VINNOVA

CAN PUBLIC PROCUREMENT SPUR INNOVATIONS IN HEALTH CARE?

24 SEPTEMBER 2009

INFORMED DECISIONS

COPENHAGEN ECONOMICS

COLOPHON

Authors: Karl Lundvall, Henrik Ballebye Okholm, Mats Marcusson, Svend T. Jespersen, Mikkel Egede Birkeland.

Client: VINNOVA

Date: 24 September 2009

Contact: SANKT ANNÆ PLADS 13, 2nd FLOOR | DK-1250 COPENHAGEN
PHONE: +45 7027 0740 | FAX: +45 7027 0741
WWW.COPENHAGENECONOMICS.COM

TABLE OF CONTENTS

PREFACE

The purpose of this report is to evaluate the potential of public procurement of innovation in health care services. The report is a part of the background material for the conference Public Procurement of Innovation – A Driver for Future Health in Europe, organised by VINNOVA in October 2009.

In the report, we introduce the concept of public procurement of innovation, and outline the context in which innovations in life science are carried out. This includes a description of the innovation system and the sectors delivering innovations to health care, namely the medical device and pharmaceutical industries.

The central part of the report comprises examples of public procurement of innovations in health care. To date, only a few examples of public procurement for innovation exist, so we analyse five cases on procurements that have been carried out or are currently under way. Furthermore, we describe the workings of organisations in the UK and in the US where they work dedicatedly with innovations in health care through the use of public procurement.

The report is written by Copenhagen Economics. Our team has been supported by an expert group with in depth knowledge about both the sector and public procurement. This group of experts includes Professor Charles Edquist, Dr Jane Clemensen and Dr Jens Laage-Hellman. The expert group has been instrumental in discussions about the content of the study, and its members have contributed to both the report and made comments during the drafting process.

Stockholm, 24 September 2009

Henrik Ballebye Okholm
Partner, Ph.D.

EXECUTIVE SUMMARY

There can be more innovations in health care if governments promise to buy them. Such public procurement of innovation can spur innovation in health care which benefits users and lowers treatment costs. It can also be used as a tool to increase overall innovation activity in the EU.

Increased innovation activity is a central part of the Lisbon strategy, which aims to make EU the most dynamic and competitive knowledge-based economy in the world. Innovations are a key ingredient in achieving sustainable growth and full employment.

But procurement of innovations is not easy. Public purchasers need be both competent and very well informed about needs, technical possibilities and market conditions. Public tenders must be set in a manner that attracts the most skilled innovators to come forward and deliver solutions to the health needs of tomorrow. This requires a strong business case and a willingness to share the risk associated with conducting R&D with public procurers.

Examples of public procurements of innovations are, indeed, few in the world. Nevertheless, those that exist tell us an inspiring story. Our five original case studies from Europe and the US provide a clear message to policy makers. We conclude that the public sector has an important role as a partner to commercial interests in achieving the innovations in health care that otherwise would not materialise.

The key characteristics of the case studies we have conducted are summarised below.

Five case studies of Public Procurement of Innovation

Case	Innovation	Benefits for patients
1: Smallpox vaccine for the US	Third generation vaccine	Includes certain patient categories that were previously excluded
2: Hearing aids in the UK	Distribution of digital hearing aids	Better functionality
3: Blood bags	DEHP free bags	Less negative side-effects
4: Design bugs out	Cleanable furniture	Less risk for contamination
5: Pneumococcal vaccine	Vaccine for children in poor countries	Decreased child mortality

Source: Copenhagen Economics

We study two cases from the pharmaceutical industry which regard vaccines. The first case is the US National Institutes of Health's procurement of a third generation smallpox vaccine. The need for a new vaccine arose from the ineffectiveness of the earlier generations from which 25 percent of the population were expected to encounter complications. The second case is the procurement of pneumococcal vaccine. Diseases such as pneumonia, meningitis and febrile bacteraemia are the cause of 1.6 million deaths annually, mainly children. The GAVI Alliance has, in cooperation with UNICEF, initiated a certain type of procurement mechanism that may inspire future initiatives of procurement of innovations.

We study three cases from the medical devices industries. One case concerns blood bags which do not contain DEHP - a type of phthalate that is classified as a reproduction toxic. Another case is about digital hearing aids in the UK which now have superior qualities com-

pared to earlier devices. The final case concerns new designs of hospital furniture in the UK. The new furniture greatly reduces the risk of the spread of infections in hospitals.

In all these cases, users and entrepreneurs worked and interacted closely. We conclude that close collaboration is a critical factor in achieving success.

In both the UK and the US, there is an integrated process of identification of technological needs, management of the innovation process and diffusion of the new technologies to the users. There is also competition between different suppliers of new technological solutions, and finally, extensive collaboration between the suppliers of new innovative solutions and the health care institutions which need them.

A successful strategy of public procurement of innovation has to comply with existing regulations. This can be done in many ways. Recently, the European Commission has described the so-called "pre-commercial procurement" as a useful approach for a government to buy innovations. Although the regulatory framework poses certain restrictions to the way public procurement of innovation is carried out, this does constitute a major obstacle. In fact, the underlying principles of both the procurement and State aid rules may even stimulate governments to design appropriate strategies for procurement of innovation.

Therefore, our overall conclusion is that public procurement can spur innovation in health care.

Recommendations

Our overall recommendation is that policy makers should further explore ways to increase the use of public procurement of innovation in health care. The experience so far shows that this can result in better products, better quality of health services and ultimately higher growth and more employment.

Specifically, we recommend that policymakers consider the following.

1. **A strong and competent public procurer**
   A well-designed organisational public structure is paramount in running successful public procurement of innovation. In particular, it is important to design organisations with an integrated process for identification of needs, a process for the formulation of specifications as well as the ability to handle the procurement process.

2. **Identifying true needs are critical**
   Any initiative of procuring innovations has to start from the users and their needs. This process should be organised such that all ideas are gathered from clinical staff, researchers, users and entrepreneurs. By organising this process systematically, the procurer can ensure that the most promising prospective innovation paths are taken forward.

3. **Tender specifications that give suppliers sufficient flexibility**
   Specification of procurement of innovation is vastly important. The specification should be focused yet not overly demanding or restrictive. It is important that it includes precise statements on the public preferences regarding the qualities of the innovation. Yet, these statements must not unduly narrow the innovation arena for the suppliers.

4. **Preserve competition**
   The innovation tenders must be characterised by competition between suppliers. This can be achieved by offering the right incentives, such as access to a new and promising market. The public procurer may allow the suppliers to retain some of the IPR in order to make a public procurement of innovation attractive for the most innovative companies. There are a range of possible IPR arrangements concerning the division of benefits between the procurer and the company. However, if the public procurer pays for the development cost via a procurement of innovation, IPR should be owned by the companies only if competition in the market for the products can be ensured in the future.

Chapter 1 | PUBLIC PROCUREMENT OF INNOVATION

Public procurement of innovation is one tool available to the public sector to improve innovative activity in Europe. Increased innovation is a central part of the Lisbon strategy to make EU the most dynamic and competitive knowledge-based economy in the world.

When a public organisation places an order for a product that does not exist at the time ordered, it is public procurement of innovation. This means that the public sector actively demands innovative products, which can contribute to increasing business' investments in research and innovation within life science industries.[1]

According this definition, public procurement of innovation occurs when a public organisation places an order for a product that does not currently exist, but can be developed within a reasonable period of time. This means that innovation activity is needed before delivery can take place.[2] Innovations are new creations of economic significance carried out largely by firms. The innovation can be a product or a process. Product innovations are new or improved products, which can be either goods or services. Examples are blood bags made from new materials or improved vaccines currently unavailable on the market. Process innovations are new or improved technological or organisational ways to produce goods or services. One example is that of a new organisation that can provide users with hearing aids.[3]

In this report, we give five examples of public procurement of innovation. These five examples illustrate various types of health care services that can be improved by using public procurement of innovation as a tool, cf. Table 1.1.

Table 1.1 Five examples of public procurement of innovation in life science

Case	Innovation
Case 1: New smallpox vaccine for the US	Improved vaccine against smallpox with a reduced risk of complications from the vaccine
Case 2: Digital hearing aids in UK	Organisational capacity to diffuse digital hearing aids in large scale, as well as technical improvement to the hearing aid
Case 3: New blood bags	New blood bags without DEHP. DEHP is classified as a reproduction toxic.
Case 4: Health care acquired infections – Design bugs out	New cleanable furniture for hospitals with the aim of reducing the risk for patients of a health care acquired infection.
Case 5: Pneumococcal vaccine in poor countries	Vaccine against pneumococcal diseases at affordable price, suitable for distribution in the developing countries.

Source: Copenhagen Economics

In this chapter, we provide the framework for addressing public procurement of innovation. Public procurement is part of a so-called system of innovation which generates the new products and processes.[4] In this system, the public sector can support innovation both through regulation and via the actual procurements.

[1] Cf. European Communities (2006)
[2] Our definition is based on Edquist (2009)
[3] Cf. Edquist (2004)
[4] See for example OECD (2009) for references of the systems of innovations theory.

1.1. SYSTEMS OF INNOVATIONS

Innovations have to be understood as systems involving the interplay of many factors. The system of innovations approach aims at providing such an understanding. According to this approach, innovation processes are regarded as results of interactions between organisations.

Organisations and institutions are important components of systems of innovation. A more dynamic view is to concentrate on the activities in innovation systems, i.e. what happens in the systems. Among these activities, interactions between organisations are central.[5]

The various *organisations* in the system of innovation play different roles at the various steps in the innovation process. Typically, universities and research institutes play important roles in the initial idea-step, while suppliers are more important in the steps involving product development and production start-up, where inputs such as intermediate goods and services are required.

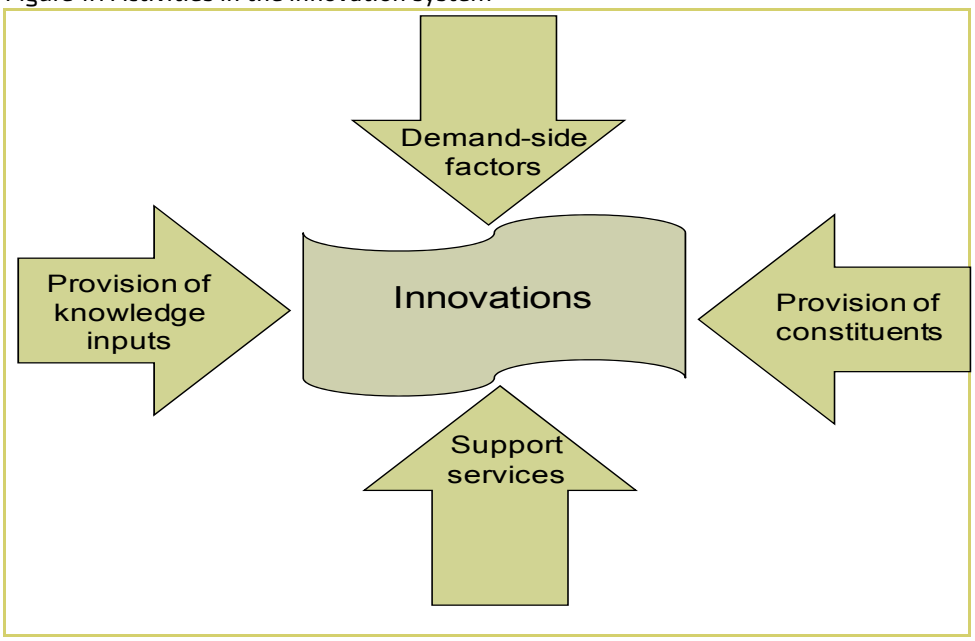
The behaviour of the innovating firm and the other organisations are shaped by *institutions* that constitute constrains or incentives for innovation. The relevant institutions may include different kinds of laws, other regulations, cultural norms, social rules and technical standards. Institutions constitute the rules of the game.

The *interaction* between organisations are necessary for the innovating firm, in order to gain, develop or exchange the information, knowledge or resources which are necessary in the innovation process. Interaction with potential users tends to take place primarily in the early idea-generation or concept-development stage. During the detailed design phase there may be less need for user involvement.

The extent to which innovations are developed and diffused within the systems is determined by the *activities* that take place. These activities can be structured according to four categories, c.f. Figure 1.1:

[5] Cf. Edquist (2009).

Figure 1.1 Activities in the innovation system



Source: Copenhagen Economics on the basis of Edquist (2009)

The first is the provision of knowledge inputs, which includes R&D as well as education and training. Therefore, this is the creation of the new knowledge required to produce the new innovative product. Provision of knowledge input from R&D at universities and clinics through funding are key elements of the national health care systems. Research is carried out within the hospitals both in the form of basic research and clinical research.[6] Competence building of doctors and nurses takes place at the universities through basic education and post graduate education. A large share of the labour force in the life science industry has another educational background. More and more of post graduate students at the medical faculties have been educated at university departments in natural science.

Demand-side activities are those which aim to ensure well functioning markets for the products. This could be clarification of the market size for the new innovative product where the procurer signals to the market the need for the product – such as the demand for cleanable furniture in hospitals. The increasing demand for health care services result in a need for new innovative solutions. But the structure of the demand for services in the EU countries impacts upon the way a system for public procurement of innovation should be considered.

Provision of constituents for systems of innovation encompasses activities regarding the rules and regulations determining the behaviour of the innovative firms. This regards IPR laws, tax laws, environment and safety regulations, R&D investment routines, etc. which impact the innovation process by providing incentives and constituting obstacles to innovation. The

[6] Cf. Arvidsson et al. (2007).

medical devices and pharmaceutical industries are major suppliers of products for the health care system. But the constituents differ between the two industries. This means that public procurement of innovation has a large potential in the medical devices sector whereas there is limited scope for public procurement of innovation regarding drugs.

Finally, support services for innovating firms regard elements such as financing of innovation processes and provision of consultancy services as being of relevance to the innovating firms. The health care system has over time become more active in support services for innovating firms. A good example of this involvement is the Center for Integration of Medicine and Innovative Technology (CIMIT) in the US. This is a consortium of Boston teaching hospitals and engineering schools with the purpose of fostering interdisciplinary collaboration among world-class experts in medicine, science and engineering, together with industry and government, to rapidly improve patient care. One aim of CIMIT is to provide access to funding for early-stage innovations with high-risk.

1.2. THE ROLE OF THE PUBLIC SECTOR

The public sector has two roles in innovation activities. The public sector acts as a procurer and as a regulator. As procurer, the government can support markets for innovative products directly through a procurement process. As regulator, the government can support markets for innovative products indirectly through different measures.

By articulating public demand as a procurer, the government can demand a product in order to accelerate the market introduction for the product or stimulate the development of a market by formulating new needs for which there are no existing solutions on the market.

As a regulator, the public sector influences the innovation activities in at least three ways.

First, the public sector can provide direct support for private demand through subsidies and enable private organisations to purchase innovative products or technologies. In health care, for example, the reimbursement system has an important impact on demand for various products.

Second, the public sector can promote the introduction of new innovative products or technologies by different kinds of awareness and information campaigns and educational support. For instance, by diffusing health-related information, the authorities can encourage people to buy new products with health-improving properties, such as functional food and vaccination services.

Third, the public sector can impact on the behaviour of the organisations and the efficiency of the innovation systems by changing the incentives for innovation.[7] For example, in health

[7] See Edquist (2009) for a more detailed description.

care many products such as drugs and medical devices are strictly regulated for safety reasons. These rules constitute important restrictions for product development, which innovators have to take into account.

The most important role of the public sector, for our purposes, is the way it influences innovation through procurement. The use of public procurement as an instrument for promoting innovation has decreased in most countries even though the interest for the innovation system approach and demand-side innovation policies have increased from policy makers since the 1990s. For instance, public procurement of innovation was used much more in Sweden in the period from mid 1900s to the 1980s, than after the 1990s.

An important explanation for this development is the introduction of stricter public procurement rules. These rules have, in general, made close collaboration between suppliers and public buyers more difficult. Such close collaboration characterises many successful examples of public procurement of innovation in the past. Recently, with the introductions of new possibilities for enhanced communication between public procurers and entrepreneurs, including "competitive dialogues", the pendulum appears to be slowly swinging back.

The potential for innovations through public procurement is reflected by the fact that public procurement accounts for a large share of demand in the EU. The government sector in the EU is, through its role as a procurer, a major customer for firms in many industries such as health care, construction, defence, energy and transport.[8]

However, since the 1980s the lion's share of public procurement is not directed towards procurement of innovation, but is characterized rather as the purchasing of existing products and services on the shelf. Transforming at least parts of this type of procurement into procurement of innovation could lead to more innovative products that better meet needs in health care. In health care, the rapid development of new knowledge creates many opportunities for innovations, and here the public sector has an important role to play as a demanding customer and a partner to innovating firms. Public procurement of innovation thus offers an opportunity for the public sector to actively support innovation and help transferring research-based inventions as well as identified user needs into commercial products to the benefit of society and individual patients.

1.3. Legal aspects of public procurement of innovation

A successful strategy of public procurement of innovation must comply with the regulations. Although the existing regulation poses certain restrictions on the scope and behaviour of public procurers in relation to procurement of innovation, they do not constitute a major obstacle. In fact, the underlying principles of both the procurement and state aid rules may

[8] Cf. Edquist (2009)

even stimulate governments to design more appropriate strategies for procurement of innovation and thereby better achieve the warranted goals.

In order to fulfil the legal requirements, the design of the procurement of innovation should:

- Comply with the procurement rules. The most appropriate way to do this is through the R&D exemption provided in the procurement rules in which the results are to be shared with the public and the industry.
- Not constitute state aid. This necessitates that contractual terms with manufacturers are consistent with those prevailing in the market.

Recently, the Commission identified so-called "pre-commercial procurement" as a useful concept in order to drive innovation in Europe and to ensure sustainable, high quality public services. The approach is consistent with the path we identified above.

In the remainder of this section, we will firstly describe the basics of the legal environment in which public procurement of innovation has to be contextualised, and go on to refer to the Commission's initiative of pre-commercial procurement.

The existing regulatory framework

The existing regulatory framework in the EU poses certain restrictions on governments when conducting procurement of innovation. The principal legal frameworks with relevance for procurement of innovation are the following:

- The Procurement Directives (2004/17/EC and 2004/18/EC)
- State aid rules (Articles 87 and 88 of the Treaty)

Most public procurement in the EU is subject to Community and international rules. The main principles of the rules are that public procurers must follow transparent and open procedures ensuring fair conditions of competition for suppliers. The equal opportunities principle is motivated by the view that market competition should be encouraged to meet public demands.

There is an important exception included in Article 16f in the Procurement Directives.[9] The Article exempts situations when a public procurer wants to buy an R&D activity and is committed to share the entirety of the output of these contracts with the public. This simplifies life for public bodies which strive to implement procurement of innovation and also introduce the important principle that the delivery must be shared with every interested party. In this way, innovations may reach the market more rapidly, since the public procurers take on some of the market risk.

[9] The article reads: "research and development services other than those where the benefits accrue exclusively to the contracting authority for use in the conduct of its own affairs, on condition that the service provided is wholly remunerated by the contracting authority." (Art 16f of 2004/18/EC)

However, any public contract that is exempted under 16f must also comply with the State aid rules. These rules outlaw aid that distorts competition between companies and affect trade between Member States. Unlawful state aid must, in principle, be repaid by the beneficiaries.

The objective of the State aid rules is to ensure fair competition and a single common market. Favoured treatment by governments to some businesses could have several detrimental effects, such as harming competitors, potentially distorting normal competitive processes in the market and possibly restricting the competitiveness of the Community in the whole long-term.

State aid can take many forms and includes any favourable treatment that deviates from that of normal market conduct.[10] The guiding principle is therefore that any favourable treatment that is alien to normal market transaction may constitute unlawful State aid.

Hence, public procurement of innovation cannot be implemented in any way that distorts competition. If a contract is awarded to a certain company, the conditions cannot deviate from what one would expect in a normal market agreement. In other words, the public procurer may not pay more, nor give any preferential treatment in future procurements to the companies that have been awarded a contract regarding innovation.

An approach to procure R&D services – pre-commercial procurement

Public procurement of innovation may very well be designed in accordance with existing rules. One way to do this is to follow the proposal set forth by the Commission in the so-called pre-commercial procurement model. The key is to design the procurement in such a way that it is exempted under Article 16f and does not constitute state aid. Competition is preserved through allowing a number of firms to participate in the pre-commercial phases.

The model was presented in a Communication in 2007 and is briefly summarized below.[11]

The concept of pre-commercial procurement should be understood as an approach to procuring R&D services which are exempted under the procurement rules and does not constitute State aid. In doing this, the Commission specifies that the approach is guided by the following three principles.

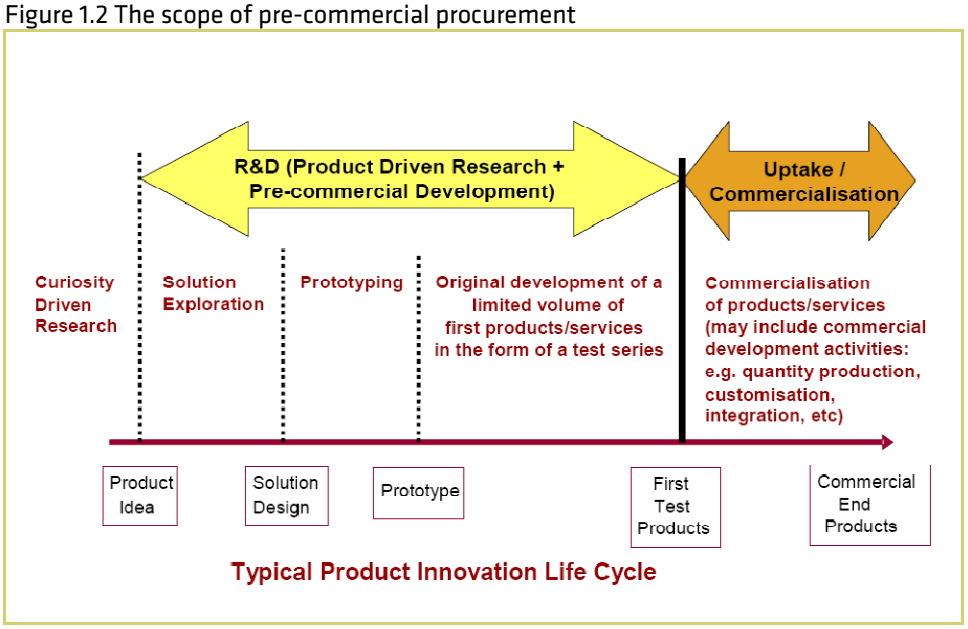
(1) The scope is only R&D services

A public body purchases activities such as solution exploration, design and prototyping. These steps in the life-cycle of a product represent the early stages up to development of a test series.

[10] Article 87(1) reads that "*any aid granted by a Member State or through State resources in any form whatsoever*".
[11] European Commission (2007a and 2007b)

What normally follows this stage is beyond the scope of the concept of pre-commercial procurement, i.e. commercial development activities such as quantity production, cf. Figure 1.2

Figure 1.2 The scope of pre-commercial procurement



Source: European Commission (2007a), Figure 1, p 3

(2) The application of risk-benefit sharing

The public purchaser must not reserve the R&D results exclusively for the purchaser's own use. Instead, the public procurer and the industry share risks and benefits of the R&D needed to develop new and innovative solutions. In order to comply with Article 16f, the risk-benefit sharing should be conducted in a way that satisfies three crucial principles.

First, risks and benefits should be shared in such a way that both parties (i.e. the procurer and the company or companies with the pre-commercial procurement contract) benefit from actively promoting wide commercialization and take-up of the newly developed solution. Sometimes it can be expected that such benefits include certain IPRs that are owned by the company. In that case, the company has to compensate the procurer at market price. This is to ensure that any company under these types of contracts is not given any form of unfair advantage in possible future procurements which would discriminate against any other potential future supplier.

Second, competition should be preserved by having a number of companies participating in the pre-commercial procurement. This will also preserve competition at later stages. In an example set up in the Communication, up to five companies could be awarded a pre-commercial contract for solution exploration, up to three companies for prototyping and at least two for the development of a test series, cf. Figure 1.2.

Third, the separation between the R&D phase and commercialization is clear. Pre-commercialization is a preparation exercise which offloads some of the burden of risk that private companies normally take. It can be viewed as an order from a public procurer to buy a solution to a specific problem, with the market subsequently deciding what extent and form commercialization should take.

(3) A competitive procurement designed to exclude State aid

The challenge for the public procurer is to organise both the risk-benefit division and the entire procurement process in such a way that ensures efficient competition, transparency, openness, fairness and pricing under market conditions. By successfully committing to these principles, the public purchaser may identify the best solutions the market can offer and also ensure that the arrangement comply with State aid rules.

1.4. PREREQUISITES FOR PUBLIC PROCUREMENT OF INNOVATION

Consider the case of an engineering firm that is close to developing a complex energy saving system, which halves the energy consumption in newly built houses. The production of the energy saving system is associated with high fixed costs which can only be covered at a very high production level. Unfortunately, the demand for this kind of new housing is not sufficient to cover the costs and render the production profitable. The firm will therefore not produce the energy saving system. If, however, the policy makers have decided that energy saving is a prioritized policy goal, they may consider supporting the production of the energy saving system. In a similar way, by subsidizing the use of expensive medical equipment that effectively cures a certain disease, firms can be stimulated to develop, produce and market such a product.

Public procurement can play a part when private firms do not supply the required products for some reason. Although these products fulfil the societal needs demanded by the health care system, firms can be unwilling to carry out the innovation because of excessively high risks, for example, or significant investment needs or lack of knowledge about the demand. Public procurement of innovation can be used as a tool when this can help meet the need in a reasonably short period of time such that it leads to a solution of the problem faster than would be the case without intervention from the public procurer.

There are a number of prerequisites that need to be in place to achieve a successful procurement of innovation. The public procurer should have the:

- ability to identify which need can be met through procurement of innovation
- technical skills to specify the innovation
- ability to organise interactive learning between partners
- ability to provide incentives to vendors

Firstly, the public procurer needs to be able to identify what kind of innovation is required, but does not yet exist, in order to satisfy a particular societal need. The assessment must also take into consideration whether it is possible to produce the innovation within a relatively short period of time and at a reasonable cost. This could be achieved by involving users in the process of indentifying subjects for public procurement of innovations

Secondly, the public procurer needs to be able to formulate the need in terms which can be translated into a procurement process leading to the development of an innovation. Public procurers need to have the technical competence to specify the procurement. The technical competence may be available within the buyer organisation, particularly within health care, as noted above. This makes the procurement easier. However, the internal competence may not be enough. Therefore, it is often necessary to access knowledge from outside one's own organisation. This can be achieved through meeting arenas, researcher networks, focus groups and through other means in order to access the necessary technical competences.

Lack of necessary technological competences on the buyer's behalf can be compensated to some extent if there are structures in place which allow for interactive learning for the buyer and vendor. Without these possibilities, an insufficient technological buyer competence can cause the procurement process to be lengthy or fail entirely.[12]

Thirdly, the procurement itself requires that the public procurer possesses the ability required to assess the tenders and manage the contract which is drawn up between the buyer and the vendor.

Fourthly, the public procurer should provide incentives for vendors by ensuring stable demand and possibilities to further sell the innovative product on other markets. Expectations of a high demand make it more likely that investments will be profitable. Incentives for vendors will ensure higher investments in R&D from the companies as well as competition between several vendors.

The vendors must possess or have access to the necessary knowledge and R&D resources to produce the innovation. Procurement is often made in terms of which functions of the product or system are required in order to satisfy a particular need or to solve societal problems. This would include specific health problems in the population. The task of specifying the product's technical properties or design is therefore left to the producer, who often is more technologically competent than the buyer.

[12] Cf. Edquist et al. (2000)

Two cases of public procurement of innovation

We illustrate the points above using two case studies. Neither of these cases is from the life sciences, but the examples allow us to draw a number of conclusions which are relevant to public procurement on innovation in health care.

The first of these cases, X2000, refers to the procurement of a high-speed train in Sweden. This illustrates how the lack of technological competence of the buyer caused delays to the procurement. This process could have been shortened if there had been a structure or mechanism in place for interactive learning between the public procurer and vendor. Lack of alternative markets may also have been a factor slowing down the process on the vendor side.

Box 1.1 X2000 – New high speed trains in Sweden

In 1964, the research and development department at SJ (Swedish State Railways) started considering the benefits of a high speed train. The reason for this was increased competition from both the airline industry and the use of private cars. There was also an increased public demand for high speed transport. This led to the procurement of a product called X2000.

The X2000 procurement process was cumbersome and slow. All in all, the procurement process lasted for four years. However, it should be noted that railway travel time between Swedish cities was reduced after the introduction of the X2000.

The finished product, X2000, consisted of a locomotive and six cars. An Italian high-speed train which was developed more quickly and put on the market before the X2000 had a more flexible design. It has an engine in each car and a train set that can consist of a variable number of cars.

A co-operative research process was started by SJ and ASEA (a Swedish railway equipment manufacturer). SJ had one fundamental requirement in the procurement process, which was that the supplier could deliver, construct and guarantee the reliability of an entire train system. This so called system competence was developed by ASEA during the cooperation with SJ and made it easier for ASEA to win the procurement process. However, ASEA's ability to produce a high-speed train was limited since SJ specified that the X2000 should consist of a locomotive and cars. In the first procurement process, nearly all functional requirements were changed. The consequence was that no supplier could fulfil SJ's requirements, possibly because these were unrealistic. This was not solved until a few years later when SJ sent out a supplementary request with a second invitation to tenders.

Source: Edquist et al. (2000) and Copenhagen Economics

There are two lessons to be learned from this case which also have relevance to procurement in life science. The first is that procurers should carefully consider how the specification of the product is devised. If the suppliers have significant technical knowledge about the products, it may be an advantage to specify the performance of a product rather than the actual design. This lesson is relevant to health care because the companies in life science often have highly skilled researchers who have specific knowledge about the best way to provide the innovation.

The second lesson of relevance is the fact that the Italian train existed well before the X2000 was developed. If the procurers had conducted a "horizontal scanning" (i.e. searched for a high-speed train in other markets) they could have considered buying the Italian train instead. This is also the reason why the National Innovation Centre under the NHS performs horizontal scanning. If more countries in the EU choose to work actively with procurement of innovation, horizontal scanning will be even more significant.

The second case concerns the procurement of energy efficient refrigerators (cf. Box 1.2). We can draw two lessons from this case. The first lesson derives from the way the specifications were drafted. The specifications were made in terms of functional requirements, leaving the design of the refrigerator to the producer. This was successful because in this case, the producers had better technical knowledge than the procurer.

The second lesson to be learned is that one should provide incentives to vendors. In this case, the procurer provided incentives which made firms willing to devote resources to participate in the procurement even though there was a risk that they would not win the contract. Further, the buyer created a market by their commitment to purchase a minimum amount from the winning vendor.

Similarly in health care, incentives are an important part of convincing companies to engage in a public procurement of innovation. For instance, in Case 4 about new cleanable furniture in the UK, the access to a large market plays a key role in creating incentives for the vendors.

Box 1.2 Energy efficient refrigerators

In the early 1990s, The Swedish National Board for Industrial and Technical Development, (NUTEK) commenced a search aiming at identifying energy saving potentials and found that refrigerators and freezers were the most energy consuming household devices, excluding heating and hot water devices. NUTEK decided to utilize this potential by taking the initiative of a public procurement of energy efficient refrigerators.

After identifying the savings potential, NUTEK formed and led a purchaser group constituting an association of housing cooperatives, an insurance and real estate company, the Swedish National Board for Consumer Policies and the Swedish National Energy Administration. The purchaser group attended conferences, held seminars and visited factories in order to be able to set up the specifications for the product in the procurement.

Two bids with different energy efficiency met the standards stated in the procurement call. The winning bid included a proposed model of a refrigerator which met specifications such as dimensions, noise level and warranties. At the same time, the model was at least 50 percent more energy efficient than existing models. The purchasing group guaranteed a purchase of at least 500 units from the winning manufacturer. Furthermore, in order to increase the incentive for manufacturers to participate in the procurement, even proposals which were not selected but still met the criteria were awarded a prize of approximately EUR 10 000.

Source: Ecomotion Report (1995), Energimyndigheten (2004) and Copenhagen Economics

Chapter 2 INNOVATION IN HEALTH CARE

There is an increasing demand for health care services. This is both due to demography, which results in an aging population and a more general demand in the population for improved health services. Innovations in health care services result both in benefits to the patients in the form of a more efficient treatment and reduce cost of the treatment. Hence, to support innovative activities in health care is a crucial step towards improving the services, and public procurement of innovation can be one tool to reach that goal.

There may be different obstacles to the efficient use of procurement of innovation in the two dominant financing models in EU Member States – the tax based financing model and the social security based financing model. In tax based systems, where there is no tradition for splitting purchaser and provider functions, the institutional framework must be established and competences must be built up to be able to identify needs and procurements processes. In social security contribution based financing, the use of public procurement of innovation as a tool may pose a challenge, if existing health insurance funds are passive producers and do not have a tradition of using purchasing as a proactive tool. Hence, the challenge in introducing public procurement of innovation is likely to differ between Member States.

The medical devices and pharmaceutical industries are major suppliers of products for the health care system. There are fundamental differences between the industries both regarding products, regulatory framework and innovation process. Jointly, the differences affect the potential for public procurement of innovation. We conclude that public procurement of innovation has a large potential in the medical devices sector. In contrast, we conclude that the scope for public procurement of innovation regarding drugs is limited to incremental innovation, i.e. improvements to existing products. This is because markets for individual products in most cases are very large and it is unlikely that a national public procurer could mobilise sufficient funds needed to procure entirely new drugs.

The essential elements in public procurement of innovation in the health sector are the identification the need, the creation of a market for the innovation, the drafting of the specifications and the co-operation between organisations in the innovation process. Hence, these are the elements to focus on when supporting innovation through public procurement.

2.1. BENEFITS FOR PATIENTS

The patients demand immediate and efficient treatment by the health care services. A high level of service is expected by patients accustomed to high standards of living. Patients will be increasingly more knowledgeable, wishing to influence aspects of treatment - “optimising their own health project”.

The patients’ need for optimal healthcare tailored to the individual constitute the driver for the innovations in life science. These needs are translated into effective demands by the health care system often in collaboration with the industry. Another key driver for innova-

tion in life science is to reduce cost for treatments and health care material and improve resource allocation within hospitals.

New, innovative treatment can contribute to higher level of services or reduce the cost of the treatment. These improvements imply direct and indirect benefits for patients.

The direct benefits for patients arise when new products, services or methods result in safer diagnostics, more efficient products and optimised courses of treatment. Patients benefit *indirectly* when the innovation implies that the treatment can be done more efficiently. This can give rise to a better allocation of resources within the health care system. Indirect benefits from increased efficiency also include lower cost of the health services.

To illustrate the patients' benefits we use an example from Denmark, the treatment of diabetic foot ulcers. The innovation in this example is to treat the patients in their homes, using a tele-medical setup. Although the example is not a case of public procurement of innovation, the example can serve to illustrate the patient benefits of an innovation.

In the case of diabetic foot ulcers the patients benefit *directly* from these improvements through an improved quality of life. The patients did not have to go to the hospital twice a week. This made treatment easier for patients since each visit took a full day. Sitting in one's best chair with one's wife by your side makes the meeting with the expert safer and non-stressful. In addition, the healing of the ulcer improved dramatically and the new approach reduced amputations.

The patients with diabetic foot ulcers benefit *indirectly* because of less use of expert resources and less absence from work. In Denmark, it is estimated that 500 – 700 people with diabetes will undergo major amputations each year and that this could be reduced by optimal treatment of diabetic foot ulcers. Each year every time an amputation is delayed, EUR 75 000 to 150 000 is saved.[13]

There are a vast number of studies which have tried to estimate the benefits from medical research, investments in health care and other improvements in health care. On a more general level, it has been estimated that the returns from health expenditures exceed costs with a factor of 0.5-1.0.[14]

[13] Cf. Danish Diabetes Association.
[14] Cf. Luce et al. (2006)

Box 2.1 Innovative treatment of diabetic foot ulcers

Diabetic foot ulcers remain a serious threat to patients, potentially leading to amputation and diminished quality of life. In all presenting forms, a diabetic foot ulcer will lead to a long-term course of treatment including frequent visits to health care professionals. This is very demanding to the patient in terms of time and effort and is a very costly form of treatment.

The innovation in this case was to use technology to virtually move experts from the hospital to the patients' home, offering a viable alternative to a visit to the out-patient clinic while at the same time sustaining satisfaction and security for patients, visiting nurses and experts at the hospital. This ambition required successful implementation of video consultations.

The project was carried out in close collaboration between researchers within health science, computer science, and engineering, the industry, a hospital, homecare and all the users. The involvement from all sectors was a key to success.

The project was divided into three phases:

- A specification phase, the purpose was to explore alternative ways of carrying out the treatment. Here it was decided to use technical equipment to make a tele-medical set-up.
- An experimental phase, a number of tests were carried out. The conclusion was to use video phones, an everyday technology.
- An implementation phase, the experts were fully satisfied with the video phone consultation.

There are three lessons learned from this example:

- The very strong and historical culture among clinicians is typically a serious barrier for implementation of new products and concepts. The participants were hesitant and negative in the beginning of the project.
- The payment for healthcare service through Diagnose Related Group (DRG) may be a barrier. Telemedicine is a new group of services which has not a DRG yet, which means that there may be no incentives for using telemedicine.
- Only one company in Denmark can deliver the product. This means that there is no competition on the market and that the supply of the service depends on only company. The innovation process should make sure that more companies are able to supply the product.

Note: The project was carried out in cooperation between Department of Nursing Science and Department of Computer Science, University of Aarhus, Medical Department, University Hospital of Aarhus, visiting nurses, a general practitioner, and the two companies Systematic Software Engineering and Dansk Telemedicin.

Source: Clemensen (2006)

2.2. DEMAND FOR HEALTH CARE SERVICES

Public procurement of innovation may help governments meet the increasing demand for health care services and reduce costs by developing more advanced and efficient services. But, as we argue in this section, the potential of procurement of innovation cannot be exploited if the tool does not "fit in" to the current financing models that are applied in EU Member States.

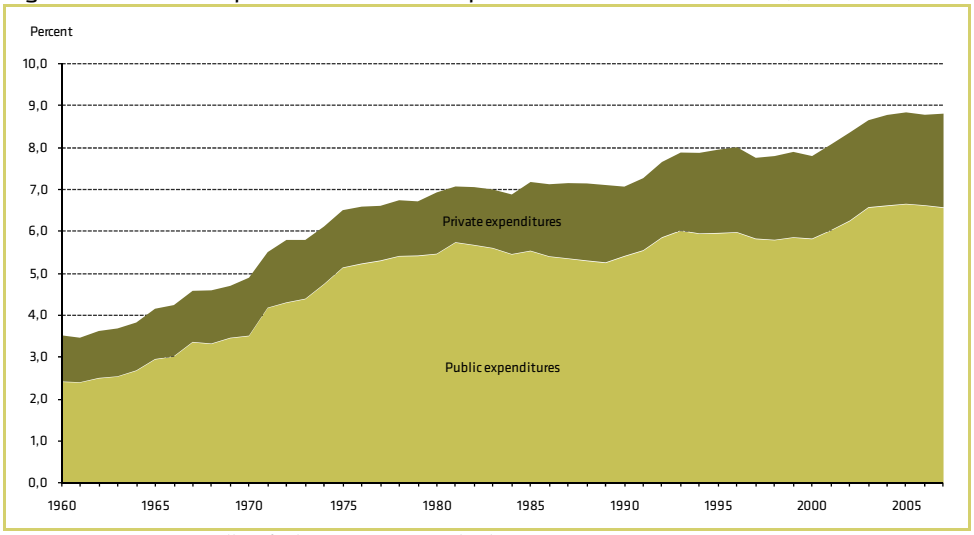
We show in this section that there might be different obstacles to the efficient use of procurement of innovation in the two dominant financing models in EU Member States – the tax based financing model and the social security based financing model. In tax based systems where there is no tradition of splitting purchaser and provider functions the institutional framework must be established and competences must be formed in order to identify needs and process procurements with partners. However, using procurement of innovation may be a rewarding exercise in tax based systems where there is central collection and planning because benefits of the procurement of innovation can be achieved on a larger scale throughout the national or regional context.

In social security contribution based financing models where purchaser and provider functions are typically separated it would be a natural step to introduce public procurement of innovation as a strategic tool. However, here the use of the tool may also provide a challenge if existing health insurance funds are passive producers and have no tradition for using purchasing as a proactive tool. In a situation with competition between health insurance funds, the funds may be risk averse and more focused on short term advantages. A clear incentive for long term focused procurement of innovation may be lacking.

Governments face increasing costs but are reluctant to raise taxes

It is a general trend across the European Union that Member States are faced with increases in health care costs as a result of increasing demands. From the beginning of 1990s where costs accounted for 7% of GDP, costs have now increased with 25% to 8.8% of GDP.

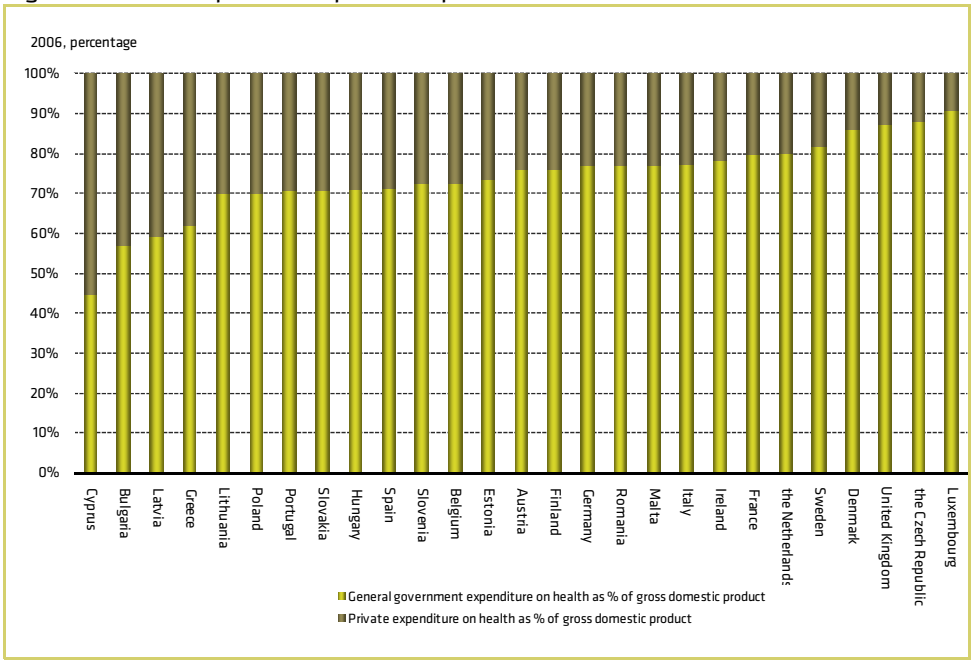
Figure 2.1 Public and private health care expenditures in 19 EU countries, % of GDP



Note: 19 EU-countries allow for long term series in the dataset
Source: OECD Health Data 2008

The share of private financing of health costs has been increasing quite dramatically in recent years, but the main burden is still carried by public expenditures. In all countries except Cyprus, the highest proportion of costs is covered by public expenditures, Figure 2.2.

Figure 2.2 Share of public and private expenditure of total health care costs in the EU



Source: Eurostat (2009)

Although policy makers allow for a greater role for private funding mechanisms, governments are faced with increasing demand and costs and it puts pressure on governments which are reluctant to raise taxes.

Consequently, governments focus on improving the capacity of health systems to create more value with the existing resources. Governments focus on reforms of service delivery and of financing systems as ways of creating more value and hence secure financial sustainability of the health care systems.[15]

Public procurement of innovation may in itself improve service delivery and is an instrument to improve service delivery in specific areas of health care. But the more fundamental question is whether public procurement of innovation can work and function in health care systems with different financing arrangements and different ways of purchasing health care services.

As we will show, health care financing mechanisms in the European Union varies considerably as do the ways in which services are purchased, which must be taken into account when introducing public procurement of innovation.

Currently, the financing arrangements and ways of purchasing services are central to ensuring greater efficiency in the production and delivery of health care services. Governments ad-

[15] Thomson et al. (2009: xvi)

just financing arrangements and introduce purchaser-provider split to ensure greater efficiency, for instance. This only stresses the need to discuss how current trends in finance arrangements and purchasing regimes can go hand in hand with public procurement of innovation.

In the following we describe the different financing systems in the European Union and ways of purchasing services and discuss how they can accommodate public procurement of innovation in the health care sector.

Financing models in EU health care systems

Overall, there is a clear split among EU countries with regard to the main mechanism that is used to finance health care services. There are three main mechanisms used, cf. Table 2.1.

Table 2.1 Different health care contribution mechanisms in EU countries

Main contribution Mechanism	EU-country
Social security Contribution	Austria, Belgium, the Czech Republic, Estonia, France, Germany, Hungary, Lithuania, Luxembourg, the Netherlands, Poland, Romania, Slovakia and Slovenia
Taxes	Denmark, Finland, Ireland, Italy, Malta, Portugal, Spain, Sweden and the UK
Out-of-pocket	Bulgaria, Cyprus, Greece and Latvia

Note: Some countries outside the European Union use a fourth mechanism namely the medical savings accounts
Source: Thompson et al., 2009, p. 29.

In the majority of countries social security contribution is the main finance mechanism used. This is the case in the first group of countries in the table above. In these countries social security contributions are levied on earnings and are often set at a certain share of income by government or by individual health insurance funds. The contribution may be paid by the employer or employee and are typically of a statutory character and, as with tax based financing mechanisms, are to be considered as a public contribution mechanism.

Where social security contributions are used there has traditionally been a split between purchaser and provider. The health insurance funds purchase health care services from health care facilities such as ambulatory visits, diagnostic tests, surgery, hospitalization etc. This happens in practice through reimbursement of providers' costs and according to contractual agreement.

In many of the newer member states the introduction of social health insurance systems has separated functions between insurance funds responsible for purchasing and hospitals responsible for service provision.

More recently, some countries such as Austria, Germany and the Netherlands have introduced competition between health insurance funds allowing individual citizens to choose from statutory insurers and purchasers. These countries have sought to transform purchasers from being relatively passive payers to become more selective purchasers according to per-

formance criteria. In a broader perspective, the move towards strategic purchasing is clearly visible but is variable in practice.[16]

In the second group of countries health costs are mainly financed through direct and indirect taxes either collected by central, regional or local government. In some cases taxes are earmarked for health care; in other cases they accrue to a central government budget.

In this group of countries, the purchasing and provider function has often been integrated. The government typically employs the personnel or allocates budgets to public health institutions that provided the healthcare services. However, a trend has been visible. A purchaser-provider split has been introduced in several of the countries like the UK and regionally in Italy, Spain and Sweden. This has involved the creation of new purchasing organisations with the aim of improving efficiency. The exceptions to this trend are Denmark, Finland, Malta and Ireland, who have stocked to the integrated purchaser and provider function in their health care systems.

The third group consists of countries which, to a large extent, still rely on out-of-pocket payment for services not covered or partly covered by statutory benefits. We see different ways of organizing the purchasing of services. In Cyprus there is no purchaser-provider split while there is a split in functions in Greece, Latvia and Bulgaria

In practice, the three main types of finance mechanisms described here are mixed. In some countries, the social security contributions often collected and channelled through health insurance funds are also partly funded by tax financed contributions, on behalf of those who because of unemployment or for other reasons do not contribute through social security contributions, for example.

Similarly in taxed based systems, additional finance of health care costs occurs through out-of-pocket payment and private insurance schemes. In fact, out-of-pocket payment is the second most popular contribution mechanism in 18 member states of the EU. It has risen as a proportion of total expenditure in 15 countries.[17]

The question is how public procurement of innovation can be applied effectively in different finance systems with different ways of organising purchasing and provision of services. The context may be quite different in tax based systems and social security contribution based systems.

[16] Figueras et al. (2005)
[17] Thompson et al. (2009)

Public procurement of innovation in tax financed health care systems

In healthcare systems with tax based financing integrated purchaser and provider function the introduction of public procurement of innovation can be a challenge, but potentially also a rewarding exercise.

Tax financed systems with central collection and pooling of resources may potentially have the ability to take the risk of initiating the procurement to address the specific need for innovations that has been identified. For the same reason the incentive for using public procurement of innovation could potentially be strong if needs could be clearly identified and the resulting innovation effectively implemented throughout the health care system in the national or regional context.

With the integrated purchaser and provider function a close dialog could be possible around the health needs that should be addressed and prioritised through the procurement of innovation. The integrated function would also be able to assess the potential benefits and risks involved in different procurement projects. Further, an integrated function may allow for more effective implementation of the innovative solutions.

There are nonetheless some potentially strong barriers that may hinder an introduction and effective implementation of public procurement of innovation in tax based systems. In health care systems where purchaser and provider functions are integrated there may not be a tradition for formulating and assessing the needs that should be addressed through long term and perhaps complex innovation processes with external partners. The provider and purchaser is mainly rewarded for and focused on the delivery of health care services within budget frames rather than long term development projects. The strategic focus may be absent or lacking.

Furthermore, the lack of experience and skills in purchasing may present a major challenge and barrier for the effective introduction and ultimate success of the procurement of innovation. If there is no experience in identifying needs, specifying functions of solutions, formulating and administrating contracts etc.

In countries with tax based systems where a split between purchaser and provider has been introduced and a purchaser organisation established, the necessary experience and skills to adopt procurement of innovation may be there. It would be a natural step to allow these organisations to become the platform for the development of public procurement of innovation.

Whether public procurement of innovation would require a specialised organisational setting should be discussed. Procurement of innovation requires a close dialogue with both providers of health care services that can point to needs that should be addressed in the procurement and external partners who could develop the solutions needed.

In any case, procurement of innovation may be a strategic tool that can be applied as a step from passive forms of purchasing to more proactive forms of purchasing in systems where a split between purchaser and provider has been introduced.

Another question that must be addressed is whether procurement of innovation should be initiated on central (national) level, regional or at the local level of institutions.

In summary, policy makers should be aware of the following when introducing public procurement on innovation in tax based health care systems:

- It may require a strong political initiative to institutionalize a proactive public procurement of innovation agenda.
- Careful planning and preparation of the procurement of innovation is critical. It should be prioritised to attract and develop necessary skills, particular in systems with integrated purchaser and provider functions.
- Special organisational settings should be considered for public procurement of innovation. This should allow for the development of dialogue with both health care providers that are users of solutions as well as the external development partners.
- Policy makers must address whether the national, regional or local level is the right level to initiate public procurement of innovation.

Public procurement of innovation in countries with social security contribution financing and out-of-pocket payment

In countries where health insurance funds are the purchasers of health care services, there should be a strong incentive to procure innovative solutions that could make health care services more effective. In particular, if health insurance funds are central there should be strong interest in applying public procurement of innovation.

However, in countries where purchasing by health care insurance funds is under-developed and not used as a strategic proactive tool to increase efficiency, the application of procurement of innovation will also present a major challenge. Here, the introduction will require careful preparation both in terms of skills and organisational set-up.

In countries where competition among purchasers has been introduced in order to stimulate more active purchasing, the situation may be different. It can be discussed whether competing funds – such as pure private insurance schemes – have strong incentives to engage in procurement of innovation.

On the one hand, they may become extremely focused on cost efficiency. This will incline them to engage in procurement of innovations that may reduce costs at least in the short term. On the other, they may be very selective in the risks they are willing to take.

A consequence may be that procurement of innovation will not be initiated if competing health insurance funds are risk averse and the advantages of engaging in procurement on innovation for the individual health insurance fund is insecure.

In summary, policy makers should be aware of the following when introducing public procurement of innovation in systems based on social security contribution:

- Public procurement of innovation will be a challenge for health funds that are mainly passive purchasers. Policy makers may play an important role in initiating procurement of innovation and in organizing the procurement structure in collaboration with the funds.
- Competing health insurance funds may be risk averse and more focused on short term advantages. Policy makers must address how incentive for procurement of innovation can be stimulated.

2.3. MAIN DIFFERENCES BETWEEN MEDICAL DEVICES AND PHARMACEUTICALS

The medical devices and pharmaceutical industries are major suppliers of products for the health care system. To understand the potential for public procurement of innovation in these industries, we will briefly address some of the relevant and fundamental differences. We choose to order these differences in three categories:

- Products and industry structure
- Regulation
- Innovation processes

Our main finding is that there are fundamental differences between the industries in all three respects. Jointly, they also affect the potential for public procurement of innovation.

We conclude that that public procurement of innovation has a large potential in the medical devices sector. Public tenders already constitute the principal procurement methodology for health care providers. Close collaboration with clinics is an important determinant for successful product development. There is often a great need to adapt new products to situation-specific requirements. In this context, public procurement of innovation may offer valuable opportunities to engage users and customers in development work. Hence, there is a large potential to use public procurement as a means to direct industrial innovation towards societal needs.

In contrast, we conclude that the scope for public procurement of innovation regarding drugs is limited to incremental innovation, i.e. improvements to existing products. This is mainly because markets for individual products are very large in most cases and the "typical" public procurer is significantly smaller. It is unlikely that a national public procurer could mobilise sufficient funds in order to attract the major and leading pharmaceutical compa-

nies. In addition, public procurement in the form of tenders plays a very limited role in the pharmaceutical industry.

However, for improvements to e.g. certain vaccines, a public purchaser may be able to conduct successful procurement of innovation. In addition, if a number of national public procurers in the EU could join forces in a supranational structure, procurement of innovative new drugs may be feasible.

By necessity, the description below is short and highlights what we believe are the main differences which are relevant to assess the potential for public procurement of innovation. It is not meant to represent a full account of how these industries differ.

Products and industry structure

Both products and industry structure differ considerably between medical devices and pharmaceuticals.

The medical devices industry can, by most standards, be described as fairly heterogeneous. The industry is relatively young and consists of a large number of companies displaying a large variation in terms of products, R&D-intensity and firm size.[18] It is dominated by the three business segments: electro-medical equipment, active and non-active implantable devices and medical disposables which together account for around 60% of employment.[19] The electro-medical firms make a broad range of products, such as equipment used for diagnostic imaging, dialysis and radio therapy.

A well-known example of an implantable device is the pacemaker. Medical disposables are numerous and include, for example, dosage cups, sponges and wound care products. Especially the two first product categories are characterized by high R&D-intensity, whereas the products in medical disposables are less R&D intensive. In this category, e.g. firms producing dental and surgical devices conduct only little R&D.[20]

The pharmaceutical industry, on the other hand, is larger both in terms of output and R&D-investments. The value of output in Europe amounts to around 190 billion EUR compared to around 70 billion EUR in the medical devices industry. The money spent on R&D reaches 25 billion EUR per year in pharmaceuticals which is almost four times more than in the medical devices industry.[21]

[18] See Vinnova (2007) and (2008) for a detailed comparison of industry structure in the pharmaceutical and medical devices industries in Sweden.
[19] Ibid. This proportion of the business segments seem to hold fairly well for the OECD.
[20] Ibid.
[21] The sources are, for medical devices, Eucomed, www.eucomed.org/abouttheindustry.aspx ; for pharmaceuticals: European Commission, DG Enterprise, http://ec.europa.eu/enterprise/phabiocom/comp_pip_faf.htm.

The development and production processes in the pharmaceutical industry are more advanced and are, to a larger extent, based on basic/applied research carried out in-house or externally by universities or biotech companies. Pharmaceutical firms therefore have larger research facilities and generally a higher share of employees with higher education (e.g. PhDs) than medical devices firms. Drugs constitute the lion's share of output, accounting for around 85-90%.[22] Firms in the pharmaceutical industry tend to be larger than firms in the medical devices industry, and the market for many drugs is dominated by multinational corporations. The EU pharmaceutical industry employs more people than the medical devices industry, but the firms are fewer and larger.[23]

Medical devices often incur significant distribution and maintenance costs in contrast to pharmaceuticals. Up-grading of existing products is also much more commonplace in the medical devices industry.

In sum, the differences concerning products and industry structure between the medical devices and pharmaceutical industries can be illustrated as follows, see Table 2.2.

Table 2.2 Main differences of products and industry structure

Dimension	Medical devices industry	Pharmaceutical industry
Number of products	A very large number of diverse products	A more limited number of products
Function of the product	Usually mechanical or physical	Usually chemical or biological
Product life-cycle	Short, the R&D investment has typically to be recouped within a few years	Often very long
Distribution cost	High, including the costs for associated supportive functions	Low, no service or maintenance costs are incurred
Up-grading	Frequent, usually based on existing products	Limited once the product is put on the market
Markets	Regional or national for most devices – moderate concentration	Global or regional for most drugs – high concentration (fewer suppliers)
Risk and profitability	Moderate to good	High risk, varying profitability
Firm size	Depends on the segment, many SMEs	Multinational firms dominate

Source: Copenhagen Economics, personal communication with Jens Laage-Hellman

Regulation

The regulatory frameworks for these industries display a number of stark differences. Generally speaking, pharmaceuticals are subject to considerably more regulatory constraints than the medical devices industry.

Intellectual property rights play an important role in both industries, but are particularly crucial for pharmaceutical firms. Patents are normally applied for by companies early on in the development process. As a result, the effective patent period is less than twenty years. In

[22] Vinnova (2007, 2008).The remainder 10-15% of the industry consists of e.g. diagnostics', drug deliveries' and bio production firms.

[23] Employment numbers for Europe are as follows: around 500 000 in medical devices, and around 650 000 in pharmaceuticals. Sources: Eucomed, www.eucomed.org/abouttheindustry.aspx ; for pharmaceuticals: European Commission, DG Enterprise, http://ec.europa.eu/enterprise/phabiocom/comp_pip_faf.htm.

this period the product can be sold on the market under protection of a patent. There is a difference in the patent conditions, however, between the industries where pharmaceutical firms may get an extension of five years for their patent through a supplementary protection certificate (SPC).[24]

Once a product has reached the commercialisation stage, it has to be approved by the relevant authorities in those markets where it is intended to be marketed. Here the industries diverge considerably, with the pharmaceutical sector being subjected to more thorough and time-consuming scrutiny.

For medical devices, the product approval process is regulated by different EU-directives.[25] These directives are transposed into the national law in the Member States. The directives prescribe the requirements of the product characteristics, quality and requirements for approval and control. The legal requirements are expressed as functional requirements. These are laid down in technical standards by the European standardization bodies, CEN, CENELEC or ETSI. Once the product is approved, it gets the CE-label and can be marketed all over the EU.

For pharmaceuticals, the drug approval process has been in force for more than forty years. Decisions of approval are today made on a European level by the European Medicines Agency (EMEA) which co-operates with the American authority, Food and Drug Administration (FDA). Approvals of products are made by EMEA on the basis of tests demanded by one or more national drug administrations.[26] These tests aim to find out how the new drug works, if it is efficient, if the side-effects are reasonably small relative to the intended effects and if the production of the drug is of high quality. The national authorities also issue permits to perform clinical testing, review planned clinical testing and perform inspections of manufacturing facilities. Firms willing to export are also subject to inspections by the national authorities in other countries, for instance the FDA carries out inspections in European pharmaceutical companies.

The regulatory requirements for clinical testing are in general stricter for drugs than for medical devices. This is due to the complex properties of drugs which may have severe non-intended hidden side-effects on patients. The conditions for approval of drugs and access to the market are crucial for the pharmaceutical industry. A well functioning co-operation with clinics is therefore crucial for the pharmaceutical industry. Clinical testing is regulated by an EC directive.[27] National regulations not covered by the directives are important in this area because they determine how well the industry can use patient data for testing of their products.

[24] The conditions for receiving a SPC are regulated by the EC directive, EG/1768/92.
[25] The most important being, directive (93/42/EC) on medical devices, Directive (90/385/EC) on active implantable medical devices, directive (98/79/EC) on medical devices for in-vitro diagnostics.
[26] See www.emea.europa.eu for a detailed description of how new drugs are approved.
[27] EC-directive (2001/20/EG)

There are also other important differences between the medical devices and pharmaceutical industries in terms of the regulation of prices and distribution. Price formation regarding pharmaceuticals usually takes place in negotiations between a public administrative body and the producer – the retail prices are then set at a uniform national level. Pharmacies have traditionally been regulated extensively in most Member States, although liberalisation has been introduced gradually in some countries.

Procurement approaches also differ: cost-containment policies have been introduced by authorities in order to control physicians' prescribing practices, especially regarding drugs. These policies aim at finding the most cost-efficient practices where the price bears a reasonable relation to the resulting patient benefits.

In sum, the differences concerning regulation between the medical devices and pharmaceutical industries can be illustrated as follows, see Table 2.3.

Table 2.3 Main differences of the regulatory conditions

Dimension	Medical devices industry	Pharmaceutical industry
Intellectual property rights	Ordinary patent protection (20 years)	Patents may be extended for a period of five years using the SPC procedure
Product approval process	Regulated by EU directives and national legislation that prescribe functional requirements. EU standardization bodies act for common approvals across Member States.	Extensive test procedures by EMEA in the EU and FDA in the US. The scrutiny considers quality and side-effects and involves clinical testing and on-site inspections at production facilities.
Parallel imports	No restriction within the EU	Certain restrictions may apply
Price regulation	No regulation	Prices are often negotiated between the public drug administrative body and the pharmaceutical company.
Distribution	No regulation	Regulated
Procurement	Predominantly through public tenders. These are becoming more and more centralized and set-up through framework agreements. The clinics have a decreasing influence in the choice of products. The influence of patients is small, with the exception of various forms of medical aids for home use.	The predominant channel is physicians who prescribe drugs to patients

Source: Copenhagen Economics, personal communication with Jens Laage-Hellman

Innovation process

Lastly, innovation processes are not the same in the medical devices industry as in pharmaceuticals. Whereas pharmaceuticals are predominantly science-based, one could regard medical devices as largely engineering-based. The innovation process is often longer, more risky and associated with higher costs in the pharmaceutical industry. This is partly explained by the nature of the products and production process in the industry but also by the fact the pharmaceutical industry is subject to more regulations than the medical devices industry.

In medical devices, the innovation process differs between radical and incremental innovations. Ideas for radical innovations, i.e. new products often come from research carried out at universities or university hospitals. The source of successful innovations of this type is often a combination of clinical and technical or pre-clinical research where researchers with different backgrounds and competencies have collaborated in joint projects. This means that the user or customer side, normally represented by clinicians working at large hospitals, is already involved in the innovation process at the initial idea stage.[28]

In incremental innovation, such as improvements to existing products, the idea often originates in feedback from users/customers – e.g. physicians or other clinical staff - who have identified specific product deficiencies or opportunities to improve the product design. It is therefore essential for medical devices firms to keep in close contact with the clinical staff through the whole innovation process in order to ensure that the product specifications adhere to the customer's needs and wishes. Clinical trials carried out in collaboration with clinics are a necessary part of the innovation process. Depending on the risk class of the product, the regulatory authorities put more or less strict demands on clinical testing as a prerequisite for registration and market approval. Published results from clinical trials may also constitute a valuable asset in the market introduction of the new product.

The starting point for the development of a new drug in the pharmaceutical industry is typically an existing medical need, i.e. a disease that is lacking adequate treatment, and the discovery of a pathological mechanism that appears to influence the disease. The medical need is usually well known to the pharmaceutical industry and the research community, that is, its identification does not require close interaction with the users or customers in the health care system. In the early phase of the project, the external input rather comes from the research side, university researchers or R&D companies which have made important scientific discoveries, such as identifying potential drug targets. Interaction with the user side, clinics, takes place primarily during the development phase and especially in connection to the clinical testing of drug candidates.

Pharmaceuticals are often very R&D intensive, take a long time to develop and require significant evaluations before products can be put on the market. In these regards, medical devices firms are less constrained.

In sum, the differences concerning innovation between the medical devices and pharmaceutical industries can be illustrated as follows, see Table 2.4.

[28] Laage-Hellman, J. (2009).

Table 2.4 Main differences of innovation processes

Dimension	Medical devices industry	Pharmaceutical industry
Identification of clinical need	Through feedback from users in the health care sector or collaboration with clinical researchers	Generally known and common across many countries
The character and intensity of R&D	Varies between subindustries. Engineering-based product development.	Science-based and highly intense. Pharmaceutical companies often have full-fledged research laboratories. Collaboration with universities is common.
Testing procedures	Close collaboration with users. Local adaptation often possible.	Clinical testing lengthy, heavily regulated and time-consuming. Often takes several years.
Time to develop a product	Most product ½ - 2 years	Most products 5-15 years

Source: Copenhagen Economics, personal communication with Jens Laage-Hellman

2.4. PUBLIC PROCUREMENT OF INNOVATION IN THE HEALTH CARE

The essential elements in public procurement of innovation in the health sector are: identifying the need; creating a market for the innovation; drafting the specifications; and co-operation between organisations in the innovation process.

In order to spur innovations in health care, the buyers in the health care have to *specify the need* which they wish to satisfy by an innovative product. This requires that they possess the competence to articulate the need and translate it into effective demand for a product which the vendors can produce. The buyers also need to have the competence to perform the procurement. This competence has to encompass both technical competence in the area of the procured innovation and competence in terms of managing the procurement process.

The buyers also need to be able to *create a market* and demand for the product. The innovation will not be produced unless the buyers can provide vendors with the incentives to devote resources to production. Vendors need to be reassured that there is high and stable demand which will generate profits substantial enough to cover their investments. The procurement of refrigerators, mentioned in the previous chapter, provides a successful example of how the buyer created a market for a product.

The *specification* of the product should be drafted in a way that gives the vendors the flexibility to design the product. This can be achieved through specifications of the functional requirements of the product, i.e. what needs the product is supposed to satisfy or through a detailed specification of the product. The needs for innovations can be very specific in different health care sectors, which make it difficult to give general recommendations in terms of how detailed the specifications should be. For instance, pharmaceutical products could be specified in terms of both functional requirements and detailed specifications of the product. The functional requirements could state that the drug should cure a specific disease and the product specifications could state what substances they should and should not include. The experiences from successful projects have demonstrated that even though specifications can

be detailed in terms of *what* to produce, it should be left to the vendor to decide *how* to produce the innovation.[29]

Allowing for *co-operation* between organisations and individuals such as individual researchers, physicians and other clinical staff can improve the possibilities for successful innovations. Especially important are interactions between buyers and vendors with possibilities for interactive learning between the organisations. The willingness of clinical staff to participate as pilot customers has been important in successful cases of innovative medical products.[30]

[29] Cf. Edquist et al. (2000)
[30] Cf. Arvidsson et al. (2007)

Chapter 3 EXAMPLES FROM HEALTH CARE

In order to illustrate the use of public procurement of innovation, we make reference to five cases. The purpose is to illustrate how public procurement of innovation has been used to fulfil needs that have been identified in health care services. The process of identifying candidate cases was cumbersome – indeed, very few examples of public procurement of innovation in the health sector appear to exist in the EU and in the rest of the world today. The cases are summarised in the table below.

Table 3.1 Five examples of public procurement of innovation in health care

Case	Country	Innovation
Case 1: New smallpox vaccine for the US	US	Vaccine
Case 2: Digital hearing aids in UK	UK	Digital hearing aids
Case 3: DEHP free blood bags	Sweden	Blood bags
Case 4: Health care acquired infections – Design bugs out	UK	Cleanable furniture
Case 5: Pneumococcal vaccine in poor countries	International	Vaccine at affordable price

In Case 1, the purpose was to develop and supply smallpox vaccines to the US-government. Smallpox is a dangerous, acute and highly infectious viral disease. Although the last case of smallpox was reported in 1977, there remains a latent threat of smallpox because there is a risk that the virus made its way into the biological weapons arsenal of the superpowers during the cold war. The need arises from the ineffectiveness of the existing smallpox vaccines for approximately 25 percent of the general population who encounter various forms of complications. Therefore, the US National Institute of Health initiated a public procurement.

Case 2 is the example of digital hearing aids in the UK. This illustrates how the public sector can take up a new technology through a procurement process and speed up the introduction of such technology whilst ensuring low prices. This is also a good example of close cooperation between the public sector, the users and the suppliers.

Case 3 concerns blood bags. Blood bags are used in large volumes in hospital care throughout the world and the most common form are PVC bags plasticised with DEHP, also known as a phthalate. DEHP is classified as reproduction toxic which means that receiving blood which has been stored in such bags may lead to reduced fertility and injuries to the foetus. The aim of the public procurement is to obtain a better solution. Behind the procurement are the Swedish County Councils, and the procurement is presently at the phase in which the requirement to the new product is specified. It remains to be seen whether the process will result in a new, improved blood bag.

Case 4 analyses health care acquired infections (HCAI). Here, the aim is to find ways to reduce the number of patients who catch infections from other patients during a hospital stay. The National Health Service in the UK has initiated the HCAI Technology Innovation Programme. It aims to speed up the development and adoption of new technologies to help combat health care associated infections.

Finally, Case 5 concerns pneumococcal vaccine for people in poor countries. Pneumococcal diseases are the cause of 1.6 million deaths annually. These diseases include pneumonia, meningitis and febrile bacteraemia. Almost all deaths occur in developing countries and about half of the deceased are children under the age of five. The GAVI Alliance has initiated a so-called Advance Market Commitment with the purpose of accelerating access to vaccines in poor countries. The aim is to ensure that children in the poorest countries receive the vaccines 15-20 years earlier than they otherwise would have been available and at prices that the governments of such countries can afford.

In total, the five cases represent different needs and different solutions that can inspire new possibilities in other areas of health care.

3.1. CASE 1: A NEW SMALLPOX VACCINE FOR THE UNITED STATES[31]

Smallpox is a dangerous, acute and highly infectious viral disease. It proved more deadly in history than any other infectious disease. There is no cure once the disease has developed, yet it can be prevented by vaccination. The variola virus that causes smallpox spreads by aerosols from person to person or through direct contact with body fluids or contaminated objects. Around one third of the infected persons die of the disease.

There were 50 million cases of smallpox reported each year in the early 1950s. As the competence grew to produce efficient freeze-dried vaccines, the numbers started to fall. In 1967 the WHO launched a global programme against smallpox. The last case of smallpox was reported in 1977, in Somalia.

The latent threat of smallpox remained even after the successful WHO campaign forty years ago. This is due to the fact that the virus supposedly made its way into the biological weapons arsenal of the superpowers during the cold war. After the fall of the Berlin wall, it became known that the Soviet Union had developed an extensive smallpox programme. A few years thereafter, both the supplies and staff fell into obscurity. In contrast to the nuclear arsenal with its authorized personnel, the biological equivalent left much less trace of its whereabouts. Suspicions arose that stocks of variola viruses existed in sites not under the auspices of the WHO. There were also indications that there was potential for the virus to be deliberately released to cause harm. Hence, smallpox returned to the agenda of most governments as a national security risk.

The reasons for the ineffectiveness of the smallpox vaccines for approximately 25 percent of the general population are due to various forms of complications. These can, at times, be fatal. For instance, individuals who are pregnant, infected with HIV or with cancer, have an organ transplant or any kind of immune disorder are prone to be at risk if vaccinated with the conventional type of smallpox vaccine. These categories of individuals may not be able to

[31] This case was developed with the help of Bavarian Nordic and the US National Health Service.

generate a sufficient immune response to control the infection. Recent experience also indicates that heart complications were reported amongst young healthy males in the US military after vaccination with the traditional smallpox vaccine.

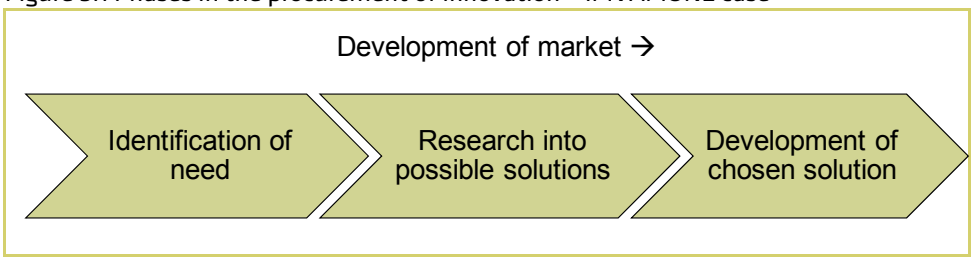
The US Government wanted more effective medical countermeasures against smallpox because of the shortcomings of the existing vaccine. Therefore, the National Institutes of Health (NIH), part of the US Department of Health and Human Services, initiated public funding of research. They subsequently contracted two private companies: Bavarian Nordic and Acambis, for the development of a vaccine which should be safe to use for children, pregnant women and people with immune system disorders or eczema. Such a vaccine was not on the market in 2003.

How was it done?

The procurement of innovation process started in 2003 and has now resulted in a large scale order by the US Government for a new smallpox vaccine. Several US Government institutions have been involved in the process, from the identification of the need to the request for information and drafting of contracts.

The procurement has been through a set of phases which may be characterized as identification of need; research into possible solutions; development of chosen solution and development of market. Figure 3.1 illustrates how the process developed. Firstly, the need was identified as part of the Department of Homeland Security assessment of bioterrorism risks to the US. The Department of Health and Human Services (through the NIH) then funded a combination of research into safe smallpox vaccines (research) and an agreement was made for the delivery of a small quantity of vaccine (development of market). In the next phase, one vaccine was chosen for further development, and a contract was issued for the delivery of a larger quantity of the vaccine.

Figure 3.1 Phases in the procurement of innovation – IMVAMUNE case



Identification of need

Throughout the 1990s there was a growing awareness in the US Government that smallpox could be used as a biological weapon. This knowledge was both generated spontaneously through independent research and through the work of the Department of Health and Human Services.

Before 9/11 the need for smallpox vaccines was only gradually being understood, but after 9/11, the process gained significant momentum. The newly formed US Department of Homeland Security (DHS) identified four categories of biological threat agents which should be considered as threats to national security. One of the four categories was smallpox.

After 9/11 a new, substantial effort was initiated by the US Government to prepare for the risk of bioterrorism. As part of this process, American military personnel who were active in the Iraq-war were vaccinated using the old, stockpiled smallpox vaccine. Some serious side-effects to the old vaccine were reported by the military.

The Department of Health and Human Services looked for potential medical countermeasures to protect the American people against the threats identified by DHS: they decided that an improved smallpox vaccine was necessary. Different types of smallpox vaccines were at a relatively advanced level of development at this time.

The identification of need was thus done in collaboration between the Department of Homeland Security; a group of users; the Department of Defence; and those responsible for public health: the Department of Health and Human Services.

Once the need was identified, the procurement of innovation was carried out in four steps, divided into so-called request for proposals (RFP):

Table 3.2 Procurement process, RFP 1-3

	RFP-1A	RFP-1B	RFP-2	RFP-3
Activities	Clinical testing Development of vaccine	Clinical testing Development of vaccine	Clinical testing Development of manufacturing process	Production of vaccine
Result	Test data, scientific reports	Test data, scientific reports	Test data, scientific reports and 500.000 doses of vaccine	20 million doses of vaccine
Payment	Cost plus	Cost plus	Cost plus	Fixed price
Number of firms	2	1	2	1

Note: RFP is an abbreviation of Request for Proposal
Source: Copenhagen Economics.

Research into possible solutions (RFP-1A)

In February 2003, The National Institutes of Health (NIH) awarded Bavarian-Nordic and Acambis part A of a so-called RFP-1 contract. For Bavarian Nordic, this particular contractual form included further clinical and technical development of the IMVAMUNE® vaccine against smallpox.

By allowing two firms into the program, NIH preserved competition in the development process.

Under RFP-1A the firms were paid on a cost-plus basis meaning that the US Government bore most of the economic risk associated with the development of the vaccine. Furthermore, the deliverables were made in the form of clinical test results and small amounts of the vaccine.

In this phase, the two competitors had incentives to win the continuation of the project and thus an incentive to keep costs low and quality high. There are indications that competition was relatively intense between the two firms, because the company who won - Bavarian Nordic - has had to defend its intellectual property against infringement on the patents.

Both quality and progress were ensured in this phase through hands-on project management by the US Government. Current procedures prescribe weekly conference calls with the contractor, quarterly program review meetings and periodic site monitoring visits involving the contractor and the US Government.

At the end of the RFP-1A contract, the results of the two companies were evaluated, and Bavarian Nordic's results and process were considered to be the best and most promising, so Bavarian Nordic received a continuation of the RFP-1 contract, but Acambis did not.

Development of the chosen solution (RFP-1B and RFP-2)

Under RFP-1B the NIH contracted with Bavarian Nordic for further development of the vaccine. In total, the RFP-1 amounted to USD 29 million.

As the RFP-1 was finalised, a new tender process was initiated. In September 2004, Bavarian Nordic and Acambis were awarded funds under the subsequent programme RFP-2. At this stage, the funding was deployed to further preclinical and clinical development of the vaccine, including the vaccination of more than 2 000 people in three clinical trials. In addition, an extensive testing programme was initiated to test the robustness of the bulk manufacturing process and a validation of the industrial process according to official requirements. The contract with Bavarian Nordic also involved the delivery of half a million doses of IMVAMUNE®. The total contract value of RFP-2 contract amounted to more than USD 100 million.

The payment principle under RFP-2 followed the principle under RFP-1. Bavarian Nordic was paid on a cost-plus basis - meaning that the US Government bore most of the economic risk associated with the development of the vaccine. The deliverables were made in the form of clinical test results and moderate amounts of the vaccine.

In this phase the US Government kept costs under control using periodic reviews and Bavarian Nordic also kept relatively open books vis-à-vis the US Government, allowing for close monitoring of project costs.

Development of the market (RFP-2 and RFP-3)

In June 2007, the US Department of Health and Human Services (through the Biomedical Advanced Research and Development Authority (BARDA)) awarded the RFP-3 contract to Bavarian Nordic following a competitive bid process. RFP-3 involves the manufacture and delivery of 20 million doses of the IMVAMUNE® smallpox vaccine. The base contract also supports additional research and development of the product and includes an optional part for an extended application of the product.

Under RFP-3 Bavarian Nordic was paid on a fixed price basis. The final deliverable was a large quantity of the final product. However, the contract also included a number of technical milestones and when each of these milestones is met, an advanced payment will be made. The advanced payments are important to bridge the funding requirements (valley of death) necessary for small biotech companies to reach full licensure.

Lessons learned

When asked, the American Government and Bavarian Nordic have more or less similar experiences from the project.

The American Government stress the importance of supporting the development of the products from inception until the stage in which they are ready for use. In the case of IMVAMUNE®, an important part of the success was that the Government did not stop funding development before the product was shelf-ready. RPF-2 was a crucial part of this successful public procurement of innovation, because it allowed for the actual manufacturing of the new vaccine.

The American Government also highlight that it is important to involve the agencies which ultimately approve the vaccine for use. The involvement of the Food and Drug Administration (FDA) in the requirements specification during the early phases has contributed to increase the likelihood that the product will be approved by the FDA in the end.

For the American Government, the IMVAMUNE® case has also served to confirm its belief that milestone-based advance payments are crucial for making such innovation possible. Advance payments make it possible for firms to survive during the very costly development process and they also reduce the level of economic risk. Such payments also make it possible to encourage private companies and even relatively small firms to participate in publicly-funded innovation of pharmaceutical products.

For the company, the IMVAMUNE® case has underscored the importance of protection against the different risks involved with the innovation of pharmaceutical products. In the

short term, there is a risk regarding the initial development. This risk was reduced by the cost plus contracts in the initial phases of the innovation project. In the long term, the risk regards acquisition and licensure. The US Government mitigates this risk by using advance payments.

3.2. CASE 2: DIGITAL HEARING AIDS IN THE UNITED KINGDOM

In this case study, the capacity to diffuse new technology on a large scale was a central part of the challenge. In addition, a number of improvements to hearing aids were introduced during the process.

In 1999, the National Health Service (NHS) realised that they had to revise the treatment of hearing disorders. At that time, the only type of hearing aid available to the public was analogue. Those hearing aids were based on 30 year old technology and were technologically inferior to digital hearing aids as well as being clumsy and unappealing. It was feared that these devices would lead to users suffering social isolation and loss of independence. At the same time, digital hearing aids were prescribed to the public in many other similar countries.[32]

Furthermore, the NHS faced a number of other problems. Of the 5 million people who could be helped by using a hearing aid, only 2 million had access to one in 1999. Users had to wait an average of 20 weeks for a new hearing aid, with waiting lists ranging between 1-19 months. In addition, only 70 percent of the users of hearing aids used them correctly.

Although the new technology existed, it was out of reach for most people. In private health care, digital hearing devices were available for a price of EUR 700-1000. The users' total price for the service would then be EUR 2500-3000. The NHS spent EUR 80 million on 450 000 users in 1999, while the private sector spent the same amount of money on 150 000 users.

For these reasons, the NHS wanted to improve the service by introducing a digital hearing aid. The innovation required was the building of an organisation able to fit more than 200 000 users with digital hearing aids every year at a reasonable price. Furthermore, during the process, the NHS took the opportunity to make a number of developments to digital hearing aids, resulting in new features regarding automatic wind and shoe detection and adaptive directionality.

How was the procurement carried out?

The process leading to the procurement was initiated by John Hutton MP, Parliamentary Under Secretary of State for Health. He announced the Modernising Hearing Aid Services (MHAS) programme in 2001. This was funded by the British government, and one the tasks

[32] Phillips, Knight, Caldwell, and Warrington (2007)

for the MHAS was to identify the important parties involved in the research, development and purchase of digital hearing aids.

An NHS Negotiating Team was established as an industry partnership to support the MHAS programme. The participants in the team were the Department of Health (DH); the Royal National Institute for Deaf People (RNID); the NHS Purchasing and Supply Agency (PASA); the Medical Research Council (MRC); and the Institute for Hearing Research (IHR). The RNID represented the needs of the users.

The aim of this cooperation was to create a new supply strategy for bringing new, advanced digital technology to the public; to create standard service protocols; to introduce measurable benefits and create a new service infrastructure for hearing aids. A list of essential and desirable features was produced. MRC and IHR worked together to establish certain requirements as well as desired features in digital hearing aids. The involvement of different actors ensured that focus was on user needs, product quality and costs. These specifications called for the latest technology. In the end, a partnership between procurers, suppliers, users and industry groups was created.[33]

Although the price for the digital hearing aid was lower than in other markets, the hearing aid companies had an incentive to supply the NHS and even develop new products. This was due to a number of reasons. Firstly, the supplying companies were guaranteed certain volumes on a simplified sales market with only one customer. Secondly, the companies had the opportunity to supply additional service and knowhow. They became responsible for software and training at NHS clinics, and developed new audiology equipment and service protocols. Finally, the suppliers could look forward to the possibility of further orders from the NHS after the initial contract.

NHS PASA became responsible for all procurement decisions. The task of NHS PASA was to evaluate commercial aspects. Aesthetics and ease of use of the products were assessed by clinicians and users, while scientists controlled the quality. With NHS PASA responsible for the procurement, the NHS could act as one purchaser of hearing aids. This was not the case previously, where the purchases by the NHS had been fragmented.[34] This gave the NHS buying power and the ability to commit to large volumes, as one out of ten of every hearing aids produced in the world is sold in the UK.

The procurement process

The contracts between the NHS and suppliers were negotiated in three waves.[35] The first wave focussed on pilot testing the approach. The second wave extended the service to more sites and in the last wave, a public-private partnership initiative was engaged in order to in-

[33] Blinks (2006)
[34] Ibid.
[35] Phillips, Knight, Caldwell, and Warrington (2007)

crease the capacity of the NHS and thereby reduce the waiting time for the patients, cf. Table 3.3.

Table 3.3 Three waves of digital hearing aids procurement

	Wave 1	Wave 2	Wave 3
Year	2000-01	2002-03	2003-04
Price of DHA	230-330 EUR	105-115 EUR	90 EUR
Activity	Establish 20 pilot sites, with focus on adults service protocols, research to learn	Establish 47 extra sites, choice of service protocol, children service	Establish 40 extra sites, PPP-arrangement
Number of firms	4	2	2

Source: Philip et al. (2007) and Copenhagen Economics.

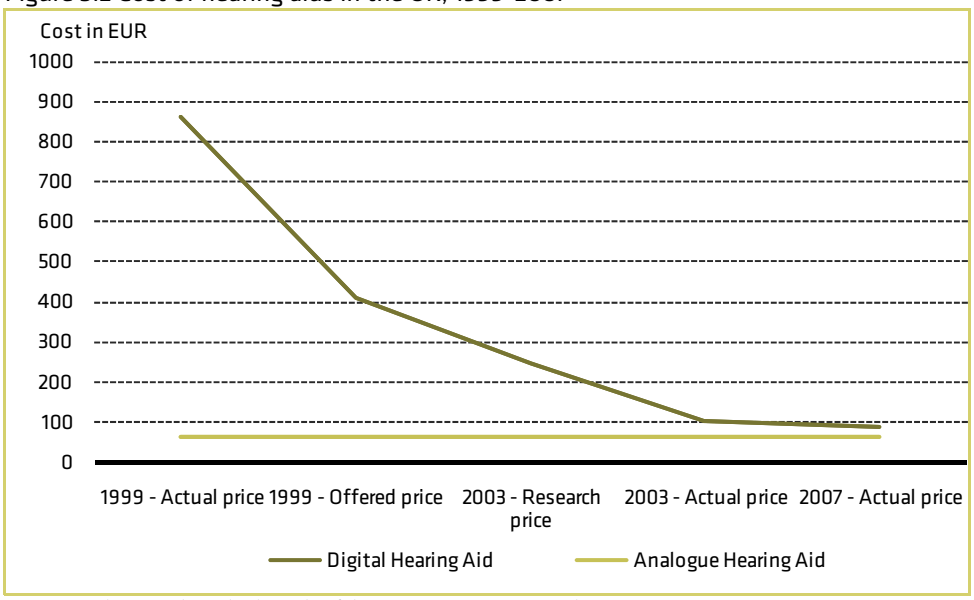
In the first wave, the aim was to produce small volumes of digital hearing aids used for research. Four different suppliers delivered these products, and the price was between EUR 230-330 per unit. As not to damage other markets, the companies wanted an NHS logo on the hearing aids. A total of 20 pilot sites were set up to provide the new digital hearing aids to the users. These pilot sites provided new digital hearing aids to the users. Furthermore, data from each of these sites was collected by researchers and used to further develop the service.

The second wave involved a total of 47 new sites, and an increased focus on children's hearing aids was implemented. In this wave, the suppliers were informed of the intended purchases. This gave an opportunity to the supplies to consider supplying large volumes of hearing aids at a lower price than they charged in their other markets.

In the third wave, another 40 sites were involved. In this wave, two suppliers, Siemens Hearing Instruments and Oticon, supplied most of the digital hearing aids. The other suppliers were GN ReSound, Phonak UK and Starkey Labs. In order to ensure continuously innovative solutions, NHS PASA devised a product introduction process. This enabled them to upgrade the products to benefit from ongoing technological improvements and did result in improvements, including adaptive directionality and automatic wind noise detection.

The price of digital hearing aids decreased considerably during the procurement process. This meant that the NHS was able to provide modern hearing aids to the users at reasonable costs, cf. Figure 3.2.

Figure 3.2 Cost of hearing aids in the UK, 1999-2007



Note: In the second graph, the scale of the x-axis is not symmetrical
Source: Binks (2006), Phillips, Knight, Caldwell, Warrington (2007) and Office for National Statistics (2009)

What did we learn?

The use of public procurement of innovation in this case meant that the users gained access to advanced digital hearing aids in a relatively short period of time at an affordable price.[36] It is likely that such modern hearing aids would have been introduced by NHS eventually, but that the rate of adoption now dramatically decreased.

The close cooperation between the public and the suppliers was the key to this achievement. This resulted in both lower prices (due to the large volumes NHS could commit to purchasing) and made new innovations to digital hearing aids accessible to users. New features such as automatic shoe and wind detection and adaptive directionality have been developed since the procurement, partly because technological development was rewarded.

3.3. CASE 3: NEW BLOOD BAGS

Blood bags are used world-wide in large volumes and the most common form is PVC bags plasticized with DEHP[37]. DEHP belongs to a group of materials which is also known as phtalates. One of the advantages of the substance, DEHP, is that it has a conservation effect on the red cells, which makes the substance difficult to replace. However, DEHP is classified as toxic to reproduction which means that transfusion of blood stored in PVC-DEHP bags

[36] Blinks (2006)
[37] Bis(2-ethylhexyl)phthalate, commonly abbreviated DEHP, is an organic compound with the formula C6H4(CO2C8H17)2. It belongs to a group of materials also known as phthalates. C6H4(CO2C8H17)2. DEHP is classified as a reproduction toxic.

may lead to reduced fertility and may also injure foetuses[38]. The largest risk of using blood bags with DEHP is for newly born babies who are given blood infusions. DEHP may diffuse from the blood bag into the blood and subsequently enter the body of the patient. Due to this, DEHP is put on the CMR list (Carcinogen, Mutagen, or Reproductive toxicant substances).

The amount of DEHP that can end up in patients depends on a number of factors, including storage time and temperature. Today, one way of reducing the risk is by minimising storage time. A shorter storage time reduces the amount of DEHP in blood, but this solution is only applicable on a small scale.

The aim of the public procurement is therefore to obtain an alternative product that does not contain any substance on the CMR list in the EU. In addition to safety, the bag should fulfil a number of requirements. A blood bag should be a feasible storage solution and have sufficient capacity for ordinary hospital needs. It needs to be safe for patients and personnel and be well adapted to and compatible with other pieces of equipment. In addition, the used blood bags should be environmentally friendly, and therefore biodegradable or reusable to a reasonable extent. Finally, international norms state that the degradation of red blood cells cannot surpass 0.8 percent.

On the international scene, other attempts to fulfil these criteria have been made, but with little success to date. These attempts have included attempts to minimize the content of DEHP in the bags, to replace DEHP with a less hazardous softener, to replace PVC and even to find alternative storage solutions. None of these paths has, as yet, proven successful. Alternative softeners do exist, but with negative additional side-effects such as skin problems and bad odour. New storage solutions based on polyolefin have also been tried but with limited success: the problem being that red blood cells survive in a too limited time period compared to the conventional blood bag.

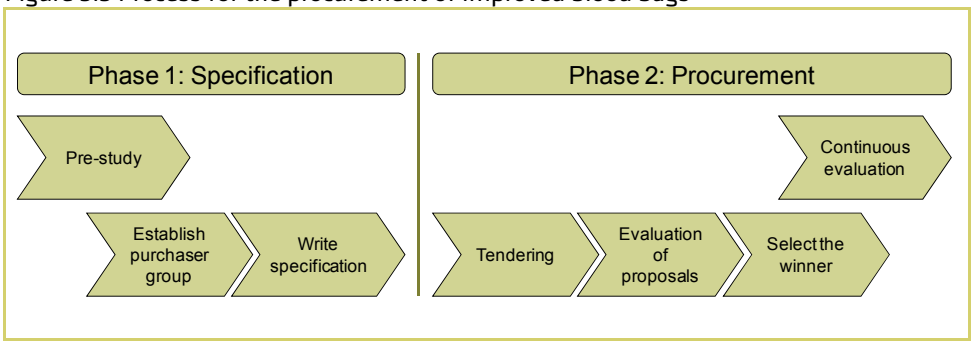
Behind the procurement are the Swedish County Councils, and the procurement is presently in the phase where the requirement to the new product is specified. Whether the procurement will result in new blood bags after the specification phase remains to be seen.

How will the procurement be carried out?

The procurement will be carried out by a group within the Swedish County Council and administered by the Jegrelius Institute for Applied Green Chemistry. The project is divided into two phases. The first phase is the specification phase, with the aim of writing a specification of the procurement. The second phase is the procurement phase where the procurement is carried out with the aim of procuring new, improved blood bags, cf. figure below.

[38] There are presently no studies demonstrating reproductive damage caused to medically-treated children where PVC with DEHP was used.

Figure 3.3 Process for the procurement of improved blood bags



Source: Jegrelius (2008)

The first phase will lay the foundation for a successful second phase. The second phase implies a concrete procurement of blood bags.

Phase 1: Specification

The specification phase is on-going. The part of the specification phase already carried out comprised a pre-study on blood bags as well as the establishment of the procurement group. The remaining step of the specification phase is to write a full specification of the procurement and create a more thorough pre-study.

The purpose of the pre-study was to highlight what already exists on the market; what has already been tested; and outline which problems have been encountered previously. Furthermore, a rough estimation of the required financing was completed and a preliminary specification of requirements was outlined. Finally, the pre-study lists the potential manufacturers who were invited to a seminar to gain further information about the initiative and to make their views known. The pre-study was financed by the Swedish Agency for Economic and Regional Growth (Nutek).

It was found in the pre-studies that blood bags were a complex product for substitution since they need to satisfy high standards regarding patient safety and since innovative product development is constrained by strict legislation. Even though the development of blood bags is an area where the Swedish County Councils have invested a great deal of work, little progress has been made. They have succeeded in substituting phthalates in many other plastic products such as gloves, infusion items, and nutritional items by proactive demands in connection to an "ordinary" procurement.

A purchasers group has been formed to stimulate the development of new blood bags. The members of the purchaser group consist of a large representation from the Swedish County Councils, with procurers, environment coordinators, users, purchasers and an expert on blood components. The set-up of a purchasing group with experts in all fields should ensure in-depth knowledge about the issue in the group. This will benefit the specification. After

companies hand in their proposals, thorough evaluation of the proposals must ensure that the feasible solutions are chosen for further development.

The first mission of the group was to compose an image of their need. This need was derived from specifications for conventional blood bags and from knowledge of already existing alternative products on the market. Experience with such alternatives shows effects such as allergic reactions by the personnel who handled the bags and a failure to uphold the same storage stability as conventional blood bags.

The remaining task of Phase 1 is to specify the procurement, which is currently in progress. The Swedish Governmental Agency for Innovation Systems, VINNOVA, is supporting this task both financially and methodologically in the specification process. One of the main points to resolve is the level of detail in the specification. One option could be to demand a PVC-free solution, though this could add risk to the project because it limits the possible solutions and may rule out a viable PVC-solution.

The requirements for blood bags can be divided into product requirements, quality requirements in the respect of blood equipment and material requirements for blood bags as well as for packaging. Together with the specification of requirements, the purchaser group described the background for the procurement, the aim of the procurement as well as which parties were included in the purchaser group.

A workshop was held with the manufacturers, to present and to discuss the suggested demands in order to receive feed-back on a preliminary specification of requirements. Six out of the eight invited manufacturers attended the workshop. Nevertheless, the two companies which decided not to attend the workshop asked to be kept informed about the continuation of the project. There was considerable interest in the concept of procurement of innovation among the attending companies, who are all familiar with the issues concerning PVC and DEHP in blood bags.

Dialogue with the manufacturers entailed adjustments in the requirements. For example, a different formulation of the environmental standards was chosen with the aim of increasing flexibility. The dialogue also entailed a number of functionality requirements, in order to give further flexibility to the suppliers in the development of new blood bags. One example is that the specification - “the material of the bag shall be able to be welded” was replaced by “the material shall be able to be sealed in a sterile way”.

Some requirements were changed from shall-requirements into evaluation criteria in order to provide the suppliers with more flexibility in finding innovative solutions during the development process. In the last version of the preliminary specification of requirements it is made apparent that the environmental requirements shall be fulfilled without forgoing any existing legislation.

Finally, the importance of the size of the purchase was highlighted through the collaboration with the manufacturers. Hence, it was pointed out that larger quantities procured the more attractive it is to participate.

Phase 2: Procurement

The procurement phase is scheduled to take place in 2010-2012. The purpose of the procurement phase is to carry out a request for proposals and to thoroughly evaluate the incoming proposals. This is the most critical phase of the project.

The first part of Phase 2 is the tendering process. There are several reasons why companies might be interested in participating in the tender process. Firstly, the purchasing group represents 60 percent of the market for blood bags in Sweden. Secondly, the supplier owns all intellectual property rights. The market for blood bags is global, and the potential for the product reaches beyond the Swedish market. Still, compensation for the development costs of the blood bags could affect the outcome of a procurement of this kind. A manufacturer may find it too risky. Even after large investments and a successful development process there is no guarantee that it will result in any revenue. At the same time, attracting a number of tenders will ensure an efficient process.

After the Jegrelius Institute for Applied Green Chemistry receives the proposals, they need to be evaluated carefully. The extensiveness of the required test depends on the extent to which the methods and materials used are well recognized. Basic information about physical and chemical properties and composition of the product is also required.

The level of complexity entailed regarding development of the new blood bag may be high. This will most likely mean that an extensive evaluation of the incoming proposals will be necessary. Specifications regarding functionality, patient security, user-friendliness, and compatibility must all be met. As regards new material solutions, it is difficult to anticipate the required tests to be included in an evaluation, since completely new innovative materials and solutions might be developed. This may, in turn, demand new types of methods for testing.

Furthermore, in order to test whether the newly developed blood bags are hazardous, ecotoxicological tests should possibly be carried out. These tests analyse how the products affect the environment, and should be made in a varied extent in the initial phase of the evaluation, and be fully completed only after the final shortlisted selection of tenders. The desired information from these tests includes data on persistence, bioaccumulation and toxicity. There may also be a number of functionality tests to carry out, which include survival studies on the red blood cells as well as stability studies on blood plasma.

Some of the tests could be carried out by the manufacturers and some should be carried out by an independent party. The manufacturers will be responsible for the tests demanded in the listed specifications.

What did we learn?

The procurement of new blood bags is under way. Therefore the lessons learned are limited to the initial activities. To date, three lessons have been learnt.

Firstly, the first phase affirmed that the competence of the public procurer in specifying the need is a critical success factor. The procurement of new blood bags requires a carefully formulated specification. Too much detail in the specification could result in excluding new and ingenious innovations. In the first draft of the specification, the guidelines were excessively restrictive: a blood bag does not necessary need to be welded, provided that the bags are sealed in a sterile way.

Secondly, the collaboration between the purchaser group and the manufacturers resulted in a number of improvements to the specification. To invite the manufacturers to discuss the process made the procurement move forward. Representatives from the companies contributed both in developing the specification of the product and in providing a first estimation of the costs for testing if the blood bag fulfilled all requirements in order to guarantee a CE-marking.

Thirdly, without the active support of a public agency, the project would not have materialised. Hence, a public procurement of innovation demands a strong public backing. The blood bag project has both been supported by the Swedish Agency for Economic and Regional Growth and by VINNOVA. These agencies have played important roles as initiators, funding agencies and facilitators. The Swedish Agency for Economic and Regional Growth ensured the basis of the procurement in the pre-study phase, and VINNOVA has supported the project giving methodological support in the process of specifying the need. The governmental support has been instrumental in designing the process.

There are high expectations both regarding the quality of the evaluation (made by the procurer) on the tenders and the prototypes as well as on the products developed by the manufacturers. Given the complexity of the product, there is the risk that no adequate product will be developed and produced.

3.4. CASE 4: HEALTH CARE ACQUIRED INFECTIONS – DESIGN BUGS OUT

Infections acquired during hospitalisation are a major problem for health care around the world, including in the UK. The infections caught include Methicillin Resistant Staphylococcus Aureus (MRSA), which is a bacterium responsible for difficult-to-treat infections. These infections can be fatal, and are thought to have caused about 18 000 hospital stay-related deaths in the US in 2005 and approximately 1,600 such deaths in the UK by the end of 2006.

There are many sources of such infections: They may be spread by the hospital staff or visitors, or may spread directly from patient to patient. It is widely believed that the best way to

fight such diseases is to ensure that good sanitary procedures are in place for hospital staff and visitors, and that hospital furniture and equipment is kept clean.

The UK was the country in which MRSA was first discovered, and the issue was of increasing severity: by 1993 there had been 51 deaths from MRSA and this number increased to approximately 1,600 by the end of 2006. Therefore, the British government has put a major effort into fighting such health care associated infections.

In 2008 the Department of Health launched its action plan, Clean, Safe Care – Reducing Infection and Saving Lives. The action plan had six focus areas, of which one was "Harnessing the latest research and technology". Under this heading, one of the major efforts was a program called "Design Bugs Out", which focused on innovation of hospital furniture which is easy to clean.

Design bugs out

Improved types of hospital furniture in the UK were necessary, because the existing furniture had been developed before health care associated infections were a major problem. However, insufficient cleaning of hospital furniture and equipment is part of the explanation for the occurrence of such infections. Bacteria may survive on surfaces and fabrics, including privacy curtains and the garments worn by hospital staff, and during inadequate cleaning of patients' environments when they are discharged from hospital. Cleaning of old-fashioned furniture and equipment is often made difficult by crevices, rough surfaces, joins and hard-to-reach contours, hampering efforts to combat such infections. Furthermore, at the time of the initiation of the program, the communication of health care needs to suppliers was infrequent and unsystematic, so the market did not adequately perceive the existence of a market for innovative hospital furniture.

The development of better types of hospital furniture was made through a design competition in which prospective designer/manufacturer-teams supplied their prototype pieces of furniture against a payment. Clear specifications were given as to what the teams should develop, for example: "Patient bedside furniture – which is easy to clean and maintain, cost effective and sustainable". Selected teams were paid £25 000 for developing prototype pieces of furniture.

How was it done?

The program started in 2007 and it was managed by the Purchasing and Supplies Agency (PASA) but involved a range of NHS institutions – primarily front line staff such as doctors, nurses and other care personnel.

The program has been through a number of phases, starting with identification of need, progressing to outlining possible solutions and a design competition, resulting in the development of prototype furniture. The plan is that procurement of furniture on a large scale starts after Christmas 2009.

The program started with the identification of requirements. An expert reference group was commissioned from the Department of Health, the NHS and industry. The experts all had considerable experience of fighting health care associated infections. An advisory board was founded simultaneously with representatives from industry, microbiology and health care, who worked with designers to guide the project at a strategic level. A team from the Design Council also collaborated with NHS hospitals to discuss specific issues. As a part of this work, around 600 NHS personnel were asked to state what they would need in order to become more effective in fighting health care associated infections. This resulted in a list of 157 ideas which were prioritised by a group of NHS senior staff and external design and manufacturing experts.

The Design Council team summarized their understanding into a set of "design briefs" to develop working prototypes of furniture and equipment. 51 design opportunities were identified, and the opportunities were grouped into 17 themes with the input from stakeholders. The themes were categorized as either "quick wins" or "national design competition". The "quick wins" were directly commissioned to the Royal College of Art for development, whereas the "national design competition" was open to British designers and manufacturers.

The Royal College of Arts assigned two research associates to manage the seven "quick wins", whereas the Design Council together with the Design Business Association launched a national competition for teams of designers and manufacturers.

The received proposals were examined by a panel of judges working in the fields of design, health care, microbiology, nursing and patient care. In total, 37 teams made proposals for solutions to the briefs, but only five teams were selected to develop their concepts. They were paid £25 000 as compensation for developing the concepts.

Project management was carried out by having the teams present their progress at regular time intervals to the external expert group and the advisory board. In the evaluation phase, an evaluation system was designed for the prototypes that were to be developed during the competition. Ultimately, 12 prototypes were chosen as candidates for procurement on the basis of a competition.

After the prototypes were developed, they were presented to hospital staff for comparison with the designs which were currently in use. The staff gave feedback on small questionnaires, which enabled early testing procedures to determine how useful the new designs were in practice.

Table 3.4 Process for Design Bugs Out

Identification of need	Outlining possible solutions	Development of prototypes
Enlisting experts in fighting health care associated infections.	"Quick wins": Royal College of Arts develops designs.	Meetings with designer/manufacturer teams.
Set up advisory board.	"National design competition": Design Council develops design competition	Developing an e valuation of the prototypes.
Discuss experiences with hospital staff.	Assessment of proposals and selection of winners	Evaluation by hospital staff.
Develop design briefs.		
Organise stakeholder meetings.		
Identify opportunities and categorize them.		

Source: Copenhagen Economics.

Lessons learned

There are at least four important lessons to be learned from this case. Two of these involve collaboration between users, procurers and suppliers. The first lesson is the importance of involving potential suppliers at the outset, when the need is formulated. Both the pooling of design and manufacturing knowledge and also thoroughly sharing information about needs helped to bring about an effective innovation process.

The second lesson is the importance of collaboration between the end-users and suppliers when the products are tested. In this way, the manufacturers gained knowledge about the needs of the hospital that they did not have prior to the procurement activities.

The third lesson is that the use of functional requirements rather than detailed specifications takes advantage of the suppliers' technical competence and creativity. Further, the use of functional requirements allows for procurement of multiple products from several producers which have met the requirements. Thus, the use of functional requirements makes it more likely that there will be competitive products on the market, as different suppliers will devise different solutions to the requirements.

The fourth lesson regards the importance of providing producers with incentives to participate in the procurement process by paying compensation to those who won the competition.

3.5. CASE 5: PNEUMOCOCCAL VACCINE IN POOR COUNTRIES

Pneumococcal diseases are the cause of 1.6 million deaths annually. These diseases include pneumonia, meningitis and febrile bacteraemia. The pneumococcal diseases especially affect young infants, the elderly and those with HIV/AIDS. Almost all deaths occur in developing countries and about half of all deceased are children under the age of five.

Vaccines for pneumococcal diseases for young children have been used in the US since 2000. However, at present the 7-valent pneumococcal conjugate vaccine (PCV7) is the only conjugate formulation that is currently licensed and has been recommended for use in developing countries with high disease burden. This is because this formulation targets the most fre-

quent serotypes in the developing countries. Because the pneumococcal vaccines currently available on the market are not designed for the developing countries, only one vaccine on the market fulfils the need of the developing countries. Further, the vaccines currently available on the market are too expensive for developing countries to acquire at the present price.

In order to make appropriate vaccines available to the inhabitants of developing countries, the GAVI Alliance has initiated a so-called Advance Market Commitment (AMC) with the purpose of accelerating access to vaccines against pneumococcal disease. The aim is to ensure that children in the poorest countries receive the vaccines 15-20 years before they otherwise would have been available and at prices that the governments of such countries can afford. [39]

The objectives of the pneumococcal AMC are:

Firstly, to accelerate the development of pneumococcal vaccines which meet developing country demand. This includes serotype composition and vaccine presentation as specified in the Target Product Profile.[40] The serotypes[41] in the vaccine formulation must cover at least 60 percent of the invasive disease isolates in the target region, and must include serotypes 1, 5 and 14 which are the most frequent isolates in GAVI eligible countries. The type of decease might differ between geographic areas.

Secondly, to give an incentive to suppliers to develop pneumococcal vaccines by guaranteeing a higher initial purchase price. This will give incentives for manufacturers to invest in scaling-up production capacity to meet demands for the vaccine in developing countries.

Thirdly, the aim is to accelerate vaccine uptake by ensuring predictable vaccine pricing for countries and manufacturers. This includes binding commitment to purchase large volumes of vaccine at low, long term and sustainable prices.

Finally, the purpose of the pneumococcal AMC is to test the approach. AMC is an innovative finance mechanism and part of the purpose is to test the effectiveness of the AMC mechanism as an incentive for required vaccines and to learn lessons for possible future AMCs.

How is it done?

The Advanced Market Commitment is administrated by the non-profit organisation GAVI Alliance. The GAVI Alliance is a global health partnership representing stakeholders in immunisation from both private and public sectors: developing world and donor governments; private sector philanthropists such as the Bill & Melinda Gates Foundation; the financial community; vaccine manufacturers; research and technical institutes; civil society organisations and multilateral organisations in the World Bank Group.

[39] AMC Press Release (2009)

[40] Cf. WHO (2008a), Part II: Target Product Profile (TPP) for the Advance Market Commitment (AMC) for Pneumococcal Conjugate Vaccines. Supplementary Information.

[41] A serotype is a group of closely related microorganisms distinguished by a characteristic set of antigens.

The pneumococcal AMC is a partnership between GAVI Alliance and UNICEF, the World Bank and the World Health Organisation (WHO). The Word Bank provides fiduciary support through a grant agreement with five governments and the Bill & Melinda Gates foundation in order to finance the AMC[42]. The WHO has established the technical criteria for a suitable vaccine and UNICEF will be responsible for the distribution of the vaccine.

The actual procurement is organised as follows. It is UNICEF that, on behalf of GAVI Alliance, issues calls for offers to manufacturers to participate in the pneumococcal AMC programme. The first such call was issued on 4 of September 2009.[43] These calls may continue at a pace up to two times a year based on recent updates of the 15-year demand forecasts.

To be eligible to submit offers, manufacturers must comply with AMC terms and conditions and sign a registration agreement. They must also be prequalified by the WHO, a process which is conducted by an independent assessment committee. Offers cannot exceed the forecasted demand and production should begin no later than five years into the future. There is no deadline – manufacturers can choose to submit offers at their own discretion. UNICEF promises to use its reasonable efforts to reach an agreement with the supplier within 40 business days.

The offers are evaluated regarding both quantitative and qualitative aspects. The quantitative criteria involve commencement date of delivery, supply commitment quantities, price quotation for the tail price (see below) and production and availability forecasts. The qualitative criteria include a range of characteristics of the individual manufacturer. The offer does not have to supply the entire forecasted demand – in this way UNICEF may allow more than one manufacturers to enter into supply agreements and stimulate competition in this way. In fact, UNICEF has the discretion of reducing offered quantities by manufacturer in order to enable more supply competition.

The purchasing offer given by GAVI to develop an affordable vaccine is, in many ways, similar to a public procurement. But instead of finding a winning manufacturer after all have submitted bids, GAVI accepts each manufacturer who offers a vaccine developed according to the standards set up by WHO. A manufacturer can decide to supply all of or a part of the quantity of vaccine called for in the offer. The offer is valid until the total supply commitments sums up to requested quantity or until the end of 2020.[44]

GAVI has an administrative role in the process. The share financed through GAVI will gradually be taken over by the recipient countries. The reason for GAVI to be the sole pur-

[42] GAVI and IBRD, (2009), page 1
[43] http://www.vaccineamc.org/manu_participation.html
[44] GAVI and IBRD, (2009), pages 3, 16

chaser is that it would be too complicated for a manufacturer to deal with all actors involved in this complex financing model.[45]

The vaccine

The minimally acceptable standards for the vaccine in the offer have been set by the WHO in the Target Product Profile[46]. The Target Product Profile defines essential criteria that relate to the public health impact and suitability of the product, covering measures of vaccine efficacy, safety, dose-scheduling, presentation and packaging. The criteria have been set in order to take into account the special conditions of those rural areas where this vaccine will be used. At the same time, the criteria are set to help to stimulate a competitive vaccine supply environment, by providing incentives to a large number of vaccine developers. Therefore, essential vaccine attributes need to be demanding, yet realistic, in relation to the innovation that can be achieved over the duration of the pneumococcal AMC.

Among the criteria are issues which manufacturers need to consider because of special needs in developing countries. This includes issues such as product presentation and storage and cold chain requirements.

Vaccine packaging and presentation need to be adapted to the requirements in developing countries. Inappropriate packaging and inappropriate vial sizes can add substantially to the cost of immunization through excessive storage requirements and product wastage. The Target Product Profile requires mono-dose and low multi-dose vials. Mono-dose presentations, particularly if available as auto-disable compact prefilled devices, help to assure safety of injection, reduce the work load of health care workers, and reduce wastage of vaccines. Low multi-dose vials have reduced storage requirements and acceptable wastage rates. While preliminary analysis suggests that vials containing between 2-5 doses are appropriate, the selection of the number of doses per vial should be defined by the manufacturer.

Storage and cold chain requirements of the vaccine are important for flexibility of the use of the vaccine. Available pneumococcal vaccines and those in advanced development are all liquid formulations requiring storage at 2 to 8 °C. These vaccines should not be frozen and should not be exposed to high temperatures. If the vaccines are freeze-sensitive, the manufactures should allow the use of the 'shake test' or other means to assess whether freeze damage has occurred. Similarly, vaccine vial monitors to measure exposure to high temperature should be attached.

When manufacturers present a vaccine, an AMC Independent Assessment Committee will assess whether it meets the standards of WHO. If it does, the manufacturer is eligible to set up a supply agreement with GAVI in order to receive AMC funding.

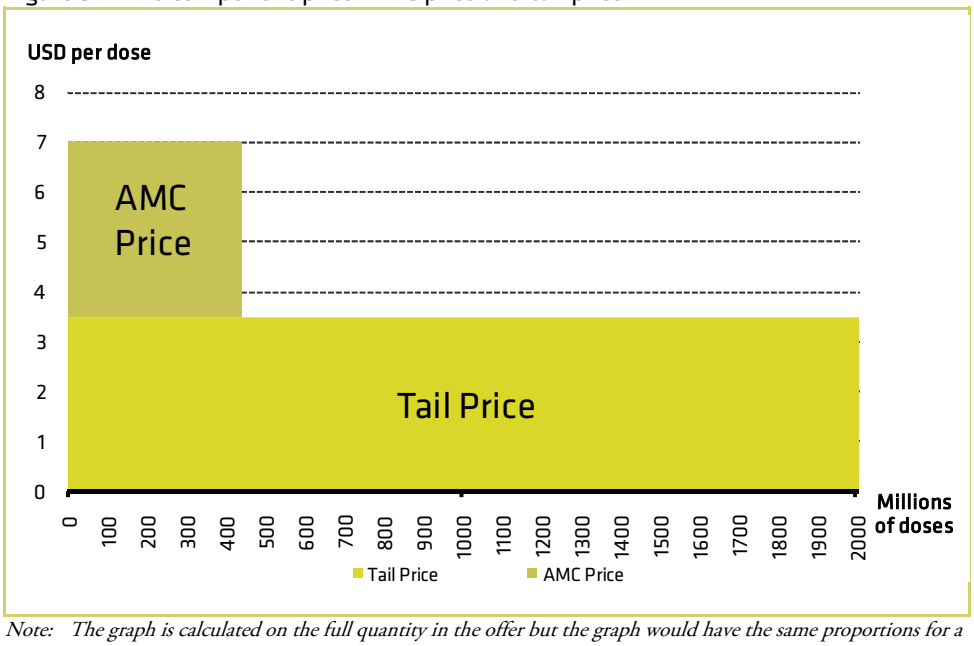
[45] GAVI and IBRD, (2009), pages 2, 12, AMC Expert Group (2008), pages 8f
[46] WHO (2008b)

In addition to the essential criteria, a number of desirable criteria were also formulated in the Target Product Profile. For instance, prolonged shelf life above 24 months is desirable in addition to increased thermo stability. This is because they permit a more flexible use of the vaccine and ideally, new vaccines would not need a cold chain. Another desirable criterion is the reduced vaccine type carriage following the vaccination. These are attributes that GAVI encourages the manufacturers to consider in their development of new vaccines. However, these attributes are not among the minimum requirements in order for manufacturers to be eligible to supply the vaccines.

AMC ensures a low, predictable price

GAVI offers to purchase 2 billion doses over a 10-year period. The initial price offered to manufacturers is USD 7. This price is paid for the first approximately 400 million doses of vaccine. The initial price consists of two components, the AMC price and the "tail price". Both components constitute USD 3.50. For the remaining approximately 1.6 billion doses, companies will receive the tail price only, USD 3.5 cf. Figure 3.4.[47]

Figure 3.4 Two component price: AMC price and tail price



Note: The graph is calculated on the full quantity in the offer but the graph would have the same proportions for a manufacturer supplying a share of the offer

Source: AMC Expert Group (2008) but recalculated to have correct proportions

The purpose of the higher initial price is to give incentives to the manufacturers to develop the necessary systems to deliver the vaccines. When the total amount of the AMC money was set, it was taken into consideration that different production methods could be used. This means that the amount of AMC money is set to allow for a number of manufacturers to participate.

[47] AMC Expert Group (2008), page 18

The AMC part will be distributed proportionally to the share of the total annual doses supplied between the participating manufacturers. For example, if a manufacturer makes a ten year commitment to supply 100 million doses annually it would receive 50 percent of the AMC contribution. When the AMC money is depleted, participating manufacturers are legally bound to continue to supply the vaccine at the tail price during the rest of the 10-year commitment.[48] The tail price is the share that the recipient country will pay per dose of the vaccine.[49]

By dividing the price into two components and spending the AMC money early in the AMC period, GAVI can make it more attractive for manufacturers to participate. Manufacturers prefer to receive a larger share of the payment early in the process in order to cover the large cost involved quickly when developing the vaccine. The costs are covered earlier in order for the company to use the profit to invest in other projects. This is why the present value of a payment is higher the earlier it is received.

If the AMC money of USD 1.5 billion had been evenly distributed over the entire period, the tail price should have been higher in order to remain as attractive as possible to manufacturers. By adjusting the price components like this, GAVI stimulates an early access as well as a stable and affordable long run supply. The manufacturers benefit by gaining access to subsidies and a long term access at a fixed price.[50]

What did we learn?

It is too early to reach conclusions as to the effectiveness of the pneumococcal AMC. However, if the initiative turns out to be successful, at least two aspects illustrate important lessons.

Firstly, the AMC is an effective way to ensure a low price while committing to the purchase of a large volume of vaccines. The vaccines that existed prior to the AMC were sold for USD 70 per dose. After the AMC a substitute to those vaccines will be available to people living in the poorest parts of the world for USD 3.50.

Secondly, the pneumococcal AMC delivers an example of a specification which aims to strike a balance between a specification that stimulate a competitive supply environment, by providing incentives to a large number of vaccine developers, whilst ensuring that the specification is realistic, in relation to the innovation that can be achieved over the duration of the pneumococcal AMC.

[48] GAVI and IBRD, (2009), pages 3, 12f, AMC Expert Group (2008), pages 9, 17

[49] The initial tail price of USD 3.50 will be subject to some variation over time, for example it will be adjusted for inflation.

[50] AMC Expert Group (2008), pp. 5, 11, 15

Furthermore, the Target Product Profile consists of a number of desired criteria as well as the essential, required criteria. The formulation of desired criteria may lead to innovations, although they are not required. This remains to be seen.

Chapter 4 ORGANISATION OF PUBLIC PROCUREMENT OF INNOVATION IN HEALTH CARE

The purpose of this chapter is to learn from the experiences of countries which work actively and systematically with public procurement of innovation in life sciences. We want to discern which institutions need to be in place and which concrete actions need to be achieved in order for public procurement of innovation in life sciences to be an effective tool.

We have chosen to describe the experiences of the UK and the US, because we have not found similar experiences in the rest of Europe. First we describe the UK approach and go on to analyse the US experience.

In the UK and the US, approaches differ considerably as regards both institutional settings and the details regarding how the public procurement of innovation task is solved. But they share the following structural characteristics:

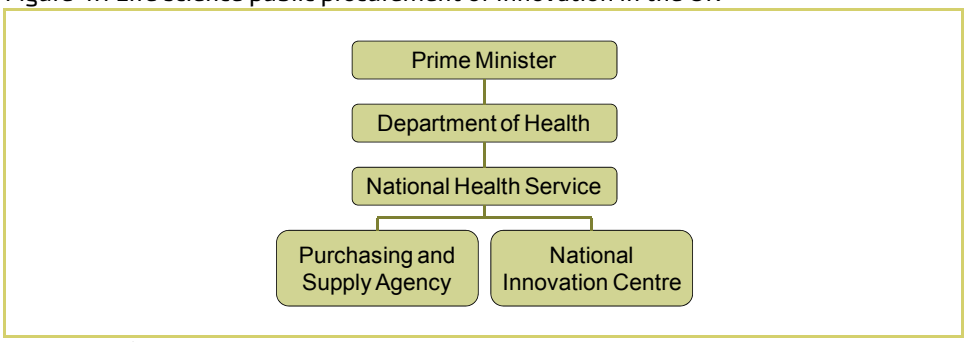
- There is an integrated process of identification of technological needs, management of the innovation process (or at least participation in the management of the innovation process) and diffusion of the new technologies to the users.
- Users participate in the identification of needs.
- There is competition between different suppliers of new technological solutions.
- There is collaboration between the suppliers of new technological solutions and the public sector institutions which demand them.

The systems of public procurement of innovation are too recent for a formal evaluation of their effect. However, it appears to be the case that public procurement of innovation in life science is effective with respect to developing new technological solutions in all the cases we have considered.

4.1. THE APPROACH IN THE UNITED KINGDOM

Public procurement of innovation in life science in the UK is organised under the National Health Service. It is split between development and procurement. The National Innovation Centre (NIC) is responsible for development and the Purchasing and Supply Agency (PASA) is responsible for procurement. The strength of the British system is the high degree of transparency, strong procedures and systematic collection of new ideas. A possible weakness of the system is the unclear link between the development efforts of NIC and the procurement work at PASA. As we shall see, the US has a more integrated approach to public procurement of innovation, where one institution takes the innovation all the way from the development stage and can also create a market for it. This is not done in the UK.

Figure 4.1 Life science public procurement of innovation in the UK



Source: Copenhagen Economics.

The National Innovation Centre

The NIC was a recommendation in the 2004 action plan: Better Health Care Through Partnership – A Programme for Action, written by the Health Industries Task Force.

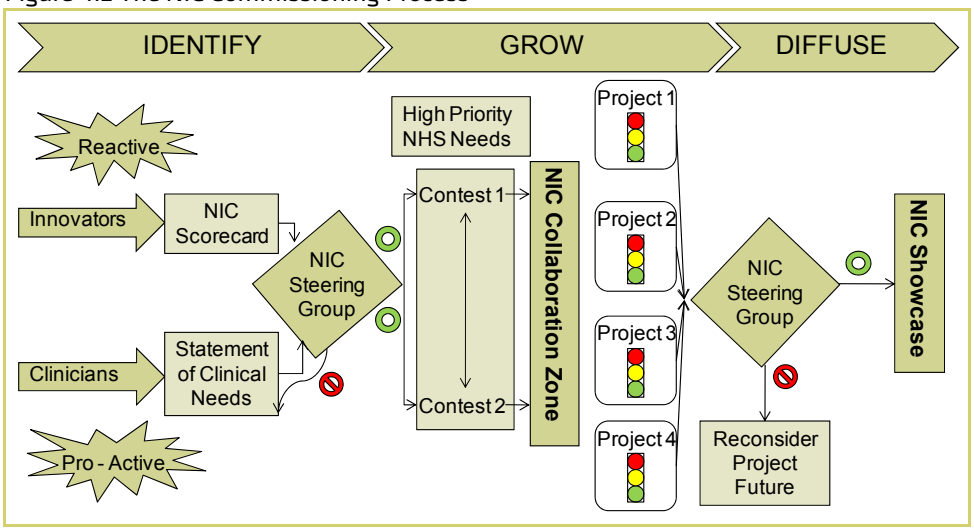
An overarching goal for the NIC's activities is to create a cheaper health care system which can solve its tasks in the ageing British society. To this end, the NIC supports innovators, clinicians and commissioners to speed up the development and use of innovations that will benefit the National Health Service.

How does the NIC contribute to public procurement of innovation?

The NIC performs three main types of activities: they identify technological needs, they "grow" new technologies and they diffuse new technologies within life sciences to the health care system in the UK.

The activities are interlinked (as shown in Figure 4.2) to ensure that the technological solutions which are developed are required by the health care practitioners, that the solutions become available when they are needed, and that the solutions actually reach the people who need them.

Figure 4.2 The NIC Commissioning Process



Source: Winn, Brian (2009).

The identification of technological needs concerns gathering and prioritizing ideas for new technological solutions which can improve health care.

There are two innovation processes used by the NIC: the proactive and the reactive innovation process.[51] These processes are ISO 2001 certified, meaning that they are highly standardized and thoroughly described with clear assignment of the responsibilities involved for the performance of all tasks in the process.

The proactive approach starts with the NIC assessing and defining a clinical need and stating it on their website. Once clinicians have formulated an idea, it is taken to the NIC's Steering Group. An expert group of clinicians help to identify the needs. The next step is to prioritize the different requirements. At the same time the NIC state their minimum requirements for the product in a statement of clinical needs. Should a product be presented to the NIC's steering group that they believe satisfy the criteria, they move on with the case. The rule for the competition is first come, first served. Should the product not fulfil NIC's requirements the future project is reconsidered. £30 000-40 000 is rewarded to the producer in the first round.

The reactive approach begins at the website and proceeds through scorecard to the Steering Group. This process is used when innovators themselves devise a new product for which the NIC have not identified a need. A scorecard is available online where innovators can assess their potential products. By using the scorecard a self-assessment is made and when the innovators think the score is sufficient they send it to the NIC. Another available resource support is a "tasks to do "group where help from experts is available. In the next step, the

[51] Telephone interview conducted with Dr Michael J Wilkinson, head of NIC (8/10-2009).

Steering group performs a professional assessment and decides whether they are interested in pursuing the product. Then the innovator can ask the NIC for the help they need to develop the product and a possible solution is discussed. At present, there are 750 registered innovators.

Personnel at the NIC are constantly surveying the market using *horizon scanning*, to see if the proposed product already exists, or if such a product is underway. If the product does in fact exist, a purchase is recommended. Should there not be a product, there is a competition between different potential suppliers.

In the growth-phase, following the identification of needs, there is a contest between different products. This is done in the NIC's Collaboration Space where high priority NHS needs are discussed. Once this is achieved, the product moves onto the last step of the growth process. Here, NIC Expert Advice is given to the project. It is then decided whether the project is given a green light which means moving on to the next step, a yellow light which means that more work is needed on the project or a red light, which means that the product development is cancelled.

The collaboration process consists of five main areas, namely Communication, User Profiles, Contact and Funding, Milestones and the Set up of Project Groups. In the communication area, innovators have access to a media space where videos can be broadcasted and blogs started. In User Profiles, registered users can let their profiles be viewed by others. In the Contract and funding zone, up to £20 000 can be given to the project by the NIC in addition to expert advice. In the Milestone zone, evidence of competition is to be provided. In the Set of Project Groups zone, project groups are started by users to address defined clinical needs.

In the diffuse phase, the NIC performs trials of new products in a clinical setting. This is used as a display to find external financing for the production of the innovation. It is also used to show the NHS the benefits of the new product so that they can agree to invest in it.

One of the NIC's aims is to facilitate the actual purchase of the innovations by the NHS. Another target is to create cost savings and increased efficiency. A different possible procurement strategy that has not yet been used by the NIC is forward commitment. This could be done in theory, but the problem is that the NIC is not a large organisation. The legal architecture exists, but the potential is not really used. The intellectual property resides with the supplier.

To summarize the concrete actions taken by the NIC, we can distinguish between the actions taken in the three phases in the following way:

Table 4.1 Actions taken by the NIC in different phases

Identify	Grow	Diffuse
Develop and analyze scorecards for ideas for new technology	Prioritize needs	Propose new products to PASA
Develop and analyze statements of clinical needs	Organise competition for innovation contracts	Develop showcases
Organise information from scorecards and statements of clinical needs	Provide expert advice to innovators	
Horizon scanning	Manage innovation projects	

Source: Copenhagen Economics.

The purchasing and supplies agency (PASA)

PASA was established 1 April 2000 as an executive agency of the Department of Health. The agency's aim is to modernise and improve the performance of NHS purchasing and supply system and become the centre of expertise, knowledge and excellence on matters of purchasing and supply for the NHS for the benefit of patients and the wider public.

PASA's purchasing activities are intended to deliver value for money both in the short and long term. The long term focus implies that the agency chooses to work strategically and may develop a diversity of suppliers to improve competition in the future.

Procurement of innovation is playing an increasing role in PASA's activities. The Integrated Procurement Framework, which has been adopted by PASA, stresses that purchasing should aim for true value rather than just the lowest price. The British government has developed a guide for public procurement of innovation, c.f. Department for Innovation, Universities and Skills and Office of Government Commerce (2006): *Finding and Procuring Innovative Solutions – Evidence-based Practical Approaches.* Finally, PASA is able to procure innovative solutions or challenge industry to innovate in situations where a solution is not readily available.

How does PASA contribute to public procurement of innovation?

PASA's activities may be called coordination and procurement.

The agency coordinates NHS purchasing, which involves defining procurement strategies, and setting up collaborative procurement hubs, where e.g. hospitals coordinate their purchases to achieve lower prices. Furthermore, the agency coordinates sourcing activities within the NHS.

The agency also does operational purchasing by negotiating national framework agreements on behalf of the NHS. The agency has responsibility for national purchases of:

- Pharmaceuticals
- Facilities (gas and oil, electricity, water, telecommunications, estates and transport)

- Agency and services (medical locums, nurses, allied health professionals, ancillary, scientific and technical staff, recruitment advertising, primary care trust purchasing and leasing)
- Medical devices (decontamination and medical maintenance)

Finally, the agency manages projects aimed at improving NHS purchasing. For example, the Health Care Associated Infections programme was managed by PASA. This programme entailed the innovation of a range of hospital equipment to reduce the risk of catching infections during hospitalization. The programme is described in more detail in Chapter 3.

Table 4.2 Actions done by PASA in different phases

Coordinate	Purchase
Managing the supply chain excellence programme, which amongst other things, sets up national procurement and collaborative procurement hubs.	Outsourcing
Set up common system for E-procurement in NHS	Framework contracts
Develop procurement strategies	Contracts

Source: Copenhagen Economics.

The legal framework of PASA

The PASA has a range of procurement tools at its disposal. However, the procurement made at PASA must obey the legal obligations relating to public procurement.

These include:

- EC and other international obligations, as implemented by British legislation or by direct effect
- Specific domestic legislation, for example, on unfair contract terms
- Contract and commercial law in general
- Domestic case law

The British, EC and international obligations include:

- *EC Treaty provisions* which prohibit: discrimination on grounds of nationality; restrictions on the free movement of goods and services; restrictions on the freedom of establishment of service providers; and measures of equivalent effect.
- *EC Public Services Directive* which: reinforces the above Treaty provisions for contracts above certain values; is based on principles of equal treatment, transparency and non-discrimination; establishes a framework of rules to which procedures for the award of supplies contracts by public bodies must be adopted; is implemented in the by Regulations (The Public Contracts Regulations 2006). Where contracts are let at a value below the current published thresholds for supplies contracts and, therefore, are outside the terms of the Directive, the general principles still apply to ensure compliance with British obligations under the Treaty of Rome.

- The World Trade Organisation (WTO) Government Procurement Agreement (GPA) under which obligations similar to those of the EC rules are enforceable by suppliers from other signatories to the GPA.
- The jurisprudence of the European Court of Justice and British courts.

Forward commitment in public procurements is an approach to procure R&D services, cf. Chapter 1 It means that e.g. the NHS commits to buy a certain product if it should appear in the market. These services can cover activities such as solution to a given problem, exploration and design of a new product as well as prototyping, provided it is only R&D services. This includes the original development of a limited volume of first products that may be used for field testing and to demonstrate the advantages with the new products.

An important aspect of forward commitment is that the procurement procedure should be designed to maximise competition and transparency throughout the process. One of the procurement requirements is to invite several companies to the development process to ensure that the best possible solution is found. The number of companies selected from the beginning should be done with consideration to the particular application field in question. At least two of these companies should participate up to the last phase of R&D.

What is not legal?

The crucial question regarding forward commitment in public procurement is whether the supplier in the procurement process receives any aid. As long as public authorities buy R&D from companies at market price, this should not constitute a problem, cf. Chapter 1 Should the procurement process not follow these guidelines, it will be regarded as State Aid and in that case assessed by the Commission according to Articles 87-88 of the EC Treaty.[52]

In the context of forward commitment of public procurement R&D does not include commercial development activities such as quantity production, supply to establish commercial viability, to recover R&D costs, nor does it include improvements to existing products or processes. The public purchaser cannot receive the R&D results exclusively in forward commitment of public procurement; instead risks and benefits have to be shared with the industry.

4.2. THE APPROACH IN THE UNITED STATES

The US has a very flexible approach to public procurement of innovation in the sense that there are many different types of programs that allow for contracting for innovation. Management of public procurement of innovation is generally done according to standard project management principles with heavy weight placed on achievement of milestones and follow-up on project progress. Public procurement of innovation has roots in laws about public

[52] EU Commission (2007a)

procurement, and there is much awareness in the public sector of the role played by public procurement of innovation.

The US has a long history of working with public procurement of innovation in life sciences. The efforts have been collected in two main organisations:

- Biomedical Advanced Research and Development Authority (BARDA)
- Defense Advanced Research Programs Agency (DARPA)

The two organisations differ in many respects, but do also share some features. We describe the organisations below.

Public procurement of innovation in BARDA

The Biomedical Advanced Research and Development Authority (BARDA) is an agency within US Department of Health and Human Services (HHS).[53] BARDA is responsible for the development and purchase of vaccines, therapies and diagnostic tools for public health medical emergencies. BARDA is built upon "The Pandemic and All Hazards Act" from 2006.

Box 4.1 The Pandemic and All Hazards Act

The Act states that:

The Secretary of Health and Human Services (HHS) is responsible for public health and medical response to public health emergiencies as defined in the National Response Plan.

To do this, the Secretary can draw on the necessary resources from other relevant Federal agencies.

The Biomedical Advanced Research and Development Agency is established within the Department of Health and Human Services.

BARDA undertakes activities which 1) are conducted after basic research and pre-clinical development, 2) are related to the manufacturing of products on a commercial scale.

BARDA's activities include: 1) testing products, 2) design or development of tests, 3) activities which facilitate manufacture of products on a commercial scale, 4) activities to increase the shelf-life of products, 5) other activities that are part of advanced stages of testing, refinement, improvement or preparation of the product.

BARDA's responsibilities are:

- Facilitate collaboration
- Support advanced research and development (among others: award contracts for product advanced research and development)
- Facilitate advice
- Support innovation (among others: award contracts, grants etc. to promote innovation)

Source: Copenhagen Economics.

BARDA is also responsible for Project BioShield where procurement and development of medical countermeasures for chemical, biological, radiological and nuclear (CBRN) weap-

[53] http://www.hhs.gov/aspr/barda/index.html

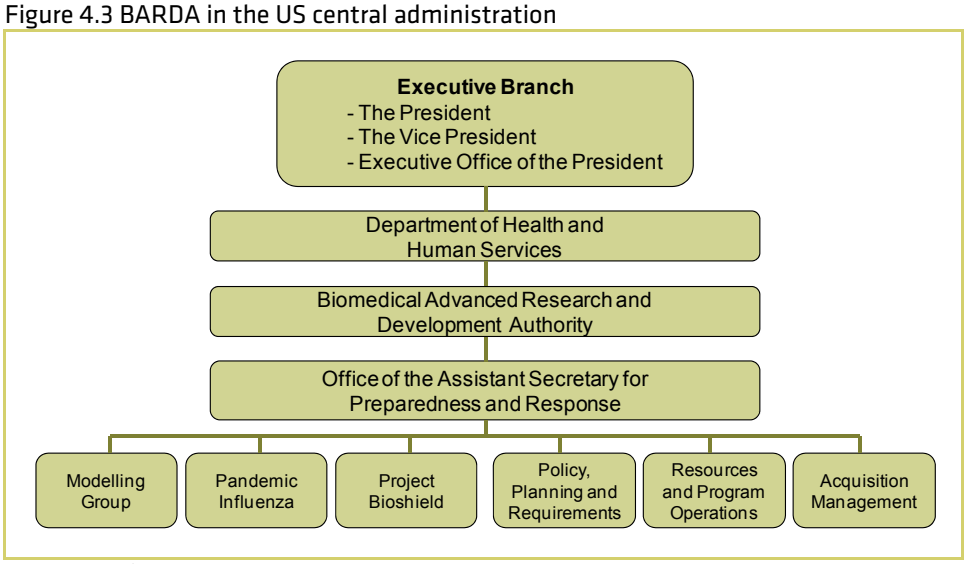
ons. The activities also include vaccines and drugs for pandemic influenza and other emerging infectious diseases.

BARDA is responsible for several medical countermeasures. These include vaccines; antimicrobial drugs; therapeutic products; diagnostics and non-pharmaceutical medical supplies and devices for public health medical emergencies including chemical, biological, radiological, and nuclear threats, pandemic influenza and emerging infectious diseases. BARDA's goal is to create multiple products in each program to create sustainability and redundancy. This enables BARDA to reduce the risk of attrition in the medical countermeasure development.

BARDA is authorized to fund research, to contract with firms for innovation and to procure final goods.

The authority is placed in the Office of the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services. It is interesting to note from the point of view of public procurement of innovation that BARDA has an entire office, which deals only with acquisition management. From Figure 4.3 we can see that acquisitions management is placed alongside the technical branches. BARDA also has a separate office for policy, planning and requirements, stressing the organisation's focus on management of innovation procurement.

Figure 4.3 BARDA in the US central administration



Source: Copenhagen Economics.

How does BARDA conduct public procurement of innovation?

The authority has four types of activities: identify, grow, diffuse and procure.

Identification of needs is done in collaboration with several government agencies through a process of possible scenarios where preparedness and response readiness is evaluated. The

Department of Homeland Security identifies threats in connection to chemical, biological, radiological or nuclear attacks. To assess the needs, gaps and effects for medical countermeasures on diseases such as smallpox and pandemic influenza, the BARDA Computer Modeling unit is used. The PMCE decision-making process is supported by BARDA's medical consequence modeling team, which conducts medical and public health consequence modeling. These projections are then used to undertake appropriate strategies to reduce health effects and estimate the quantity of medical countermeasures needed. Importantly, the Food and Drugs Administration, which is the final approver of drugs, is also involved in the process of specifying needs.

Technology Watch is another of BARDA's processes that consists of personnel seeking out all open-source information on candidate medical countermeasure products. This is done by searching scientific literature and visitations of conferences and industry presentations.

Stakeholders have the possibility of directly communicating information on candidate products by scheduling presentations to BARDA. They also have the possibility to respond to requests issued by BARDA. At the new website for stakeholders, MedicalCountermeasures.gov, they are able to request their technological accomplishments, products and programs.

Box 4.2 Medical countermeasure requirements

Medical countermeasure requirements are created through the use of four central documents that address different needs for planning:

- Threat-Specific White Paper: Gives a scientific background on the threat and health effects in case of exposure.
- Scenario-Based Requirements Paper: Specifies the currently available treatment and states the types and quantities of medicines needed in case of an attack.
- Utilization Policy: States the role of medical countermeasures before, during and after an attack. Examples of this are pre-event use and prioritization during a major attack.
- Product-Specific Requirements Paper: Gives the details of minimum and ideal characteristics of a medical countermeasure.

Further, the medical countermeasures requirements are reviewed in connection to three key questions:

- What types of medical countermeasures that could help given the severity of the illness?
- How many medical counterparts that are needed given the specific threat?
- What kind of product-specific characteristics of medical countermeasure would be effective in the case of a mass casualty event.

Source: http://www.hhs.gov/aspr/barda/index.html

An example of BARDA's activities to grow technologies is the construction as well as renovation of facilities for medical countermeasure manufacturing, in order to increase capacity and flexibility. Multiproduct manufacturing facilities are also used to further increase flexibility. Lastly, a network of manufacturers for emergency production and distribution has been created.

Another of BARDA's tasks in the grow phase is to manage programmatic risks.[54] This is achieved through a close observation of acquisition contracts. Examples of this are periodic

[54] US Department of Health and Human Services (2009)

conference calls with the contractor, periodic program review meetings with the contractor, periodic site monitoring visits and a provision of technical assistance to contractors to help resolve technical issues.

A Program Protection Office (PPO) was established by BARDA in 2007 to ensure security during the acquisition of medical countermeasures under the different BioShield programs. PPO's office is responsible for compliance with comprehensive security practices relating to physical security, information security and transportation security. Security awareness programs are also conducted at all contractor facilities that are supporting Project BioShield. Another responsibility for PPO is to coordinate with local, state, federal and foreign law enforcement agencies to share information on behalf of BARDA.

Finally, BARDA manages the procurement of medical devices and diffuses them to the relevant stockpiles around the US. The authority has access to many different tools in the procurement process including forward or advance market commitment, advance payments and other kinds of risk sharing arrangements. The diffusion of products is achieved through close collaboration with the Department of Homeland Security, which manages the stockpiles.

Table 4.3 Actions done by BARDA in different phases

Identify	Grow	Procure	Diffuse
White papers	Prioritize needs	Design contracts and write contracts	Facilitation of contact to other Health and Human Services agencies.
Technology watch	Organise competition for innovation contracts		Ensure delivery of products.
Requirements specifications	Provide expert advice to innovators		
Health risk assessments	Manage innovation projects (conference calls, meetings, follow-up, risk assessments)		

Source: Copenhagen Economics.

Public procurement of innovation in DARPA

DARPA finances high risk-high reward research with the aim of maintaining the technological superiority of the US military and to prevent technological surprises from harming national security. It also enables an effective transition from research to use of innovations.

The agency was founded shortly after the Soviet Union successfully sent Sputnik into space. This event was a shock to the US Government, who understood that the US should never be surprised by technological advancement in future. Therefore DARPA was founded in a directive from the Department of Defense in 1958.

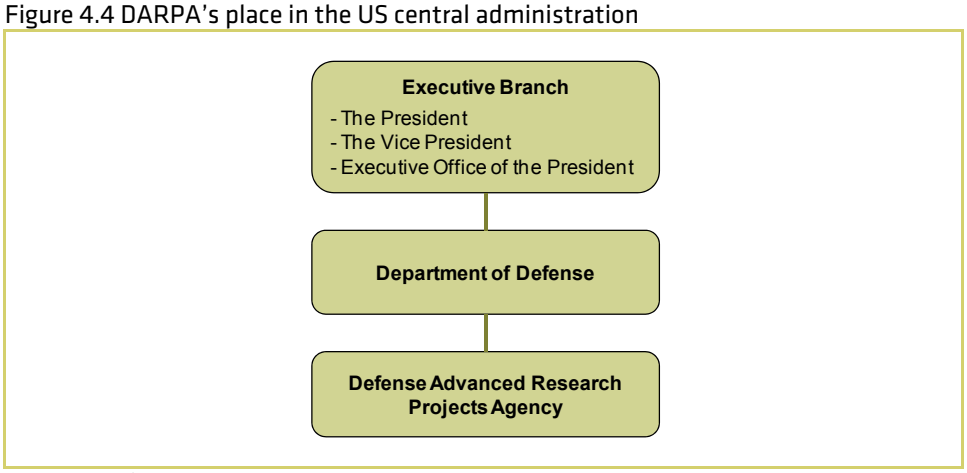
The directive specifies that DARPA is responsible for direction or performance of such advanced projects in the field of research and development as defined by the Secretary of Defense. DARPA is authorized to direct such research and development projects within the Department of Defense. It is also authorized to arrange for the performance of such projects

by other parts of government. Finally, it is also authorized to enter into contractual agreements for performance of projects by individuals, firms or educational, research and scientific institutions. DARPA is authorized to acquire or construct research, development and test facilities and equipment. DARPA's procurement activities are regulated by the Federal Acquisition Regulation, which allows DARPA to negotiate contracts on a competitive or non-competitive procedure.

We define DARPA's work as public procurement of innovation, because it often solicits the development of technical solutions to problems, where the solution is a well-defined product, which is delivered in the form of a prototype.

DARPA is placed relatively high in the US central administration, answering directly to the Secretary of Defense, as can be seen in Figure 4.4. This illustrates how high on the agenda public procurement of innovation is in the US, and the high level of awareness which exists regarding such work.

Figure 4.4 DARPA's place in the US central administration



Note: Copenhagen Economics.

DARPA monitors scientific development in a wide range of fields and considers how scientific breakthroughs can be put to military use. Therefore, DARPA plays a key role in defining the needs and potential for public procurement of innovation. It has both a proactive approach to public procurement of innovation, where DARPA defines the needs, and a reactive approach, where interested suppliers can contact a DARPA program officer and suggest a project, which may then be accepted for funding/contracting.

The tools used by DARPA to identify needs and potentials are workshops with academia and industry, but also horizon scanning work done by DARPA employees.

When a need has been identified, DARPA has several instruments to use for initiating a process towards meeting the need. Procurement contracts are used for products and services

which can be defined well enough for a contract to be issued. Grants are used for more basic research, where the outcome and the timing of the outcome are more difficult to specify. A cooperative agreement is similar to a grant, but there is a difference in how DARPA is involved in the project management. A grant is characterized by "hands-off" management, but a cooperative agreement is more "hands-on". Only procurement contracts are considered as public procurement of innovation.

A procurement of innovation starts with a request for proposals, where DARPA invites individuals and organisations to propose solutions to a specific innovation task. Then an evaluation of the received proposals is done, and a contract is awarded to the best proposal. After the contract has been awarded, DARPA manages the contractual relationship with the supplier. The Federal Acquisition Regulation contains specific tasks that the federal buyer has to perform to manage the contract. These tasks include status reporting, for example.

An example of a DARPA research project is Accelerated Manufacture of Pharmaceuticals – a program intended to result in process innovations which induce faster and cheaper production of pharmaceutics.

Table 4.4 Actions done by BARDA in different phases

Identify	Grow	Procure	Diffuse
Workshops and networking with academia, industry and Department of Defense	Requests for information	Design and writing contracts	Demonstrations of innovations.
	Requests for proposals		
	Contract and project management		

Source: Copenhagen Economics.

Chapter 5 THE FUTURE

More innovation is a central part of the Lisbon strategy, which aims to make EU the most dynamic and competitive knowledge-based economy in the world. Innovations are a key ingredient in achieving sustainable growth and full employment. Innovations are therefore also a key ingredient in an active industrial policy by governments.

Traditionally, Member States have supported various parts of the innovation system in a direct way, typically with a focus on creating attractive research and development environments. Very little attention has been given to the situation in which governments arguably affect markets most significantly, when acting as buyers.

The potential of using the public procurement tool as a vehicle for more innovation is vast. Representing 16 percent of European GDP[55], it is somewhat surprising that it has largely been neglected as an innovation policy tool for so long. The Commission has recently highlighted potential to stimulate more innovations. By introducing innovation as a more important evaluation criterion in public tenders, authorities can give firms the incentive to invest in the research of new solutions and products.

Public procurement of innovation is one way to achieve this. It occurs when a public organisation places an order for a product that does not currently exist, but could be developed within a reasonable period of time.

The purpose of this report is to evaluate the potential of public procurement of innovation in realising the warranted goals. We focus on health services – a significant sector in the EU. Our conclusions and recommendations below are based on in-depth case studies and extensive literature reviews.

5.1. CAN PUBLIC PROCUREMENT SPUR INNOVATION IN HEALTH CARE?

We conclude that public procurement of innovation in health may constitute an important tool to enable more and better innovations. Although the real-world examples are few, the ones we have scrutinised present a powerful case.

We have identified and analysed a handful of examples that, when taken together, clearly demonstrate that public procurement of innovation does occur and that it works. It delivers innovations which improve health care services. These examples can serve as inspiration for policy-makers and pave the way for more efficient innovation strategies.

Our cases are both from the pharmaceutical and the medical devices industries (see Table 5.1 below).

[55] European Commission (2005), page 10

Table 5.1 Cases of public procurement of innovation

Case	Innovation	Benefits for patients
1: Smallpox vaccine for the US	Third generation vaccine	Includes certain patient categories that previously were exclude
2: Hearing aids in the UK	Distribution of digital hearing aids	Better functionality
3: Blood bags	DEHP free bags	Less negative side-effects
4: Design bugs out	Cleanable furniture	Less risk for contamination
5: Pneumococcal vaccine	Vaccine for children in poor countries	Decreased child mortality

Source: Copenhagen Economics

These innovations were all achieved by means of public procurement of innovation. We conclude that the public procurer has an important role to play in encouraging such innovations. We also conclude that successful procurements of innovation require an efficient and appropriate organisational set-up.

The experience from the case studies indicates that there may well be potential benefits from using public procurement of innovation as a tool to improve health care services. Public procurement can play an important role in developing new products, services and processes that can provide benefits to patients and users of health care services. Public procurement of innovation can be used as a tool when new products are required in a reasonably short period of time, such that it leads to a solution of the problem more quickly than would have been the case without intervention from the public procurer.

5.2. WHAT ARE THE CRITICAL QUALITIES OF THE PUBLIC PROCURER?

An important message from the case studies is that procuring innovations is not easy. The exercise of defining the scope and aim of the procurement requires thorough knowledge of cutting-edge technologies and the main players in the market. The demands on the public purchasing agency are probably even higher in these cases than they are in more conventional tenders.

In the UK and the US, institutions have been established to carry out public procurement of innovation in health. We have not found similar institutions in the rest of Europe. Although the approaches in the UK and in the US differ considerably, they share a number of characteristics. There is an integrated process in which users participate, which serves to identify medical needs, to manage the innovation process and to diffuse the new technologies. There is also close collaboration between the public procurer and suppliers of innovative solutions, which is organised in such a way as to maintain competition between the suppliers.

There are a number of prerequisites that need to be in place to achieve a successful procurement of innovation. The public procurer should have the ability to:

- identify the need which will be met through procurement of innovation;
- provide a clear specification on the functional requirements of the innovation;
- provide incentives to the industry and ensure competition.

Firstly, the public procurer needs to be able to identify what kind of innovation is required, but does not yet exist, to satisfy the societal need. The assessment must also take into consideration whether it is possible to create the innovation within a relatively short period of time and to a reasonable cost. This could be done by taking a systematic approach where users are involved in the process of identifying problems, for instance. This has been a successful approach in both Case 2 about hearing aids and Case 4 regarding new furniture. In the first example, users were involved in identifying improvements to the hearing aid and in the latter, the designers observed potential improvements in hospital furniture.

Secondly, the public procurer needs to be able to formulate the need in terms of a specification of the innovation needed. Hence, the public procurers need to have the technical competence to specify the procurement. There will often be a high level of technical competence in the industry that creates the innovation. Limited technological competences on the behalf of the public procurer can be compensated with structures which allow for interactive learning between industry, researchers and the public procurer. Cooperation between the industry and the public procurer characterises all five cases in this report. In Case 3 on new blood bags, the industry commented on early versions of the specification, which led to a more flexible specification with a higher probability of delivering successful innovations.

Thirdly, the procurement need be set up in such a way that ensures sufficient incentives for the industry to embark on long and risky R&D projects. This could be done, for example, by giving access to a large market as is the case in Case 4 on new furniture, where the NHS indicates that they will order significant quantities. In Case 2 regarding hearing aids, incentives for the hearing aid producers were ensured access to deliver a number of services along with the hearing aids. However, competition needs be preserved throughout the process as far as possible.

5.3. Do we need new procurement agencies?

Hence, without a competent public procurer, there will be limited possibility of achieving successful procurement of innovations. The question then arises as to whether existing procuring bodies possess, or within reasonable efforts can acquire, the necessary skills.

In all cases studies, the procurer was an agency or organisation with a special focus on public procurement of innovation. These bodies have, in all cases, specified innovation as a prime quality of the suppliers which will be sought during the tender process. Drawing on these experiences, we conclude that a separate innovation procurement agency is a useful way to organise more procurements of innovation.

Drawing on the success of organisations in the UK and the US, we believe that an organisation with similar structural characteristics is an option worth exploring further for policy-

makers. In particular, the organisation should be arranged in order to consider fully the prerequisites listed in the previous section. Thus, we recommend an organisation which:

- has an integrated process for identification of needs and management of the innovation process which allows for an interactive learning process between buyers, vendors and end-users;
- has an integrated process for the formulation of specifications, which allows for an interactive learning process between buyers, vendors and end-users;
- has a process for procurement, which gives incentives to the industry to engage in the innovation, whilst at the same time ensuring competition between different suppliers of innovative products.

The experience in the UK and the US can be used as a starting point for such new organisations. The National Innovation Centre (NIC) in the UK has set up an organisational structure for the collaboration between NIC and clinical staff. And the specifications for the innovative products are formulated in collaboration with the industry and clinical staff.

The procurement agency should obviously comply with the regulations in the EU. The regulation poses certain restrictions to the scope and behaviour of public procurers in relation to procurement of innovation, but they do not constitute an obstacle. In fact, the underlying principles of both the procurement and state aid rules may even stimulate governments to design appropriate strategies for procurement of innovation which allows for both innovations and competition between suppliers.

5.4. OUR RECOMMENDATIONS

Our overall recommendation is that governments and the Commission should further explore ways to increase the volume of public procurement of innovations. The experience so far indicates that this policy tool can result in better products in the health care sector, better quality of health services and ultimately higher growth and increased employment.

Specifically, we recommend policymakers to consider the following:

1. A strong and competent public procurer

Drawing on the successful procurement of innovation organisations in the UK and the US, it is clear that a well-designed organisational public structure facilitates successful public procurement of innovations. We recommend that EU Member States consider these examples. In particular, it is important to design organisations with an integrated process for identification of needs, a process for the formulation of specifications as well as the ability to handle the procurement process. There are two ways of implementation: one is to establish a new public body responsible for public procurement of innovation in health. Another is to reform existing structures in order to meet the same demands.

2. Identifying true needs are critical

The first critical task of the public procurer of innovation is to clearly identify the needs. This process should be organised such that all ideas are gathered from clinical staff, researchers, users and entrepreneurs. By organising this process systematically, the procurer can ensure that the most promising prospective innovation paths are taken forward.

3. Tender specifications need give entrepreneurs sufficient flexibility

Next, specification of the aim of the procurement of innovation is vastly important. The specification should be focused yet not overly demanding or restrictive. For instance, there is a trade-off between the coverage of pneumococcal vaccines and the cost of developing new vaccines. Vaccines that take into account regional differences between developing countries would be more costly to develop and could lead to fewer companies wishing to make the necessary investments or being able to supply the vaccines.

Whether the specification is defined in terms of improved performance, or in terms of the technical requirements, must depend on the specific product. However, giving too strict guidelines about the actual design may result in omitting viable solutions. For instance, a blood bag does not necessary need to be welded, provided that the bags are sealed in a sterile way.

4. Preserve competition throughout the process

Finally, the innovation tenders must be characterised by competition between suppliers. Adequate compensation for costs should be considered, but at market prices.

This can be achieved by offering the right incentives. The incentives could take the form of access to a new and promising market. If the public procurer pays for the development cost via a procurement of innovation, IPR should be owned by the companies only if competition in the market for the products can be ensured in the future.

To a certain extent, it may be necessary to allow the suppliers to retain some of the IPR ownership rights in order to make a public procurement of innovation attractive for the most innovative companies. There are a range of possible arrangements concerning the division of benefits between the procurer and the company concerning IPR rights. However, any such arrangement has to ensure that all potential bidders have equal chances to bid and that it does not discriminate against anyone.

REFERENCES

AMC Expert Group (2008), *Advance Market Commitment for Pneumococcal Vaccines*, Advanced Market Commitments for vaccines Consultation and Advisory Process.

AMC Press Release (2009), *GAVI Partners Fulfill Promise to Fight Pneumococcal Disease*, GAVI Alliance http://www.gavialliance.org/media_centre/press_releases/2009_06_12_AMC_lecce_kick_off.php

Arvidsson, Göran, Bergström, H., Edquist, C., Högberg, D., & Jönsson, B., (2007), *Medicin för Sverige! Nytt liv i en framtidsbransch*, SNS Förlag.

Binks, James (2006), *Using Public Procurement to Drive Skills and Innovation - A Report for the Department of Trade and Industry*, Local Futures.

Clemensen, J. (2006), *Pervasive Healthcare: Home Treatment of Patients with Diabetic Foot Ulcers*, Thesis, University of Aarhus.

Ecomotion, (1995), *Swedish Refrigerator Procurement*, The Results Centre. http://www.ecomotion.us/results/108.htm

Edquist Charles, Hammarqvist P. & Hommen ,L. (2000), in Edquist et al. (2000), *Public Technology Procurement and Innovation*, USA.

Edquist, Charles (2004), in Vinnova (2004), *Svensk innovationskraft – visionen måste vara starkare än motståndet, VFI 2004:02.*

Edquist, Charles (2009), *Public Procurement for Innovation (PPI) – a Pilot Study*, Lund University.

Edquist, Charles., Hommen, L. & Tsipouri, L. (eds) (2000), in Edquist et al. (2000), *Public Technology Procurement and Innovation*, Springer.

Energimyndigheten (2004), *Teknikupphandling som styrmedel – metodik och exempel*, Statens energimyndighet.

European Commission (2007a), *Pre-commercial Procurement: Driving innovation to ensure sustainable high quality public services in Europe*, COM(2007) 799 final, Brussels.

EU Commission (2007b), *Accompanying document to the Pre-commercial Procurement: Driving innovation to ensure sustainable high quality public services in Europe – Example of a possible approach for procuring R&D services applying risk-benefit sharing at market conditions, i.e. pre-commercial procurement*, COM(2007) 1668, Brussels.

European Communities (2006), *Creating and Innovative Europe*, EUR 22005, Brussels.

European Communities (2005), Public Procurement for Research and Innovation. Developing procurement practices favourable to R&D and innovation. Expert group report. Directorate General for Research

Eurostat (2009), Public Health, Data from 2006. http://epp.eurostat.ec.europa.eu/portal/page/portal/health/public_health/database

Figueras, J. et al., (2005), *Purchasing to Improve Health Systems Performance*, WHO.

GAVI and IBRD (2009), *Offer Agreement relating to the Advance Market Commitment for Pneumococcal Vaccines*.

Jegrelius (2008), *Projektbeskrivning: Innovationsupphandling av blodpåsar – ett pilotfall för stimulera miljöanpassad produktutveckling inom sjukvården*, Projektbeskrivning, Jegrelius Forskningscenter.

Laage-Hellman, J. (2009), "How are successful innovations created in life science?", Unpublished paper, Chalmers University of Technology, Dept. of Technology Management and Economics

Luce, B. et al. (2006), in Arvidsson, Göran, Bergström, H., Edquist, C., Högberg, D., & Jönsson, B., (2007), *Medicin för Sverige! Nytt liv i en framtidsbransch*, SNS Förlag.

OECD (2008), *OECD Health Data 2008*, OECD Publications.

OECD (2009), *OECD Work on Innovation – A Stocktaking of Existing Work*, STI Working Paper 2009/2, Unclassified.

Office for National Statistics (2009), *Expenditure on Health Care in the UK*, Office for National Statistics. http://www.statistics.gov.uk/articles/nojournal/Expenditure-on-health-09.pdf

Vinnova (2007), National and Regional Cluster Profiles – Companies in biotechnologies, pharmaceuticals and medical technology in Sweden, VA 2007:16.

Vinnova (2008), A Benchmarking Study of the Swedish and British Life Science Innovation Systems – Comparison of Policies and Funding, VA 2008:12.

Phillips, Wendy, Knight, L., Caldwell, N. & Warrington, J., (2007), Policy Through Procurement – The Introduction of Digital Signal Process (DSP) Hearing Aids into the English NHS, Health Policy, Volume 80, Issue 1, pp 77-85.

Thomsson, Sarah, Foubister, T., & Mossialos, E. (2009), *Financing Health Care in the European Union – Challenges and Policy Responses*, European Observatory on Health Systems and Policies.

U.S. Department of Health & Human Services (2009). http://www.hhs.gov/aspr/barda/index.html.

WHO (2008a), *Part II: Target Product Profile (TPP) for the Advance Market Commitment (AMC) for Pneumococcal Conjugate Vaccines Supplementary Information, WHO.*

WHO (2008b), *Pneumococcal Regional Serotype Distribution for Pneumococcal AMC TPP, WHO.*

Winn, Brian (2009) *The NIC Commissioning Process*, Innovation Centre.

The purpose of this report is to evaluate the potential of public procurement of innovation in health care services. The report is a part of the background material for the conference Public Procurement of Innovation – A Driver for Future Health in Europe, organised by VINNOVA in October 2009.

Examples of public procurements of innovations are, indeed, few in the world. Nevertheless, those that exist tell us an inspiring story. Our five original case studies from Europe and the US provide a clear message to policy makers. We conclude that the public sector has an important role as a partner to commercial interests in achieving the innovations in health care that otherwise would not materialise.

COPENHAGEN ECONOMICS