stop being innovative. Rather, they fail to be innovative in the disruptive technology.

In a survey conducted on UK firms' innovative activities over the years 1945 to 1983 Pavitt et al. (1987) found the size distribution of innovative firms to be U-shaped, i.e. suggesting smaller firms (between 500 and 1000 employees) and larger firms to be the most innovation intensive. Medium-sized firms (between 2000-999 employees) had below average innovation

intensity. Variances were however found for specific sectors. In mining and defence for instance, most innovations where conducted by large firms (50000 employees). Smaller firms were relatively more innovation intensive in the service, R&D and instrument sector (ibid, 1987). Such sector differences were also reported by Acs and Audretsch drawing on US data recorded for 1982 (Acs and Audretsch, 1988). In contrast to the study by Pavitt et al., (1987) Acs and Audretsch did however not find variation related to firm size. Instead, they found that "there does not appear to be a great difference in the "quality" and signify-cance of the innovations between large and small firms. However, the extent of innovative activity does not necessarily correspond to the market values of the innovations. It is conceivable that larger firms may tend to focus on innovations with a higher market value" (Acs and Audretsch, 1988, p. 681). Pavitt et al (1987) concluded that "our findings do not point to easy or obvious prescriptions for the policy-maker. Given the high variance in the size distribution of innovating firms both within and between sectors, grand generalisations are often likely to be wrong, and grand policies often likely to be inappropriate. It is tempting to conclude that, under such circumstances, diversity and pluralism should be the only objectives of policy. (Pavitt et al., 1987, p. 314)". Later, Cohen and Klepper found the relation between the size of the business unit and R&D effort stronger than the overall size of the (multi-product) firm. Also, in industries where innovations are saleable in disembodied form (through e.g. licensing) and/ or when there are better possibilities for growth due to innovation the importance of size is reduced (Cohen and Klepper, 1996).

3. Barriers to public procurement of innovation

If one then leaves aside the rather inconclusive support for policies promoting SME support the question remains what hinders the further involvement of SME's in public procurement. In spite of the potential benefits, and the emphasis given by innovation policy makers, commercialisation of innovative solutions may be prevented by certain barriers occurring in the interaction with public procurers. Rolfstam, Phillips, Bakker (2011) listed nine barriers encountered in the process of introducing an innovative catheter in to NHS hospitals (see table 1).

Institutional Barrier	**Description**
Getting into the supply chain	A product available in existing supply systems will be favoured before products not available in existing supply systems.
Organised scepticism	Clinical staff requiring a high level of proof before an innovation can be adopted.
No technology champion	In comparison to other healthcare technologies, there appeared to be no clear champion catheters.
Decentralised decision structure	A centrally made decision to make certain technologies available may not necessarily lead to adoption in lower layers of the organisation.
Silo budgeting	Spending and gains from spending do not affect the same budget, which removes spending incentives.
Price	An innovation may be more expensive per unit (although less expensive over its lifecycle) than already existing technology.
Demonstrating value of innovation	Problems in showing the value of innovation (and hence justifying adoption) never tried out before in a practical setting.
De-spending	Although proof supports the value of innovation the question remains what should be removed from the budget, to allow the adoption of the innovation
Existing supplier agreements	Commitments made in current contracts prevent re-allocating of resources.

Table 1. Examples of barriers encountered by suppliers of innovative health-technology

An extensive literature review by Loader (2013), provides a list of twenty-three barriers faced by SME's organised into three main categories, barriers that relates to public policy; those relating to the procurement process and those relating to SME's specifically. In the first category belong issues such as conflicting procurement objectives and cultural barriers such as risk averse attitudes, i.e. environmental elements affecting public procurers. The second category includes uncertainty regarding the technical aspects of public procurement, such as lack of knowledge on procedures and challenges regarding the requirement to demonstrate a track record, or negative consequences of (too large) contract volumes. In the third category belongs issues regarding to what extent SME's have resources, skills and attitudes that would make them prone to participate I public procurement processes (ibid, 2013).

Karjalainen and Kemppainen (2008) found lack of legal expertise and lack of administrative to be such a barrier. Also the size within the SME spectrum matters. Smaller SME's perceived to larger extent than larger SME's that the lack of legal expertise and administrative capability made out barriers for participating in public procurement. They also found that SME's using electronic order and invoice systems would be more likely to get involved in state level procurement. Walker et al. (2008) mention an array of barriers related to SME's and sustainable procurement; Some SME's fail to adopt their market strategies for the public sector. SME's might also be seen as inducing larger risks for the procurers. Another tension between efficiency and the promotion of SME's has been the policy pressure imposed on procurers in the UK towards bundling contracts as a means to aggregate demand and therefore increase negotiation power. According to procurers interviewed in the study, such bundling worked to reduce SME participation. The latter is noteworthy as bundling in combination with encouraging bids from consortia consisting of SME's has sometimes been brought forward as a means to encourage SME participation. One question that appears not well investigated in the literature concerns the difference between barriers perceived by SME's and large firms.

For the purposes here, it appears that research on barriers reflects two main foci, barriers manifesting in the realm of public procurers, and SME's in general. What seems to be a gap in this literature is the special focus on a sub-category of SME's, namely innovative SME's. A generic question that comes with that distinction is to what extent such firms encounter specific barriers that if not addressed properly, would reduce their possibility to become public procurement of innovation suppliers. The purpose with this working paper is therefore to explore barriers encountered by small innovative firms prone to become suppliers of health-tech innovations.

4. Methods

The selected candidates were treated as individual cases following a case study methodology (Yin, 1994). Before proceeding to the data collection stage, two methodological measures were taken. Firstly, a case study protocol was developed. The case study protocol summarized important aspects of the project, such as purpose, practical procedures and interview questions. As the research design consisted of a series of cases where data were to be collected by a team of investigators the case study protocol filled two purposes; to provide a guide for the data collection and to maintain reliability. Secondly, a workshop was held with the case study team, where the case study protocol was discussed. The workshop was set up to establish a mutual understanding of the purpose with the project and procedures to follow throughout the data collection stage.

The principle selection criteria applied were as follows: a. Candidates should be in project status (not incorporated) or SMEs in the life-science sector; b. They should be involved in innovative products developed in cooperation with hospitals; c. Being willing to present their case, as well as interact with the HealthPort project. Other selection criteria applied came with the specific set-up of the HealthPort project. The ambition was to achieve technological variance, i.e. to select firms engaged in different technology areas.
Another issue concerned the time-line of the projects. Cases were selected based on the probability of seeing progress during the study period. A further criteria concerned to what extent it selected firms would benefit from the support offered by the HealthPort project. A final criteria concerned the judgement of the potential for the BSR Bioregion and to what extent support the candidate would contribute to the development of a better health care market in the BSR Bioregion.

For each case two main events of data collection and interaction were organised. The main reason for this set-up was due to the set-up of the HealthPort project. Participating firms were offered a support scheme consisting of EUR 10.000 to be spent on activities aiming at facilitating the commercialisation of the respective innovation. The intervention part of the HealthPort project is however omitted in this paper due to the page limits of a working paper.
All initial meetings where conducted as physical meetings. In four of the cases the second meetings were conducted either as telephone meetings or video conference (SKYPE, Teamviewer). The meetings were recorded and transcribed. To respondents where send out summaries of the interviews allowing for any comments and corrections to be made. Additional communication occurred through email and telephone over the project duration. The purpose with the first meeting was to collect data as specified in the case study protocol and identify and agree on needs to be supported by the HealthPort project. The main purpose with the second meeting was to evaluate the effects of activities supported by the HealthPort project. The time between the first meeting and second meeting was 4-7 months. See table 2.

Case no.	Initial meeting (date, type)	Evaluation meeting (date, type)
1	4 April visit	23 August visit
2	19 April visit	27 August Teamviewer conference
3	30 January 2013 visit	26 September Skype conference
4	1 February 2013 visit	13 August Skype conference
5	11 April 2013 visit	27 August 2013 skype conference
6	20 February 2013 visit	26 August 2013 visit

Table 2. Main events of data collection in the six cases

5. Results

Included as cases were firms established or about to be established in the Baltic Sea area, Estonia, Denmark, Finland, Germany and Sweden. Technologies represented were IT/ software development, telemedicine, health tech appliances and drugs. Each case and their respective innovations are displayed in table 3.

Case no.	Innovation	Benefit
1	Cloud-based IT system for patient management	Enable better services for patients, faster and adequate decisions, long term analysis.
2	Personalized diabetes treatment system	Due to increased control making patients able to live more ‘normal’ lives. Reduce number of emergency

		responses due to increased control
3	Intelligent container for transporting organic samples	Increased efficiency for laboratories due to automated process. Reduced number of ruined samples in transport due to improved safety.
4	Angiogenesis inhibitor, which starves tumors by cutting off their blood supply	More efficient treatment leading to improved patient satisfaction.
5	Tele medicine solution	Provision of distributed healthcare in remote areas at a reduced cost.
6	Catheter with impregnated anti-microbial protection	Catheter can be in place for prolonged times, rendering fewer infections, reducing number of catheters that needs to be used.

Table 3. Description of the six cases.

*Case 1.*The firm was established 2007. The innovation project was as a cloud-based IT system that assists health care professionals dealing with patients with multiple sclerosis (MS). This started as a project within the company 2010. Technical development started 2011. The system provides relevant information faster which makes it easier for the doctors to make right decisions faster. A central feature of the design is usability seen for instance in that the system is set up to avoid double entering of data, as some parts can be done by the system automatically. The system includes also some analytical services which might facilitate research and the possibility to compare individual patient data with non-personal data on patients stored in the system's data-base. During 2013, the firm scheduled to implement and test their technology at five major hospitals on their domestic market (four university hospital and a regional hospital). Subsequently the firm envisages to identify and exploit international markets.

*Case 2.*This firm has a history reaching more than 60 years back in time. It focuses on both treatment and research on diabetes. The project included in this study is an outcome of the results of forty years of research on diabetes. The project is about personalization of diabetes treatment, a system which allows for monitoring and taking into consideration all factors that influence blood sugar levels. By monitoring over time, these factors can be altered to allow for an individualized diabetes control scheme for each patient. The next development step for the system is a portable service, such as an app, which reduces the need for the patients to visit treatment centers. The aim is to be able to control diabetes better, making patients able to live more 'normal' lives and save a lot of the emergency procedures associated with lack of or failing diabetes control. A test version of the system is in operation. It is envisaged to diffuse the system, initially by getting acceptance from clinicians on the domestic market, and subsequently to exploit international markets.

*Case 3.*The firm was established in 2006 and works with software development for automated logistics solutions many times as a sub supplier to larger companies. The project studied here evolved around the development of intelligent transport box, a box for transporting organic samples to and from laboratories in an efficient, safe and monitored way. The product was not finished or ready for actual trials. The product is thought to increase efficiency at the laboratories, because of the level of automation that will enable safer transport of the samples. It is expected to mean that fewer of these samples are ruined during transport, whereby both money and time is saved for patient and laboratory alike.

*Case 4.*This case concerned a commercial project (i.e. on organisation not established as a firm) owned by a holding company in turn fully owned by a university. The project benefits also from close collaboration with a research firm. The firm owning the project was established in 2011. The idea is based on more than 10 years of research in this field. The firm

is transnational in the sense that its owners originate from two different countries. The research is mainly being done in one of the countries, while the management and commercial operations are based in the other. The innovation studied is an angiogenesis inhibitor, a drug that starves tumors by cutting off their blood supply. Expected benefits are a more efficient treatment and better patient satisfaction. Following initial studies, the drug is perceived as very promising, and appears to have positive effects.

*Case 5.*The firm, established in 2004, works with IT infrastructure and telemedicine. The firm has already introduced some products on their domestic market and is working on both developing further levels of telemedicine solutions. The firm considers however their home market to be too small. Instead the focus is to explore international markets with the products already implemented in their home country. The product portfolio ranges between products that the patient is able to use on her own to services where a unit, such as a bus, is taken to the patients in remote areas. There are also products enabling communication between physicians. There are more products and services in the pipeline that are further developments of the current services. The main idea is to get the patient a better and faster service, which is currently either denied her, or at best is very expensive. In this manner, the patient will either be in contact with health care personal over an IT solution, or basic health care services are taken to patients in mobile units, and the net result will be a better service at a cheaper price. The solutions are relevant in all countries where part of the population live in remote areas of the country.

*Case 6.*The firm was founded in 2006, initially focusing service provision in the life science industry. The firm's focus has moved towards getting a first successful product on the market. The innovation dealt with here concerns the development of a catheter with impregnated anti-microbial protection. The problem with existing catheter coatings is that they are fragile and short lived. The novelty of the catheter in question is that it uses an impregnated anti-microbial protection, based on impregnation of active components. This creates a drug depot and a transport route to the surface of the catheter allowing for a self-regenerative surface. This means that the catheter can be in place for a prolonged period of time, which in turn reduces the number of catheters that needs to be used. The solution renders also fewer infections.

6. Discussion

Five main barriers were identified by the firms. These are discussed in the following.

Encountering regulations

Case 1 that dealt with an IT solution handling patient data reported perceived challenges in relations to the specific regulations. In order to market the system on the domestic market, the firm had to interact with the national health authorities and the agency regulating management of personal data in order to be able to proof that their system would comply with the firm perceived as a very strict law. For case 4, concerning the development of an angiogenesis inhibitor, concerned the rules and regulations necessary to comply with in connection with test and trials. The firm perceived that the amount of regulations makes it difficult and expensive for a project to get to the latter stages of trials, and that this discourages a lot of potential successful projects from trying altogether. It was suggested that the rules could be softened without patient safety being at risk. Also in case 5, involving tele-medicine solutions, prevailed some viewpoints regarding regulations. Similar to case 1, this firm also perceived

data protection rules as a barrier. A particular product-specific issue concerned the use of the solutions in a cross-border setting, requiring patient data to cross national borders. Another legal challenge concerned whether the products offered should be considered as software technology or a medical device, as this decision determines what laws apply. The case reported also about legal uncertainty regarding less known markets.

Exploring and exploiting international markets

Many barriers identified by the firm studied in case 1 concerned their ambition to exploit international markets. The firm reported a need to gather information to secure that the right markets were targeted. The firm also reported a problem related to "national pride", i.e. a tendency other countries would prefer a solution developed by a domestic firm, rather than buying from a foreign firm. The firm in case 2 perceived it as hard to bring the innovation to market and to adapt the system to different health systems in the different countries. Also case 5 reported about challenges due to differences in regulations in different international markets.

Negotiating oligarchical markets

Case 1 reported about a technical challenge related to integrating the new system with existing technology supplied by incumbent firms. Although it is changing, what for this firm has been an oligarchical domestic market has in the past prevented entries of new suppliers of health-tech. A similar view was found also in case 3, which also reflects a concern regarding the chances as a small firm to compete with larger firms. The firm perceived as a barrier the tendency that larger firms "block out" smaller firms from the market.

Funding

The project in case 1 received funding from a national innovation agency. The process of getting the funding meant engaging in activities that in retrospect appears as side projects which were not central to the development of the innovation per se. After funding was secured focus instead turned to making the system work. The funding from the national innovation agency was perceived as a critical success factor for the newly started firm which did not have any other references. The fact that they received funding was communicated to the market as a way of legitimising the firm. One challenge reported by the firm in case 4 was to find a major investor that could finance the further development of the drug. It had been fairly easy to get access to smaller amounts of money, below 10.000€. There was some funding available in one of the countries available primarily to domestic firms. The fact that the firm is based in two countries excluded this opportunity for funding that would have been available if the firm would have been established as a completely domestic firm in that country. The firm had managed to get funding from the innovation support agencies in the other country. The firm reported, however, allocating funding of magnitudes between 50.000€ or 100.000€, perceived as necessary for the further development was much more difficult.

Interaction with public customers

The main challenges reported by the firm in case 2 concerned getting the product on the market, which was a matter determined by how the health care is financed. The way this is organized in their domestic country, the insurance companies are the main funding source, and patients and doctors will expect the insurance companies to pay for a service of the kind

provided by the firm. This means in turn that doctors have to be convinced of the relevance of the system first. This is potentially difficult because it means that doctors are not solely in charge of the diagnosis and treatment of the patient. For the firm it was perceived an advantage that they are part of a recognized organization with long experience in diabetes, which raises credibility amongst peers and make it more likely to be accepted by the doctors.
What was considered an important issue in case 3, was that the firm lacked understanding on how the public sector is organized and what perhaps could be labelled cultural aspects necessary to identify business opportunities; i.e. issues such as relational and political elements at work inside the health care organizations; how the decision making process works and who influences this process. Case 6 reported about an interesting work-around of problems potentially encountered on European markets. The firm had made the decision to focus on the US market, because of legal incentives imposed on health providers to deal with bacterial related illness and epidemics at hospitals. According to the firm, this is not the case in other countries. The perception was reported that in the USA, they generally think in socioeconomics and benefits on a more holistic and societal level when looking at acquiring innovative products. This strengthens the business case for products that can achieve those goals better than existing products.

Engaging in public procurement

It is noteworthy that the firms in case 1, case 2, case 4 and case 6 did not report any experience as a contract owner awarded through a public tender process. In case 3 the firm reported negative perceptions of public procurement, even if the firm, similar to those in case 1 and case 2, had no previous experiences as a contract owner. They had however experience as a member of a consortium. Getting involved with a consortium was also the strategy chosen for future engagements as a supplier to public agencies. The only firm reporting having experience from acting as a contractor in public procurement was the one included in case 5. They also stated that they have the necessary competences to participate in public procurement.

7. Conclusions

A preliminary analysis of the interviews reveals an array of problems and issues somewhat depending on the specific case, such as securing venture capital, IPR, uncertainty regarding regulations, how to adequately choose business model, uncertainty regarding foreign markets, issues on validation studies and finding relevant partners. Concerning the actual procurement process, most of the companies lacked sufficient knowledge on the process as defined in procurement law. Interviewees also reported that they lacked understanding of how decisions are made within public agencies, as well as a perceived lack of interaction possibilities with public agencies. Two tentative conclusions can be made: Most of the issues encountered were out of range from the domain of public procurement. Secondly, the empirical material provided no evidence supporting a claim that the procurement rules per se should prevent innovation.

These conclusions have implications for the general emphasis on involving SME’s in public procurement seen recently in policy making. It appears unlikely the public procurement of innovation policy will be able to negotiate the barriers to commercialisation these types of innovative firms encounter, but should probably be addressed by more general innovation policies.

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