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Report

Value-based procurement of hospital medicines

Denmark

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Value-based procurement of hospital medicines – Denmark

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VIVE was established on 1 July 2017 following a merger of KORA and SFI. The Centre is an independent government institution that is to provide knowledge that contributes to developing the welfare state and the public sector. The subject areas and tasks of VIVE are the same as those of the two former organisations.

Foreword

Along with ambitions of using procurement practices to maximise health outcomes per money spent, new questions arise about the organisation of procurement processes and the application of evaluation criteria. Novartis Healthcare A/S has approached VIVE to obtain an overview of Danish experiences with the inclusion of other evaluation criteria than price in the procurement of hospital medicines. The present report presents the results of this study.

The report builds on document analysis and interviews with key stakeholders. The authors wish to thank the informants for their time and valuable input to the report.

Prior to publishing, the report was reviewed by the two external reviewers, Lars Nielsen and Jan Sørensen, who the authors also wish to thank.

Pia Kürstein Kjellberg, Head of Research, VIVE, Health
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Resumé

In recent years, an increased focus on value has gained prominence in health policy debates and inspired healthcare reforms. In the wake of this, calls have been made for governments to use public procurement mechanisms to obtain more public value for the money. This study explores current endeavours to install value-based procurement of pharmaceuticals in the Danish hospital services. We define value-based procurement as the endeavours of procurers to use their purchasing power to stimulate competition on parameters other than price or on price in combination with other criteria.

Based on document analysis and 11 semi-structured interviews with 13 stakeholders, the aim of the study is to:

1. map current initiatives of Danish healthcare authorities to use procurement mechanisms to stimulate competition on other parameters than price
2. identify challenges and opportunities for healthcare authorities and pharmaceutical companies in relation to the ambition of 'value-basing' pharmaceutical procurement
3. provide a brief comparison with the Danish market for medical devices to tease out any lessons pertaining to value-based procurement
4. discuss the results in relation to the wider political agenda of value-based healthcare and make recommendations for future investigations.

Important steps taken towards value-based procurement in the Danish hospital services

As in several other Nordic countries, pharmaceutical procurement in Denmark is characterised by a high degree of centralisation. Denmark has a single national set-up for the procurement and supply of hospital medicines and has a tradition of national tenders of hospital medicines dating back to 1990. Recently, Denmark has taken important steps towards a procurement system that recognises multiple dimensions of pharmaceutical value. Several attempts, covering a range of market situations, have been made to stimulate competition on parameters other than price.

As of 2017, an evaluation model for hospital medicines, combines health technology assessment (HTA) with price negotiations for newly marketed products and products with new indications. The evaluation model provides for an encompassing conception of pharmaceutical value that includes clinical effectiveness, safety, quality of life or other patient-relevant outcomes, in addition to treatment costs pertaining not just to hospitals but also other healthcare providers, patients and their relatives. In addition, tendering – the most widely used procurement mechanism – has increasingly come to encompass other dimensions of value than price. In some cases, this is done directly in the process of tendering through the inclusion of evaluation criteria, such as the storage life of products and safe drug administration. In other cases, it is done indirectly through the coordination of tenders with clinical guidelines. This implies that tender prices are included in an encompassing cost analysis (restricted societal perspective), which in turn informs a ranking of products under groups of treatments deemed to be therapeutically equivalent.

Whereas these procurement mechanisms set the stage for an encompassing conception of pharmaceutical value, the actual impact of patient-relevant outcomes appears limited. Constraints include a lack of clarity regarding what constitutes acceptable outcome measures and documentation requirements imposed by evidence assessment tools. On the cost side, a range of parameters can be counted in, but their actual impacts tend to depend on the drug price. For patent-protected products, the price will typically drive most of the incremental costs. In effect, this often makes price the most influential parameter.

Currently, there is no experience with performance-based risk-sharing in Denmark, and neither indication-based pricing nor bundling is accepted. However, possibilities for indication-based pricing is being negotiated among industry representatives and healthcare authorities.

Support of the idea of value-based procurement but practical constraints

Overall, the idea of value-based procurement enjoys support from the interviewed political and administrative actors at the national and regional level, as well as the pharmaceutical industry associations. However, stakeholders also express concern over the idea of value-based procurement.

While the legal framework generally allows procurers to stimulate competition on parameters other than price, as long as principles of transparency and non-discrimination are respected, the stakeholders draw attention to the resulting documentation requirements and administrative costs.

The national and regional healthcare authorities, in particular, express concern about monitoring requirements in relation to performance-based risk-sharing and indication-based pricing. Outcome-based payment for medicine raises important questions about how outcomes are to be documented, which data count as valid evidence, how to demonstrate causality between treatment and outcomes, and who is to pay for the generation of evidence. The general perception among the interviewed stakeholders is that clear answers to these questions are still lacking. Furthermore, they see it as a real challenge to establish consensus about these answers, because the demonstration of product value constitutes a key parameter of competition among pharmaceutical manufacturers.

In addition to these reservations, public authorities raise concern over the possibility of a more direct involvement of pharmaceutical companies in patient treatment, and express distrust in the willingness of manufacturers to accept financial risks.

Importantly, value-based procurement can also impose costs on manufacturers, as they have to prove their case. If a manufacturer is unable to provide documentation for its case in a direct competition, they can be forced to lower their prices to stay competitive.

Generally, the interviews indicated that when the value of a given innovation is stated as merely being a matter of patient convenience it is less likely to influence procurement decisions than if a convincing case can be made for potential savings or improved treatment outcomes. In particular, public authorities expressed an interest in solutions that can facilitate easier and safer administration of medicine outside the hospitals. However, historical examples demonstrate that local budget constraints can limit the actual demand, even if public procurers embrace innovative and cost-effective solutions.

Glossary

CEA	Cost-effectiveness analysis
EMA	The European Medicines Agency
HTA	Health Technology Assessment
IGL	The Danish Generic and Biosimilars Medicines Industry Association
GRADE	Refers to a particular approach to the rating of evidence quality, developed by the Cochrane collaboration. GRADE stands for Grading of Recommendations, Assessment, Development and Evaluation.
KRIS	KoordineringsRådet for Ibrugtagning af Sygehusmedicin (council for coordinated introduction of hospital medicines). Established in 2009. Replaced by the Danish Medicines Council from 2017.
Lif	Lægemiddelindustriforeningen; The Danish Association of the Pharmaceutical Industry. The industry association for research-active pharmaceutical companies.
MEAT	the Most Economically Advantageous Tender; award criterion in EU tenders
PRO	Patient-Reported Outcomes
RADS	Rådet for Anvendelse af Dyr Sygehusmedicin (council for use of expensive hospital medicines). Established in 2009. Replaced by the Danish Medicines Council from 2017.
QALY	Quality-Adjusted Life Years; outcome measure used in, for instance, health economic evaluations

1 Introduction

In healthcare regulation, an increased focus on value has recently gained political traction. This can be seen in, for instance, the spread of *value-based healthcare* as a healthcare reform strategy (Ebbevi et al. 2016)[1] and debates on value-based procurement in the pharmaceutical and medtech industries. While specific initiatives aiming at 'value-basing' the healthcare services differ (Frederiksson, Ebbevi & Savage 2015; Rud Petersen & KORA 2015), they typically share an ambition of moving from volume to outcomes meaning that payment for healthcare services is linked more closely to the results of given interventions.

Following these tendencies, public procurement practices have also been subject to debate. Following the revision of EU public procurement legislation[2], calls have been made for governments to use public procurement mechanisms actively to stimulate innovation of medical products such as biological medicines (EuropaBio 2015). Meanwhile, government policies aiming to control pharmaceutical costs increasingly include value-based criteria (Comanor et al. 2018).

'Value' is an empty signifier, in the sense that it may mean different things to different people. Therefore, the ambition of linking payment for healthcare interventions more closely to the value they create raises important questions of how to define and operationalise the 'value' of healthcare interventions such as pharmacological treatments. More generally, the ambition of actively using procurement practices to stimulate innovation on product traits deemed valuable recasts the relationship between state and market: from the neoclassical viewpoint that government intervention is warranted only in case of market failure, this calls for an active market-making and market-shaping approach of government institutions (Mazzucato & Semieniuk 2017).

1.1 Project aims

This report explores current attempts at 'value-basing' the procurement of pharmaceuticals in the Danish hospital services. Based on document analysis and interviews with key stakeholders, the aim is to:

1. map current initiatives of Danish healthcare authorities to use procurement mechanisms to stimulate competition on parameters other than price
2. identify challenges and opportunities for healthcare authorities and pharmaceutical companies in relation to the ambition of 'value-basing' pharmaceutical procurement
3. provide a brief comparison with the Danish market for medical devices to tease out any lessons pertaining to value-based procurement
4. discuss the results in relation to the wider political agenda of value-based healthcare and make recommendations for future investigations.

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[1] The concept of value-based healthcare originates from the work of Harvard professors Michael E. Porter and Elisabeth O. Teisberg (2006). It was developed as part of an overarching philosophy for reorganising the American healthcare system, but the idea has spread far and rapidly. A quick search on google.scholar indicates that in ten years (2006-2016) Porter & Teisberg's book Redefining Health Care: Creating Value-Based Competition on Results has been cited about 1400 times. Their work has inspired changes in hospital payment systems (Indrakanti et al., 2012), performance measurement systems (Hillary, Justin, Bharat & Jitendra, 2016) and programs of patient involvement (Ebbevi et al. 2016; Hillary et al. 2016), for instance.

[2] https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:32014L0024.

1.2 Structure of the report

We start by developing the framework for the analysis, and explaining central concepts and the scope of the analysis. In the subsequent analysis, we first provide a brief description of the organisation and regulation of the Danish market for hospital medicines, and describe current initiatives of the healthcare authorities to use procurement mechanisms to stimulate competition on parameters other than price. Then, we discuss the challenges and opportunities that the stakeholders identified in relation to value-based procurement. The stakeholders include the joint regional procurement institution, Amgros; the interest organisation for the five regional authorities in Denmark, Danish Regions; a regional politician; the Ministry of Health; the Ministry of Finance; the pharmaceutical industry associations Lif and IGL; and the Danish Cancer Society. Lastly, we provide a brief comparison with the Danish market for medical devices, before summing up with a discussion. The comparison with the medical device market builds primarily on interviews with Medicoindustrien – the industry association for medical device manufacturers – Coloplast and Alcon. A description of the methodological approach can be found in Appendix 1.

2 Central concepts and scope of the analysis

2.1 Hospital medicines

In Denmark, the regulation of pharmaceutical procurement differs depending on the site of procurement and dispensing (Højgaard et al. 2017). This project focuses on the procurement of hospital medicines, i.e. pharmaceuticals procured by hospitals and used for the treatment of patients who are hospitalised or receive medicine from the hospital for treatment outside the hospital (Danish Ministry of Health and Prevention 2009). For instance, some forms of chemotherapy may be dispensed from a hospital pharmacy for the home-treatment of a patient. The Danish Pharmacy Act (Apotekerloven)[3] establishes rather strict limits for the situations in which pharmaceuticals can be dispensed from hospitals for treatment of patients outside the hospital setting.

2.2 Value-based procurement

Attempts to define the 'value' of pharmacological treatments are varied. Aspects to consider include – but are not limited to – clinical efficacy and effectiveness, safety and tolerability, security of supply, secure packaging, effects on patients' quality of life, patient preferences, ease of use, direct and indirect healthcare costs, societal productivity gains, risk reduction (e.g. related to the spread of infection or environmental impact) and treatment innovation. Which aspects are taken into consideration will depend on the perspective from which the value is assessed, such as the perspective of patients, healthcare systems or society at large (Drummond et al. 2005: 17-20).

In this project, value-based procurement is defined as the attempts of procurers to use their purchasing power to stimulate competition on parameters other than price or on price in combination with other criteria. This definition does not specify *a priori* what value is. Hence, it allows for open exploration of what dimensions various stakeholders see as important in assessments of the value of pharmaceuticals[4].

The focus on procurers implies that we take a national perspective. Clearly, national procurement practices are not independent of supranational policies and practices. As pharmaceutical products are increasingly introduced to national markets based on centralised assessment by the European Medicines Agency (EMA), safety and effectiveness criteria are harmonised. Such supranational standards are likely to inform evidence production, e.g. through the choice of outcome measures, and thereby the availability of data to document the value of a given treatment in conjunction with national procurement practices. While the interplay among supranational and national standards for the assessment of pharmaceuticals warrants further analysis, this is outside the scope of this analysis.

2.3 A life-cycle perspective on pharmaceutical procurement

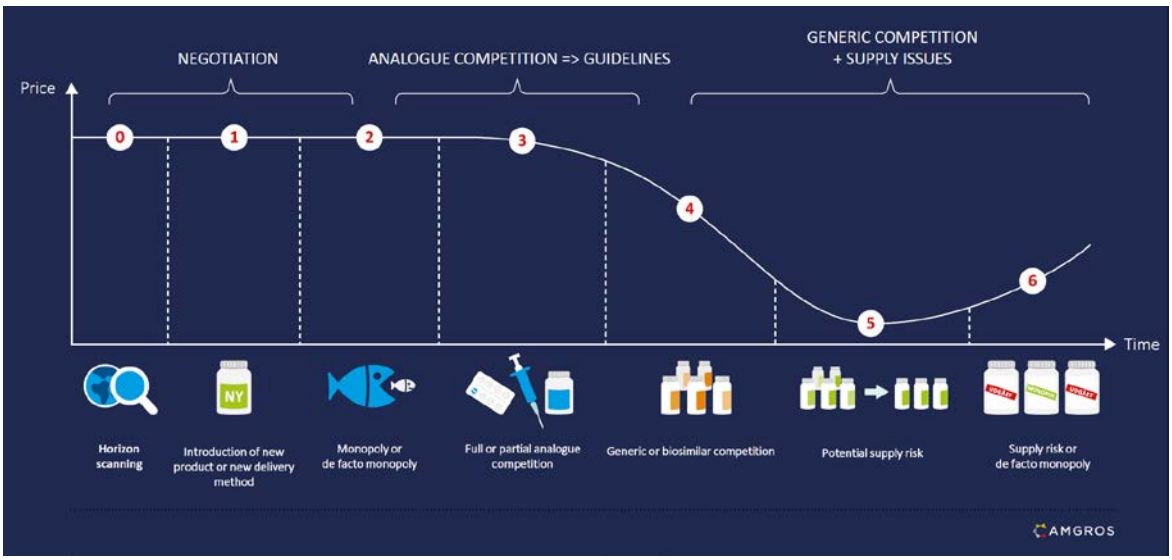
When studying the attempts of procurers to stimulate competition on price and other parameters, it is key to acknowledge that different market situations provide different opportunities for procurers to use their purchasing power (Kettl 1993: 36-39). One way to illustrate this in the pharmaceutical

[3] Apotekerloven § 55 and § 56.

[4] This explorative approach differs from most health economic analyses, which define *a priori* what is conceived as value, and is also distinct from Porter's notion of value, which is basically modelled over a cost-effectiveness logic (value as 'the health outcomes achieved per dollar spent' cf. Porter 2008, p. 503).

market is to sketch how the market situation varies according to the stage of market development in a given therapeutic field. Borrowing from the Danish procurement organisation for medical products, Amgros, we refer to this as a life-cycle perspective on pharmaceutical procurement. Figure 1 depicts various stages of market development. In this report, we deal with stages 1-4. Rather than an empirical representation, the figure is intended as an ideal model, to foster conceptual understanding. Importantly, the stages are not static, nor is the development given. Rather, the strategies of providers as well as procurers in each of the stages can influence the course of development. These points will be developed below.

Figure 2.1 Life-cycle perspective on market conditions and procurement mechanisms



Source: Amgros (copyright holder).

2.3.1 Early stages of market development

When a new product or delivery method is introduced to the market, patent regulation limits the competition, and the manufacturers will typically be able to demand a relatively high price due to market exclusivity. A monopoly or *de facto* monopoly situation arises when the innovation breaks with existing treatment regimes, for example if a disease-modifying treatment is marketed for an indication for which only symptom relief has previously been possible.

In these situations (stages 1-2), an opportunity for procurers is to stimulate *indirect* competition through benchmarking of a new product against existing standard treatment. In Europe, this is increasingly done through health technology assessments (HTAs) (Brousselle and Lessard 2011; Drummond et al. 2011). While there is some convergence among the European countries in terms of the regulatory measures used to deal with situations of limited competition, the status and regulatory use of HTAs differ considerably among European countries (Højgaard et al. 2016).

In the past decade, European countries have experimented with various types of pricing schemes, ranging from price-volume agreements to various forms of risk-sharing arrangements, bundling and indication-based pricing (Rasmussen et al. 2011; Drummond 2015). While price-volume agreements are used in several European countries, experiences with indication-based pricing and risk-sharing are more limited (Rasmussen et al. 2011; Gonçalves et al. 2018).

Indication-based pricing refers to a situation where different prices are charged for the same product depending on the documented effectiveness for given indications[5]. This practice is disputed among economists. Proponents argue that it will create an incentive for manufacturers to reduce prices for indications for which their products confer less benefit. Critics, however, caution that while this form of price discrimination may expand access for products currently priced so high that they are unavailable for some indications, the same 'access-expanding pricing flexibility' also allows manufacturers to increase prices for what is seen as 'high-value' indications, and there is no guarantee that this will not increase overall spending (Chandra 2017).

Performance-based risk-sharing refers to schemes in which the payment (or the reimbursement) of a product is conditional on the demonstration of therapeutic benefit through post-market data generation (Drummond 2015). Such arrangements may include 'no cure – no pay' agreements or *post hoc* price regulation based on demonstration of clinical effectiveness. According to economist Michael Drummond (2015), risk-sharing can be a valid option when clinical or economic benefit can be defined and measured in a valid way, when further studies are likely to reduce uncertainty about the clinical or economic benefit within an acceptable time frame, when there is sufficient organisational capacity to implement the required set-up for data generation and analysis and when unambiguous contractual conditions can be defined.

2.3.2 Later stages of market development

When several products are marketed for the same indication (stages 3-4), procurers have the opportunity to stimulate *direct* competition through tenders. Within the legal framework set by procurement regulation and competition rules, procurement agencies are in a position to shape market dynamics through the definition of what to buy and by setting criteria for the assessment of bids. Before patent expiration, price competition will typically be limited. By contrast, the introduction of generic competition after patent expiration typically involves rather fierce price competition. Concerning biosimilars, the market situation differs somewhat among the European countries (Moorkens et al. 2017), possibly because of varying conceptions among clinicians as to the equivalence of biological treatments and biosimilar alternatives.

Importantly, the procurement mechanisms used in one stage may influence the dynamics in subsequent stages. For instance, if the use of innovative pricing agreements in the early stages effectively limits the incentives for competitors to enter or stay in the market, the possibilities for procurers to stimulate direct competition through tenders in later stages are limited. Also, if tenders (stage 4) reduce the price level of certain products too effectively, manufacturers may withdraw, thus reducing market diversity and increasing the risk of supply shortage and *de facto* monopoly with rising prices (stage 5-6).

[5] In oncology, for instance, the treatment response of patients to a treatment typically varies depending on the type of tumour and the stage of the disease.

3 Pharmaceutical procurement in the Danish hospital sector

3.1 Brief description of the Danish hospital sector

Denmark is a small and relatively wealthy welfare state. Five regional authorities are politically and administratively responsible for organising health service delivery, including the tax-funded and publicly owned hospital sector. Healthcare professionals working in the hospital sector are public employees.

The regional healthcare budget is laid down in yearly negotiations with the Ministry of Finance and is allocated to the five regions as a block grant. Democratically elected members of the regional councils have the overall responsibility for keeping the budget and allocating resources. This also implies that it is the responsibility of the regional authorities to effectuate cost-reducing initiatives, if expenditures, e.g. for pharmaceuticals, exceed the expected level. According to the interest organisation for the five regions, Danish Regions, the regions can request dialogue with the government (through the Ministry of Finance) about the pharmaceutical expenses, after the budget agreement has been made. However, this does not imply that the regions are guaranteed extra resources; it is merely an opening for discussion about the budget. Representatives from the Ministry of Finance confirm that pharmaceutical expenditure is not a specific field of interest for the central authorities, but a responsibility of the regions.

In principle, the pricing of pharmaceuticals is free in Denmark. In practice, though, pricing is regulated through voluntary agreements. For hospital medicines, the prices are regulated based on a model of reference pricing agreed upon by the pharmaceutical industry association, Lif, and the national and regional healthcare authorities. In addition, these parties have agreed upon a 10% reduction in official list prices for hospital medicines from 2016-2019 (Ministry of Health & Danish Regions 2016).

There is no co-funding for patients for hospital medicines, meaning that the Regions pay all costs of hospital medicines. Since 2012, hospital medicines have accounted for most of the public expenses on medicines. From 2008 to 2017, the expenses (2017 prices) for hospital medicines increased from DKK 5,523 million to DKK 8,441 million (53%). In 2016, the expenses for hospital medicines accounted for 60% of the total pharmaceutical expenses. From 2008 to 2017, the public expenses (2017 prices) for medicines dispensed in the practice sector decreased from DKK 8,331 million to DKK 5,598 million (33%). Overall, the pharmaceutical expenses increased from DKK 13,854 million in 2008 to DKK 14,039 (1%) in 2017[6].

Hospitals are compensated for medicine expenses by the regions on a running basis. Because of decentralised budget responsibility, there is an economic incentive for the hospitals to keep within the budget allocated from the Regions. Generally, the hospitals are compensated for a large share of the increasing medicine expenses through the budgeting, but there are certain differences between the financial control models applied by the Regions, as illustrated in Table 3.1. In The North Denmark Region, the expected expenditure growth is included directly in the hospital budgets. Therefore, the hospitals do not receive any reimbursement from the regions for costs that exceed the allocated budget. In the other regions, the expected expenditure growth is included in a regional medicines account, which places the major budget risk at the regional level, but also the option of

[6] The estimates were made by the authors based on data from Amgros and Statistics Denmark. The price adjustment is based on the index provided by the Danish Ministry of Finance: https://modst.dk/oekonomi/bevillingslove/indeks/fastprisberegninger/.

re-allocating potential savings. For costs that exceed the allocated budget, the degree of compensation varies a little among the regions: 80% in the Capital Region and 100% in the other three regions. In most of the regions, compensation is conditional on compliance with national or regional guidelines or approval from the hospital management and the regional pharmaceutical committee (Danish Regions 2016a). As such, the financial control models provide strong economic incentives for hospitals to comply with formal treatment recommendations. To the extent that procurement agreements are aligned with or integrated into regional guidelines, the financial control models also provide indirect incentives for the implementation of these agreements.

Table 3.1 Financial control models for hospital medicines expenses in the five regions

Regions	Capital	Zealand	Southern Denmark	Central Denmark	North Denmark
Major budget risk	Regional level	Regional level	Regional level	Regional level	Hospital level*
Automatic compensation for hospitals for costs exceeding the allocated budget	80%	100%	100%	100%	0%
Conditions for compensation	Compensation conditional on compliance with national treatment recommendations or approval from the regional pharmaceutical committee	Compensation only given for medicines included in regional positive list	Compensation conditional on compliance with national treatment recommendations	Compensation only given for medicines included in regional positive list	Hospitals can request compensation, if budgets are exceeded. Re-allocation of potential savings require regional approval.

Note: *One university hospital accounts for 85% of the total hospital medicines expenses in the Region.
Source: Table content developed based on Danish Regions 2016a.

3.2 Organisation and regulation of pharmaceutical procurement

As in several of the Nordic countries, and in contrast to many other European countries, pharmaceutical procurement in Denmark is characterised by a high degree of centralisation (Højgaard et al. 2016; Højgaard et al. 2017).

Following public debate on the increasing expenditures for hospital medicines, the regional authorities launched a new model for the evaluation and procurement of hospital medicines in 2016. The model has been in force since January 2017 and is informed by seven principles of priority setting decided on by the Parliament in 2016 (Danish Ministry of Health 2016)[7]. According to the Danish Regions, the model is still under development and needs further qualification through dialogue with stakeholders. Generally, the interviewed stakeholders perceive this development as an important step towards value-based procurement, because the new model explicitly links the therapeutic benefit of pharmacological treatments with the treatment costs.

This new model introduces a specific procedure for price negotiation for newly marketed products. The most widely used procurement mechanism for hospital medicines is still tendering, however (COWI 2009). There is a tradition of national tenders of hospital medicines dating back to 1990, when the joint regional procurement institution, Amgros, was established. Since 2007, Amgros has

[7] According to these principles, the evaluation of hospital medicines should be based on a 'thorough and systematic assessment of the therapeutic benefit for patients and its evidence base', involving 'the necessary and sufficient expertise' and using 'objective criteria'. Moreover, the evaluations should be undertaken 'independently' of the political level, with 'openness about processes, methods and criteria' and in a manner that ensures 'uniform use of pharmaceuticals across the country', 'equal access for large and small patient groups', 'responsiveness to individual patient needs', and 'fast introduction of new, effective medicines' with a 'fair' price compared to the 'added value' it offers.

been responsible for the procurement of medicines for all publicly owned hospitals in the country. Hence, there is one national set-up for the procurement and supply of hospital medicines for the eight hospital pharmacies and 50 hospitals. Over the past decade, a development towards more tenders and more specific requirements has taken place, implying that tenders are used still more actively as a governance mechanism. In 2017, Amgros informs, more than 350 tenders were conducted. Meanwhile, whereas tendering was traditionally used only as a mechanism for stimulating price competition, it has increasingly come to encompass also other dimensions of value.

Overall, the representatives from the pharmaceutical industry associations, Lif and IGL, found that the centralised organisation and administration of the procurement practices contribute to making the Danish market for pharmaceuticals an open and rather predictable market with very limited distortion of competition. Moreover, the introduction of new products has been quite rapid, and in the experience of the Lif representative, it has not been more restrictive than in other European countries. It remains to be seen how the new evaluation model will affect this market situation.

In the following, we describe the organisation of pharmaceutical procurement in more detail. Following the life cycle perspective presented in Figure 1, we focus first on procurement mechanisms used to deal with situations of limited competition (early stages), including HTA coupled with price negotiation and various forms of purchasing agreements. Then we move on to situations where direct competition is possible (later stages), to describe current tendering practices in the Danish pharmaceutical market.

3.2.1 HTA coupled with price negotiation

A main reason for the introduction of the new model for the evaluation and procurement of hospital medicines has been a perceived lack of possibilities for dealing with the regulatory challenges that stem from the introduction of still more targeted and often highly priced treatments. The model therefore includes a distinct procedure for newly marketed products and new indications. According to this procedure, companies can apply for an evaluation of their product by the Danish Medicines Council.

The Danish Medicines Council

The Danish Medicines Council is an assessment body that was established jointly by the five regions and mandated to operate independently of the political level. The Danish Medicines Council consists of three units: the Council, the Secretariat and a number of expert working groups. *The Council* has the overall responsibility for making recommendations about the use of new medicines, based on advice from expert working groups and Amgros[8]. *The expert working groups* consist of medical specialists appointed by the medical societies, pharmacologists and at least one patient representative appointed by the umbrella organisation for Danish patient organisations (Danish Regions 2017b). *The Secretariat* prepares the assessment of clinical benefit to be conducted by the expert working groups, manages the evaluation process and drives the development of the evaluation methods.

The Danish Medicines Council has replaced Rådet for Anvendelse af Dyr Sygehusmedicin, RADS (the council for use of expensive hospital medicines) and KoordineringsRådet for Ibrugtagning af Sygehusmedicin, KRIS (the council for coordinated introduction of hospital medicines). The Danish Medicines Council builds upon the practices already established by these councils, while also adding

[8] The Council chairs are appointed by the Danish Regions, and the members consist of five hospital directors with a medical background, three representatives from the Danish Medical Societies, two clinical pharmacologists and a hospital pharmacist appointed by the regional authorities, and two patient representatives. Also, passive members with an observatory role are appointed by the pharmaceutical industry association (Lif), the Danish Board of Health and the Danish Board of Medicines.

new elements, most notably an explicit categorisation of new hospital medicines according to their 'added value' and the inclusion of treatment costs.

The evaluation process

The evaluation process involves a categorisation of the 'added value' of the product. Added value is defined as 'the extra value a pharmaceutical offers compared to existing treatment in terms of prolonging of life, adverse effects and quality of life' (Danish Regions 2016, authors' translation). Assisted by the Secretariat, an expert working group will develop a protocol for the analysis that underpins the categorisation. This implies that the expert working group is responsible for specifying the patient population, the intervention and the follow-up period, defining and weighting outcome measures, specifying comparators and determining the 'least clinically relevant difference' within the framework established in the methods guidelines of the Danish Medicines Council (Danish Medicines Council 2017: 7-8). The protocol is published on the website of the Danish Medicines Council.

Based on the analysis, which is to be conducted by the company applying, the expert group suggests a classification according to six pre-specified categories of 'added value': 'Major added value', 'important added value', 'minor added value', 'no added value', 'negative added value' and 'non-demonstrable added value' (Danish Medicines Council 2017: 14). The assessment report is sent to the applying company for a hearing. Following the hearing, the Council decides on the final classification, which may involve an up or downgrading of the category suggested by the expert group, if the Council disagrees with the assessment.

After approval of the classification by the Council, Amgros prepares an analysis of the expected treatment costs and budget implications based on the list price stated by the company. The cost analysis and the added value classification provide a basis for Amgros to estimate an 'acceptable' price range for the given treatment and enter into confidential price negotiations with the company (Danish Medicines Council 2017). The methods guidelines of Amgros does not specify how the 'acceptable' price range is to be determined. Following the price negotiation, Amgros makes a suggestion to the Council as to whether the product in question should be used as a 'standard treatment' in the public hospital services. It is the responsibility of the Council to settle on a final recommendation. The assessment report and the recommendation of the Council is published on the website of the Danish Medicines Council.

A product being recommended as a standard treatment implies that it is introduced as a general treatment offer to a given patient group and that it is readily available at the relevant hospital departments. The Council can choose to recommend a restricted use of a product, thereby posing stricter criteria for access than those approved during marketing authorization. In cases with scant evidence, the Council may recommend experimental use for a limited group of patients for a limited period to allow for further data generation (Da. protokolleret ibrugtagning) (Danish Regions 2016). Since the Council is mandated only to 'recommend' not decide, the statements made by the Council are formally non-binding for the regions (Danish Regions 2017b). While there are examples of clinical practice variation among the regions, it has been the experience from the former councils (RADS and KRIS) that there is a high level of compliance with the national treatment recommendations (see also section 3.3).

Re-assessments are possible, if new evidence becomes available or the applying company offers to revise its price. Also, it is not mandatory for companies to apply for an evaluation. Still, a large case load in the Danish Medicines Council indicates that the vast majority of products go through the process. Welcoming this flexibility, the representative from the Pharmaceutical Industry Association, Lif, explained that some companies choose not to apply for an evaluation in order to prioritise

more rapid market access. This can be a strategic option, for instance if it allows the company to time market access with a tendering process (see more on tenders in section 3.2.3).

It is not possible to appeal a classification or recommendation made by the Danish Medicines Council. Any cases of complaints are to be handled through the legal system.

The assessment criteria

To understand what this attempt at 'value-basing' the uptake of new hospital medicines implies, a more detailed look at the assessment criteria is warranted. It is through the choice of specific outcome measures and the application of particular assessment methods that the 'value' of pharmaceuticals is operationalised. We will first take a closer look at the criteria used in the categorisation of the added clinical value, before turning to the cost assessment.

According to the methods guidelines of the Danish Medicines Council, the outcome measures used in the added-value categorisation 'can include clinical events', such as 'death, disease progression or stroke', and 'other patient-relevant outcome measures', such as 'symptoms, quality of life and functional ability' (Danish Medicines Council 2017: 8, authors' translation). In addition, 'relevant adverse effects should always be included', just as it is stated that 'quality of life is included as an outcome measure in every evaluation of the added clinical value of new pharmaceuticals/new indications' (Danish Medicines Council 2017: 8-9, authors' translation). Concerning the quality of life measures, the methods guidelines of the Danish Medicines Council state that 'generic measuring tools' are 'preferred' and only 'absolute effect differences' are given weight (Danish Medicines Council 2017: 9, 14, authors' translation). Overall, this methodological framework sets the stage for a rather comprehensive operationalisation of 'added value'.

In practice, patient-experienced outcomes typically have limited influence on the assessment of the added clinical value. The tool used for assessing the strength of the evidence (GRADE) establishes criteria that can be difficult to meet for patient-experienced outcomes, such as quality of life. For example, the strength of evidence will be downgraded, if effect estimates are deemed 'imprecise' (broad confidence intervals) (Danish Medicines Council 2017: 19). While this principle is methodologically sound, it is difficult to apply equally for all types of effect measures, since clinical trials are typically powered to demonstrate significant effects on clinical endpoints rather than patient-experienced outcomes. Similarly, it can be difficult for treatments targeted at small patient populations to meet the GRADE criteria.

Regarding the cost assessment, the methods guidelines also provide for a comprehensive conceptualisation of pharmaceutical value. The estimation of the incremental costs must follow a 'restricted societal perspective' meaning that all relevant treatment-related costs should be included, regardless of who carries the costs. In addition to expenses related directly to the hospital treatment (e.g. costs for medicine, materials, staff, laboratory tests, diagnostic tests, outpatient visits and adverse effects), costs borne by healthcare providers outside the hospital (e.g. follow-up visits in GP clinics, transportation assistance, aids or rehabilitation provided by municipalities) should be included, as well as costs for patients and relatives (e.g. transportation costs and time spent). Time spent on treatment by patients and relatives is priced based on the average wage of salaried employees in Denmark (Amgros 2017a: 7), which can be considered a relatively high pricing. Due to equality concerns, productivity gains or losses are *not* included in the cost analysis, as they would favour treatments targeted at people in the labour force compared to other groups, e.g. children and elderly persons (Amgros 2017b: 5).

In practice, the possibilities for including cost implications are also limited by the assessment of the added clinical value. No extrapolation of effects exceeding the actual follow-up time in trials is currently allowed by the methods guidelines of the Danish Medicines Council (Danish Medicines Council 2017: 8). The fact that the follow-up time typically is relatively short also limits the opportunities for including long-term costs and savings in the analysis of treatment costs.

3.2.2 Risk-sharing and other forms of purchasing agreements

In Denmark, the use of risk-sharing agreements is limited. Currently, there is no experience with performance-based risk-sharing, and the public authorities have expressed scepticism about this possibility (this is developed in section 4.1.2). According to Amgros, there is some experience with volume-based risk-sharing agreements for hospital medicines. Examples include a scheme in which a fixed price was agreed upon for dialysis solution, regardless of the volume used. The agreement was terminated, however, due to local budget concerns (see also section 4.3.1).

At present, indication-based pricing is not accepted in Denmark, but the topic is subject to debate among the pharmaceutical industry, the regions and Amgros[9]. Amgros and the healthcare authorities acknowledge that some products are brought into play for only one or few indications, in which they have competitive advantages, to allow manufacturers to charge a relatively high price. Thus, the competitive power of these products cannot be used in tenders for other indications. Still, reservations about indication-based pricing were expressed by the public authorities.

Bundling is not accepted either. Amgros rejects bundling based on concerns that it may violate legal principles of transparency and non-discrimination: when a given price is conditional on the procurement of different products from the same manufacturer, Amgros cannot rule out that a better offer could have been obtained from competitors for each of the products.

3.2.3 National tenders

Tenders for hospital medicines are regulated through the EU Directive on Public Procurement[10], which is fully implemented into Danish law by the Danish Act on Public Procurement[11].

Pursuant to both the EU Directive and the Danish Act on Public Procurement, the procurer is to base the award of contract on the most economically advantageous tender (MEAT)[12]. The procurer can choose to identify the most advantageous tender based on the price only or on the best price-quality ratio. If the procurer chooses to apply the best price-quality ratio, the procurer shall determine the criteria based upon which the tenders are to be assessed. The procurer has a wide discretion to determine the criteria. The only requirements are that the chosen criteria must be clearly linked to the subject matter of the contract, ensure the possibility of effective competition and be pre-specified in a way that allows the information provided by tenderers to be effectively verified, in order to assess how well the tenders meet the criteria[13].

Criteria do not need to be quantitative, but can include qualitative, environmental and/or social aspects. Criteria may comprise, for instance, quality (such as technical, aesthetic and functional characteristics, accessibility, design for all users, social, environmental and innovative characteristics),

9 It can be noted that price differentiation is allowed for products with differing concentration of the active agent and different package sizes only if the procurer demands different concentrations and/or package sizes.

10 Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC.

11 Law no. 1564 of December 15, 2015

12 Directive 2014/24/EU, section 67, subsection 1, and the Danish Act on Public Procurement (law no. 1564 of December 15, 2015) § 161.

13 Directive 2014/24/EU, section 67, subsection 4, and the Danish Act on Public Procurement (law no. 1564 of December 15, 2015) §§ 163 and 164.

after-sales service, technical assistance and delivery conditions[14]. The procurer is to specify, in the procurement documents, the relative weighting that it gives to each of the criteria chosen to determine the most economically advantageous tender[15]. The procurer is also to describe the evaluation method to be applied, in order for the most economically advantageous tender to be identified. This is a special Danish rule aiming at making the tender evaluation more transparent.

Prices are published by Amgros unless specific agreements about confidentiality are made. According to Amgros, confidentiality agreements are currently made in about 8% of the tenders. Importantly, the confidentiality agreement only assures that prices are not published by Amgros since hospital pharmacists and leading physicians with budget responsibility will know the tender prices because of their involvement in local procurement practices.

Generally, four types of tenders are used for the procurement of hospital medicines in Denmark, as illustrated in Table 3.2.

Table 3.2 Types of tenders used for procurement of hospital medicines

	Award criterion	No. of winners	Examples
1	Lowest price	One	e.g. Paracetamol (500 mg, tablets)
2	Lowest price	Several (ranked)	e.g. biological products, such as Remicade, and biosimilar alternatives
3	MEAT*	One	e.g. parentenal nutrients**
4	MEAT*	Several (ranked)	e.g. infusion solutions, products used for home dialysis and chemotherapy.

Notes: * Most economically advantageous tender
** MEAT with one winner has been used only once (in 2016).

According to Amgros, some experience has been gained with MEAT. Lowest price is used as the award criterion in the vast majority of tenders (one or several winners). However, there are a few examples of tenders in which price has weighed less than 50%. For example, in a 2018 tender of cytostatics (tender no. 2018-2.3.b) storage life weighed 35%, price 25%, non-contamination of container surfaces 25% and product quality including packaging 15%.[16]

Amgros is mandated to determine the organisation of tenders and the criteria used, and Amgros employees evaluate the bids. The tender period is typically 1-2 years. According to Amgros, there are no formal obstacles for using tenders to stimulate competition on other parameters than price. This merely requires that the value added by a given criterion can be described and justified in an objective manner, to ensure non-discrimination. In practice, rather high minimum requirements for market entry limit the dimensions on which manufacturers can differentiate pharmaceutical products compared to, for instance, the market for medical devices. Hence, the EMA safety and effectiveness requirements for market access can be seen as a 'pre-qualification' for pharmaceutical products to enter the competition. In addition, Amgros has rather strict requirements for safety of supply and timely delivery.

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14 Directive 2014/24/EU, section 67, subsection 2, and the Danish Act on Public Procurement (law no. 1564 of December 15, 2015) § 162.

15 Directive 2014/24/EU, section 67, subsection 5, and the Danish Act on Public Procurement (law no. 1564 of December 15, 2015) § 165.

16 Other recent examples include a 2017 tender of growth hormone, in which price weighed 45%, quality of devices 40% and the storage life of the product 15% (tender no. 2017 -2.451.b); a 2017 tender of permetrexed, in which the storage life of the product weighed 35%, price 25%, non-contamination of container surfaces 25%, and the quality and design of the packaging 15% (tender no. 2017 – 2.254.b); two 2017 tenders of infusion solutions, in which the quality and design of packaging weighed 60%, and the price 40% (tenders no. 2.105.b and 2.106.b); a 2015 tender of plasma in which the collaboration between provider and Blood Centre weighed 45%, price 30%, product quality 20%, and the provision of tests 5% (tender no. 2015-2.800.a).

In cases where price is combined with other criteria, evaluation criteria include (non-exhaustive list):

- *storage life* of products (e.g. storage life of cytostatic solution when prepared for infusion),
- *safe administration* of products (e.g. preference for dialysis products without hormonally disruptive agents),
- production processes that minimise the contamination of container surfaces, and thereby the risk for staff when handling products such as cytostatics,
- injection devices that are easy to use for patients and reduce the risk of incorrect dosage,
- design of containers that reduce the risk of mix-up when products are dispensed),
- *compatibility with existing product assortments* (e.g. standardised size of connecting pieces)[17].

According to Amgros, such criteria will typically be most influential when the unit price of products is relatively low. For patent-protected products, the price will often constitute the major share of the incremental treatment costs. Therefore, savings related to, for instance, expedient packaging or a new form of administration will be of minor importance in the overall assessment.

It appears that most of the examples given by informants of other criteria than price concerned combinations of pharmaceuticals and medical devices. According to the IGL representative, the possibilities of differentiation will typically be greater for combinations of pharmaceuticals and devices than for pharmaceuticals; at least when it comes to generic medicines, which are highly standardised products[18]. Importantly, this does not mean that the patent-protected products are qualified in relation to price only. To comprehend this, it is key to understand how tenders interact with the development of national clinical guidelines, as we will show in the next section.

3.2.4 Tendering coordinated with national clinical guidelines

Since 2009, when RADS was established, it has been practice in Denmark to coordinate tenders of hospital medicines with national clinical guidelines. This practice is continued under the Danish Medicines Council. According to the Danish Regions, the purpose of this practice is threefold: to provide clarity as to the evidence basis, to reduce unwarranted clinical practice variation and to obtain lower prices.

National clinical guidelines are developed for therapeutic fields characterised by considerable budget implications, high spending growth, perceived need for consensus about treatment practices or a potential for quality improvement (Danish Medicines Council 2017b: 3). Typically, national guidelines are developed for therapeutic fields where multiple products are marketed and patent protection limits competition (cf. Figure 1, stage 3).

While the coordination of tenders with national clinical guidelines has turned out to be an effective vehicle for stimulating price competition, it is also of interest to the current debates on value-based procurement. Since the practice involves a ranking of treatment alternatives according to clinical benefit and costs, it conveys certain conceptions of pharmaceutical value and contributes to stimulating competition on other parameters than price.

The process

The Danish Medicines Council has the authority to decide in which therapeutic fields a national guideline is to be developed or renewed based on the council's own oversight and biannual input

[17] The examples were provided by Amgros and IGL.
[18] Still, it may be possible to work with various types of packaging solutions to differentiate these products; e.g. to allow for easier handling of the medicine for patients with rheumatism.

from stakeholders. An expert working group is responsible for formulating the protocol for the assessment. In contrast to the evaluation of new products and indications, manufacturers of the products in question do not perform the analysis but are invited to give input to the Danish Medicines Council during the process. The analysis involves assessment of the clinical benefit and safety of existing therapies in a field. Based on this, the Council – based on recommendations from the expert working group – defines groups of therapeutically equivalent treatments (treatment lines). This can imply that products with different active substances and form of administration are grouped together, since the defining principle is not chemical or biological similarity but the ability of a given treatment to produce a given therapeutic outcome.

Meanwhile, Amgros prepares a cost analysis and invites tenders.[19] Subsequently, the tender prices are applied in the cost analysis. In each group of therapeutically equivalent treatments, the treatments are then ranked by the Danish Medicines Council, according to costs following the logic of a cost-minimisation analysis (Drummond et al. 2005). This procedure is to ensure that cost concerns cannot trump clinical concerns. Finally, the Danish Medicines Council are to collate the outcome of these processes into a national treatment guideline in which recommendations are made about 1st, 2nd and 3rd line treatment, etcetera, for defined patient populations. Within each line of treatment, specific products are ranked according to price. Prices are treated confidentially, in the sense that they are not published by Amgros. However, hospital pharmacists, who are responsible for medicine procurement at the hospital level, are informed about the tender prices.

The assessment criteria

According to the methods guidelines issued by the Danish Medicines Council (2017b) and Amgros, the outcome measures and assessment methods correspond to those used in the assessment of new products and indications. This allows for a rather broad conception of pharmaceutical value that takes into account clinical effectiveness, safety and treatment-related costs borne by hospitals, other healthcare providers, and patients and relatives, and – to a lesser extent – health-related quality of life (cf. section 3.2.1).

Overall, the coordination of tenders with national clinical guidelines creates an incentive for manufacturers to offer an attractive price, because the winner can expect a large market share. Since the guidelines are non-binding, a given market share is not guaranteed, but targets for guideline adherence are typically set around 80%, and guideline adherence tends to be quite high among hospital-based physicians in Denmark. In the following, we consider some of the reasons for this, under our description of the mechanisms for implementation of procurement agreements and guidelines.

3.3 Implementation of procurement agreements and guidelines

While neither the purchasing agreements nor the treatment recommendations are binding for the regions, the regions generally support the implementation.

Reflecting the overall organisation of the public hospital sector, the procurement agreements and guidelines are implemented through a hierarchical line of management. In each of the five regions, pharmaceutical committees are responsible for informing clinicians about treatment guidelines, providing training in 'rational pharmacotherapy' and monitoring compliance with the national treatment recommendations. When required by the regions, the committees are also mandated to ap-

[19] In cases where national clinical guidelines already exist, Amgros prepares the tenders, in accordance with the treatment recommendations.

prove treatment that deviates from the recommendations, including experimental treatment. Moreover, the regional payment models for hospital medicines are generally designed to enforce compliance with the recommendations (cf. Table 3.1).

All regions monitor the medical expenses closely on a monthly basis. Through sales data generated by the hospital pharmacies, Amgros also monitors the consumption of hospital medicines at the level of hospital departments. However, because of still more specialised indications and detailed treatment recommendations, data are often not detailed enough to allow for accurate follow-up on guideline adherence (Danish Regions 2016).

According to the Danish Regions and Lif, the experience from the previous councils (RADS and KRIS) is that new products with added clinical value have been introduced relatively rapidly in the Danish hospitals compared to in other European countries, and that the time of introduction is closely correlated with the issuing of national treatment recommendations. Also, a high degree of guideline adherence is evidenced in examples of very rapid shifts from biological to biosimilar products across all hospitals and acceptance among clinicians of shifting even well-treated patients to other products considered more cost-effective by the councils (RADS 2016).

A key reason for the high levels of compliance, the representative from the Danish regions contended, is the inclusion of clinical expertise in the regulatory processes. As members of expert working groups, clinical experts define the parameters of evaluation within the framework of the Danish Medicines Council. Moreover, several of the Council members also hold management positions in the hospitals and/or are members of the regional pharmaceutical committees. By bringing together these actors and proving an organisational and processual structure that encourages consensus, treatment recommendations are sanctioned by people who are able to influence the actual use of pharmaceuticals. According to the Danish Regions, this does not mean that these processes are without friction. However, the friction is most often dealt with *within* the structures provided by the organisational set-up rather than becoming a subject of public and/or political debate.

In addition to these organisational features, the financial control models applied by the regions create strong economic incentives for guideline adherence (cf. section 3.1). Hence, the clinical autonomy is constrained by the budgetary limits. According to the principles of priority setting determined by the Danish Parliament, ‘it should be possible to use pharmaceuticals that have been rejected as standard treatment, based on a concrete medical assessment’ (Danish Ministry of Health 2016). While the procedures defined by the Regions do allow for this, it typically requires approval by the hospital management and/or the regional pharmaceutical committee, thus restricting the autonomy of individual clinicians. Certain recommendations made by the Danish Medicines Council have sparked heated debate among members of the national parliament about the limits of professional discretion and decision autonomy; most notably in the case of nusinersen (Spinraza), which is not recommended as a standard treatment in Denmark. At the time of writing, work has been initiated by the Region of Southern Denmark to investigate more closely the level of adherence with treatment recommendations made by the Danish Medicines Council in selected treatment areas (personal communication, Kim Brixen).

4 Value-based procurement: challenges and opportunities

As the previous chapter demonstrates, important steps have been taken in the Danish hospital sector to organise procurement in ways that support a rather broad conception of pharmaceutical value. While all the interviewed stakeholders approved of this development, they also identified points meriting attention. In this chapter, we discuss these points and the challenges and opportunities they present for various groups of stakeholders. We distinguish between legal, political and economic issues, depending on whether they appear to be grounded in the legal framework for pharmaceutical procurement, conflicting priorities and convictions of the stakeholders, or the economic steering models of the healthcare system. In relation to the legal issues, we also treat issues of data and documentation. We emphasise that the legal issues mentioned reflect stakeholders' *perceptions* of the legal framework. It is outside the competencies of VIVE to judge the correctness of these perceptions.

4.1 Legal matters

4.1.1 No immediate constraints in the legal framework

According to the interviewed stakeholders, the legal framework generally allows procurers to stimulate competition on parameters other than price, as long as principles of transparency and non-discrimination are respected.

In Denmark, the procurement of hospital medicines is characterised by few cases of complaints[20]. For procurers and manufacturers alike it is important to maintain a situation with few cases of complaints because of the costs associated with handling of complaints. It can only be guessed how potential changes in the procurement practices of Amgros might affect the number of complaints. Relying more on qualitative criteria in the evaluation of bids can increase the vulnerability of a procurer to criticism and potential complaints. However, Danish legal practice recognises a wide discretion for procurers to assess bids in relation to qualitative criteria, potentially limiting the manufacturers' chances of winning complaint cases on this basis alone[21]. Nevertheless, the resources required to go through potential cases of complaints are important from a public sector perspective.

So far, the evaluation practices anchored in the Danish Medicines Council (and the former councils RADS and KRIS) have not led to lawsuits.

4.1.2 The devil is in the detail: risk sharing and documentation requirements

While the legal principles may open possibilities for procurement practices that reward other virtues than price, the documentation requirements that follow spur practical concerns. Hence, concerns

[20] There may be several explanations for this. The vast majority of tenders are conducted as traditional tenders, and contracts are mainly awarded based on the price only. Over the past decade, Amgros has built up considerable expertise as a public procurement institution specialised in the field of pharmaceuticals, medical devises and hearing aids. Since Amgros constitutes a 'monopolist' procurer, it can also be unwise for manufacturers to fall out of favour with this procurer.

[21] The interpretive notes for § 160 in the Danish Act on Public Procurement stipulate that the procurer has a wide discretion within the framework defined by the tender documents, when evaluating bids in relation to qualitative criteria. This discretion has been further buttressed through several cases brought up in the Danish Complaints Board for Public Procurement.

over data and administrative costs were expressed in relation to risk-sharing agreements and indication-based pricing by the representatives from the public authorities, the regional political level and the Danish Cancer Society.

Outcome-based payment for medicine raises important questions about how outcomes are to be documented, what data count as valid evidence and how to demonstrate causality between treatment and outcome. The devil is in the detail when answers to these questions are sought, as noted by the representative from the Danish Cancer Society. He envisioned that it might be difficult for public health authorities and pharmaceutical manufacturers to reach agreement on these matters. Along these lines, the representatives from the Ministry of Health expressed scepticism about the possibilities of developing unambiguous quality and outcome measures.

Even if agreement is reached on outcome measures, this will create a demand for valid outcome data, with associated costs of generating and analysing the data and administrating the agreement. Similarly, if payment for pharmaceutical products is contingent on the indication for which it is used, rather detailed monitoring of actual medicine use at the hospitals will be required. This was a main concern of Amgros and the national and regional level authorities.

The existing Danish registries do not allow for automated follow-up on the prescription/dispensing of medicine in hospitals. According to the national and regional level healthcare authorities, a new registry for hospital medicines is under development that will create new possibilities for monitoring. According to the Ministry of Health, the registry is designed to allow for better pharmacovigilance, i.e. monitoring of adverse effects, and administrative follow-up on medicine use. However, the representative expressed doubts as to whether the registry data would be detailed enough to provide for valid analyses of treatment outcomes for highly specialised treatments (e.g. indications based on genetic profiling). From the perspective of the Ministry, manual data generation at the hospital departments to support outcome-based risk-sharing agreements would not constitute a good use of resources. The healthcare authorities generally expressed a more positive attitude towards volume-based risk-sharing agreements, though still with some reservations regarding the administrative load.

Seen in a longer perspective, the representative from the cancer society expressed concern about potential cost shifting: If pharmaceutical products are increasingly approved for marketing with limited documentation of clinical effectiveness, and the introduction in national markets is increasingly conditional on post-marketing data generation (often referred to as phase IV studies or real-life evidence), the burden of documentation will shift from manufacturers to the healthcare systems. At present, the Danish healthcare authorities provide the infrastructure necessary for generating post-marketing outcome data when the Danish Medicines Council recommends experimental use of a product and further data generation (Da. protokolleret ibrugtagning), while also paying for the product.

4.2 Political issues

4.2.1 Industry associations organise competing interests

When asked about their conception of pharmaceutical value, the representatives from the pharmaceutical industry associations, Lif and IGL, made clear that the associations organise companies with competing interests and different views on the matter of value-based procurement. According to the IGL representative, the most pertinent concern for their members as an industry is to retain

market diversity. 'A basic dilemma' in the debate about value-based procurement, the Lif representative explained, is that companies that are well-established in lucrative and relatively stable markets with limited competition are less likely to support an altering of tender criteria than newcomers in a market, who seek to challenge the status quo. The companies who are able to document what comes to count as 'value' – whether this ability stems from capacity inferred by size, strategic research investment or subspecialisation – will necessarily have a better position in the competition, making the conceptualisation and documentation of value a strategic parameter of competition.

For these reasons, it can be difficult for the industry associations to push actively for a broadening of the criteria used in Amgros tenders or the outcome measures used in the evaluation processes of the Danish Medicines Council. Generally, they emphasise the importance of adhering to principles of transparency, accuracy and non-discrimination. Moreover, as an industry association for research-based pharmaceutical companies, Lif generally supports the focus on total costs rather than just the price and calls for this focus to be strengthened in Amgros tenders – but with due consideration of the administrative costs for both companies and healthcare authorities.

4.2.2 Focus on treatment costs supported but no political acceptance of CEA

Consolidated with the Parliament's principles of priority setting, the inclusion of treatment costs in the assessment of hospital medicines constitutes a notable innovation of the new evaluation model. All the interviewed stakeholders supported this development and endorsed the relatively broad analytical perspective allowed by Amgros' methods guidelines. Also the Danish Cancer Society, which previously has criticised the evaluation model (Wadmann 2017), expressed the view that treatment costs, though secondary to efficacy and safety, constitute an important parameter.

Patient organisations more generally have publicly questioned concrete recommendations made by the Danish Medicines Council to restrict access to new treatments because the costs were deemed too high compared with the demonstrated effectiveness (most notably in the case of Spinraza). Nevertheless, the patient organisations have chosen to remain part of the Danish Medicines Council[22]. Currently, the patient organisations have two seats in the Council and 1-2 representatives in each expert working group.

A reasonable relationship between costs and added value is required by the national principles of priority setting for hospital medicines: '*For a new pharmaceutical to become standard treatment, it requires a reasonable relationship between the price of the pharmaceutical and the added value it is expected to offer compared to existing standard treatment'* (Danish Ministry of Health 2016). However, there is currently no political support for the use of QALY-based cost-utility analysis. At the time of writing, the methods guidelines of Amgros do not specify how treatment costs are to be compared with treatment benefits to judge whether the relationship is 'reasonable'. According to the pharmaceutical industry association Lif, this makes transparency a real challenge as it provides no safeguards for the manufacturers against the risk of differential treatment. However, when asked about which methods of assessment are recommended by the industry association, the representative responded that agreement had not been reached among their members on this matter. Therefore, they are unable to speak with one voice as an industry on this matter, for the moment. As an industry association, they observe the recommendations being made by the Danish Medicines Council and find that the appropriateness of the Danish model should be judged based on the concrete experiences obtained.

[22] This stands in contrast to the experience of the Swedish equivalent to the Danish Medicines Council, NT-Rådet (The Council for New Therapies). The patient representatives decided to omit their seats in NT-Rådet after only two meetings (Højgaard et al. 2016, p. 154).

More geneally, the ambition of taking into account several dimensions of pharmaceutical value in procurement processes raises important and difficult methodological questions about how to weigh these dimensions together in a fairly consistent and transparent manner.

4.2.3 Inclusion of patient perspectives supported but lack of clarity about measures

Generally, the interviewed stakeholders supported the attempts of the Danish Medicines Council to include patient perspectives in the evaluation of hospital medicines. According to the Danish Regions, the emphasis on patient perspectives reflects a broader political agenda of strengthening the 'user perspective' in the healthcare services. However, there is room for development concerning how the views of patients are to be included.

Currently, there is no political acceptance of the use of quality-adjusted life years (QALY) as a standardised outcome measure in the evaluation of hospital medicines in Denmark (Wadmann 2017). This institutes a national demand for other patient-relevant outcome measures that live up to the methodological requirements of the Danish Medicines Council [23]. Since evidence production on pharmaceuticals is increasingly organised on a global level, and QALYs are used in HTA assessments in several countries (Højgaard et al. 2016; Højgaard et al. 2017), manufacturers are likely to encounter challenges in meeting the Danish data requirements. According to the Danish Regions, the experience so far is that the clinical studies rarely include quality of life measures in a way that corresponds with the criteria set by the Danish Medicines Council. Consequently, even if priority is given to patient-relevant outcomes in the assessment protocols defined by the Danish Medicines Council, these protocols will often have limited practical influence on the assessment.

The regional representatives we interviewed encouraged manufacturers to include patient-relevant measures in pre- and post-marketing evidence production. However, when asked about which measures would count as acceptable evidence the representative from the Danish Regions explained that the methods are still in the making and invited dialogue with research institutions, to establish which measures are relevant and sufficiently robust.

The representative from the Danish Cancer Society expressed the view that more systematic inclusion of patients' assessments of medical treatments is needed in clinical research, as well as HTAs. Through its extensive research program, the cancer society is actively engaged in developing and testing quality-of-life measures in relation to cancer treatment, including the EORTC QLQ-c30 assessment tool[24] and patient-reported outcomes (PRO)[25]. According to the representative, there are somewhat different traditions for including patient perspectives in clinical and health economic research, and varying preferences for specific measures. These issues merit attention in relation to method development.

Also the Lif representative identified patient experiences as a relevant area of methodological development. Furthermore, he made it clear that a high level of systemisation and consistency in the assessment are required, if patient experiences are to be included directly as an assessment criterion in tenders.

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23 Generic rather than disease-specific outcome measures and absolute rather than relative effects.

24 This tool includes generic questions about quality of life, and a subsection of the questions have been used to develop a quality of life index that has been tested in resent health economic research. According to the representative from the Danish Cancer Society, some of the EORTC tools need updating to be usable in practice. See more about the EORTC-tools at the website: http://qol.eortc.org/.

25 Activities include a lung cancer trial testing the effectiveness of PRO measurement in addition to CT scanning in detecting relapse and complications compared to only CT scanning.

4.2.4 Treatment innovation relating to other aspects than therapeutic effect: safety-by-design and ready-to-use products as potential areas of development

In the light of task-shifting from specialised to primary care, and since medication errors account for a sizeable share of hospital contacts (Pirmohamed et al. 2004), the regional authorities and Amgros expressed interest in solutions that can facilitate easier and safer administration of medicine outside hospitals.

According to the representative from the Danish Regions, the vision is that still more treatments will be undertaken in the patients' homes; a development that potentially warrants rethinking of the current regulatory categorisation of hospital medicines. Envisioning a great potential for improved treatment and reduced hospitalisations, he encouraged manufacturers to develop solutions that can contribute to reducing medication errors; e.g. through combinations of pharmaceuticals and devices.

The Amgros representative explained that the procurer has sought to stimulate a market for ready-to-use products because of a potential for safer and cost-effective solutions. While there are a few examples of politically induced demand for ready-to-use products at the regional level[26], economic constraints at hospital level can limit the actual demand (this point is developed in section 4.3.1).

A related issue concerns the valuation of innovation in relation to drug formulation, such as the development of subcutaneous infusion or tablets instead of intravenous fusion. According to Amgros, this is an ongoing subject of discussion among the manufacturers and the procurement institution. The Lif representative suggested that such innovations can be recognised through inclusion in the cost analysis performed by Amgros for the Danish Medicines Council; an option which the methods guidelines of Amgros already allow for.

Treatment innovation relating to other aspects than therapeutic benefit, such as convenience or various forms of patient support (e.g. through apps), has not been discussed much in the Danish Cancer Society. According to the representative from the society, a more pertinent problem, from their point of view, concerns the documentation of clinical effectiveness. In particular, the representative was critical about the tendency of still more drugs obtaining marketing authorisation without data on overall survival rates[27].

Generally, the interviews indicated that when the value of a given innovation is stated merely as a matter of patient convenience, it may influence procurement decisions to a lesser degree than if a convincing case can be made regarding potential savings or improved treatment outcomes. Historical examples of HIV treatment, for instance, demonstrate a lack of willingness to pay for higher priced combination treatment, which reduces the number of pills for patients to take but without demonstrably improving treatment outcomes.

Asked whether Amgros could imagine inviting tenders for more broadly defined treatment solutions than specific products[28], the Amgros-representative answered that they would not reject the idea. Immediate concerns raised by Amgros pertaining to this option include the risk of favouring one or a few large companies with the capacity to meet such a demand and the possibility of nurturing a

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[26] One example involves a political decision in Northern Denmark to accept additional costs for penicillin, which does not need to be mixed at the hospitals, in order to reduce the risk of antimicrobial resistance.

[27] Between 1999 and 2014, 48 indications for medicines were approved by the U.S. Food and Drug Administration without any randomised controlled trial evidence, not even for the same medicine in other indications. In Europe, 36 indications for drugs were approved during the same period. Examples include imatinib for chronic myeloid leukemia, gefitinib for non-small-cell lung cancer and alglucosidase alfa for Pompe disease (Hatswell et al. 2016). For cancer drugs specifically, it has been demonstrated that there was a significant prolongation of survival in only 35% of indications approved by EMA from 2009 to 2013 and that the magnitude of the effect on overall survival ranged from 1.0 to 5.8 months. An improvement of quality of life was demonstrated in only 10% of the cases. At a minimum of 3.3 years after market entry, there was still no conclusive evidence that the drugs extended or improved life for most cancer indications (Davis et al. 2017).

[28] For instance, an assortment tender for all medication used for the treatment of a given patient group for a given period.

market for distributors to coordinate bids among tenderers with the associated risks of transaction costs and less transparency in the market. Besides, it would be likely to require considerable resources at hospital level to change treatment regime between tender periods, and place a large responsibility on one or a few providers, with associated risks in relation to security of supply.

4.2.5 Performance-based risk-sharing: concerns about industry involvement and lacking risk appetite

While performance-based risk-sharing is currently not used in Denmark, the pharmaceutical industry association Lif perceived this option as a valid solution, in cases where the evidence of treatment effects is uncertain. For instance, in cases where products have obtained EMA marketing approval based on phase II data only. To avoid conflict with principles of transparency and non-discrimination, the Lif representative suggested that such procurement agreements could be used in cases where direct competition cannot be obtained; typically in the early phases of market development. By contrast, the interviewed healthcare authorities and politicians generally expressed scepticism about performance-based risk-sharing. In addition to their reservations concerning administrative costs (cf. section 4.1.2), concern was also raised about the possibility of more direct involvement of pharmaceutical companies in patient treatment, and distrust was expressed in the willingness of manufacturers to accept financial risks.

The regional level politician in particular expressed concern that payment conditional on patient outcomes can generate economic incentives for manufacturers to try to influence patient treatment in a very direct way. She envisioned what she saw as an altered role of the industry in the publicly funded healthcare system and a too close involvement of pharmaceutical companies in patient treatment; a concern that was shared by the representative from the Danish Cancer Society. Also, it can be noted that the form of regulation imposed by the agreements (contract regulation) introduces legal restrictions for healthcare authorities to take into account, in case they wish to intervene in developments that appear undesirable, thus limiting the possibilities of the authorities to intervene directly through the hierarchical, political line of government.

Furthermore, based on previous dialogue with pharmaceutical companies about new forms of payment agreements, Amgros and Danish Regions expressed distrust in the willingness of manufacturers to accept financial risks. In the experience of the Danish Regions, the companies were mainly willing to accept risks related to uncertain areas of income, such as new or uncertain indications. The Lif representative acknowledged that Amgros has demonstrated willingness to explore possibilities for risk-sharing and other types of procurement agreements, and noted that agreement as to concrete models had not been reached between Amgros and the manufacturers.

4.3 Economic factors

4.3.1 Local budget constraints can limit the uptake of innovations

Even if healthcare authorities may seek to stimulate a market for certain forms of innovation, such as ready-to-use or safety-by-design solutions, budget constraints at hospital level may limit the actual demand. Amgros provided a concrete example: compelling studies of pre-filled syringes used in gastroenterological treatment suggest that such solutions can generate added therapeutic and economic value for patients and hospitals[29]. Still, when the procurer sought to stimulate a market for such solutions, the experience was that hospitals were not inclined to buy the products. When

[29] See Risør et al. 2017.

confronted with this experience, the regional representatives confirmed that short-term budget constraints can limit the hospitals' ability to buy innovative products that are cost-effective on a longer term; a perception that was shared by the IGL-representative. Besides, it can be difficult for hospital departments to realise the estimated long-term savings in practice because administrative regulations, such as staffing capacity requirements, hamper the practical possibilities for realising savings.

In a similar vein, another example of Amgros indicates that the decentralising of budget responsibility can make it difficult to realise potential savings, if the economic implications differ among hospital departments. Some years ago the procurer invited tenders for peritoneal dialysis treatment requiring a fixed price per 24 hours rather than payment per volume. According to the Amgros representative, a good price was obtained and the agreement ensured that the budget implications were predictable. Still, some of the hospitals withdrew. As they realised that the amount of dialysis fluid used differed somewhat among the hospitals, those who used the smallest amounts were unwilling to bear the costs for those who used the largest amounts.

4.3.2 Measures taken to overcome silos

Separation of budget responsibility between regions and municipalities implies that the regions, who pay all expenses for hospital medicines, will not benefit from potential savings realised in the municipal healthcare services. Conversely, potential savings in the regions can also lead to increased municipal costs; for instance if an altered form of medicine administration allows for home treatment instead of hospitalisation. Some measures have been taken by Amgros and the Danish Medicines Council to overcome these administrative silos. Thus, the restricted societal perspective in the cost analyses of Amgros implies that expenses and savings for healthcare providers outside the hospital sector are also included in the evaluation of new products and indications, and when national clinical guidelines are made for therapeutic fields. According to the Danish Regions, this methodological choice reflects more overarching political priorities of ensuring better cohesion in the healthcare system and allowing tasks to be handled at the most cost-effective level of expertise; priorities that are also central to the current discussions on value-based healthcare.

5 Comparison with the Danish market for medical devices

In parallel to the recent changes in the organisation of pharmaceutical procurement, discussions have also been initiated among the Danish Regions and the industry association for medical device manufacturers (Medicoindustrien) about potential models for value-based procurement. Moreover, Medicoindustrien is currently engaged in a Nordic project that aims to generate experience with various methods for the documentation and evaluation of medical devices (Medicoindustrien 2018). As yet, no concrete proposals for value-based procurement of medical devices have been launched.

As in the market for hospital medicines, medical devices are typically procured through tenders. While there is some overlap in the regulation and organisation of procurement practices in the two markets, there are also notable differences. Like in the pharmaceutical market, the overall financial framework encourages procurers of medical devices to obtain savings through price competition, but there is also an increasing focus on value-based procurement (Huntley 2017: 288-89). In contrast to the pharmaceutical market, tenders for medical devices might include maintenance services, training of staff and various forms of assistance that allows for a more broadly defined conception of product value (Piester & Rosager 2017: 27).

In this chapter, we take a brief look at some of the similarities and differences between the two markets, to tease out any lessons of importance to the current discussions of value-based procurement in the pharmaceutical market.

5.1 Varying opportunities for product differentiation

Like in the pharmaceutical market, product approval requirements establish *de facto* minimum requirements for products to enter the market. In Europe, the CE Mark certification and compliance with relevant ISO standards are key (Huntley 2017: 273) [30]. However, the requirements focus mainly on safety, not efficacy, and the documentation requirements tend to differ from those in the pharmaceutical market. The clinical testing of medical devices does not rely on a tradition of clinical trial stretching back more than 50 years, as is the case for pharmaceuticals[31]. Such requirements have only recently started to enter the market for medical devices[32]. Documentation of product safety and usability, and clinical documentation of compliance through clinical testing constitute the main requirements for product approval in the market for medical devices. According to Medicoindustrien, the distinction between clinical testing in the device market and clinical trials in the pharmaceutical market is somewhat unclear. However, clinical testing of medical devices tends to be of shorter duration and to involve no formalised comparison with existing products. Like the pharmacovigilance in the pharmaceutical market, medical device companies are also required to do post-marketing surveillance and monitoring to demonstrate the safety of their products in everyday clinical use. In connection with procurement, the quality of medical devices is also assessed based on immediate

30 The documentation required for the European CE marking includes demonstration of the adequacy of the internal quality management system for product manufacturing, compliance with sterilisation demands, the usability of the product for a given intended usage (corresponding to the indication of pharmaceutical products), measures taken to prevent or limit potential risks associated with use of the product, an acceptable plan for post-market surveillance and appropriate measures taken to ensure the traceability of the product. The specific documentation requirements vary depending on the risk categorisation of the product (Huntley 2017).

31 In the wake of WWII, the pharmaceutical market rapidly evolved in pace with significant advances in medical research, such as the development of the randomised controlled trial (Greene 2008).

32 More emphasis is put on clinical evidence through clinical trials or testing with the new set of EU regulations for MedTech products, decided upon in 2017. Full implementation of the regulations is scheduled for 2020 for devices and 2022 for diagnostics (Huntley 2017).

sensorial impressions and/or practical experience with the use of products. This opens up possibilities for product differentiation pertaining to, for instance, product design.

While, from a public sector perspective, the traction of value-based procurement is the possibility of stimulating innovation that can generate added value for patients and healthcare systems, an attraction for manufacturers is a widening of opportunities for product differentiation. The highly regulated market access in the pharmaceutical market fosters a rather high degree of product standardisation, implying that competition on safety and effectiveness is possible only above certain minimum standards. This is crucial from a public health perspective. From a manufacturer perspective, it can constitute a limitation, if the minimum standards for market access are used to justify mere price competition.

For pharmaceutical companies, a broadening of assessment criteria in procurement practices might open up new possibilities for product differentiation. The specific strategies of product differentiation in the medical device market are unlikely to be directly applicable in the pharmaceutical market, because of the different traditions for the documentation of product value. Moreover, the demand for additional services appears to be very limited in the pharmaceutical market because pharmacological expertise is already available in hospitals. However, experiences relating to product design appear also to be relevant to product innovation in the pharmaceutical market, e.g. in relation to safety-by-design solutions.

5.2 Market mediation can limit possibilities of product differentiation

Medical devices are procured through several procurement institutions[33] with various degrees and areas of specialisation, which gives rise to some diversity in tendering practices. Moreover, the legal framework varies depending on whether devices are procured in the regional or the municipal healthcare services. Notably, the Service Act (Da. Serviceloven) provides patients the right to individualised services/aids in the municipal healthcare system, leading to a demand for broad assortments. Since manufacturers are typically unable to cover the whole range of products, private distributors, such as Medic or OneMed, function as intermediaries between manufacturers and municipalities. By contrast, manufacturers place their bid directly in the regional tenders.

According to the representatives from the device market, the central role of distributors in the municipal market severely limits the possibilities for manufacturers to differentiate their products based on the additional services they can deliver. Due to the wide range of products that distributors need to cover[34] they typically offer only one service agreement per product area, and services tend to concern ordering and delivery conditions more than specialised support.

If value-based procurement is to open up new dimensions for product differentiation, these experiences indicate that the organisation of procurement practices should allow for manufacturers to interact directly with procurers rather than through distributors. From a public sector point of view, this would also limit market mediation costs.

[33] Det Kommunale Fællesindkøb, Regionernes Fællesindkøb (RFI), Staten og Kommunernes Indkøbsservice (SKI) and Amgros.
[34] According to the representatives from the medical device industry, it is not unusual for distributors to cover about 15,000 item numbers.

5.3 Price structures can influence the weighing of tender criteria

Even if MEAT is used in both the municipal and the regional market for medical devices, it appears that the weight that price is given differs somewhat. In the experience of the Coloplast representative, price is typically given less weight in the regional market relative to the municipal market. Since unit prices tend to be rather low in the regional market, quality will typically be given equal or more weight than price in the regional tenders. By contrast, the experience from the municipal market, where prices tend to be higher, is that price is typically given most weight, even though quality criteria are increasingly also included in this market.

These experiences indicate that even if tender criteria are broadened the actual impact of quality criteria will depend on the price structure. From a public sector perspective, value-based procurement does not imply insensitivity to price. This is important to bear in mind in the pharmaceutical market also. Because of rather firm budgetary control at all levels of the public hospital services, value-based procurement constitutes a tool for re-allocation of resources rather than a vehicle for budget expansion.

5.4 Increasing influence of legal expertise

While procurement practices have previously involved technical and clinical expertise, it is the experience of Medicoindustrien that still more emphasis is put on legal expertise. Because tendering is resource demanding, manufacturers and procurers gear up for potential complaints, the representative from Medicoindustrien explained. In his view, the fear of complaints constitutes a challenge for the attempts to work with value-based procurement. The awarding of contracts based on costs rather than price will increase the investments necessary for the manufacturers to enter the competition because of the need for evidence generation and analysis. Furthermore, a potential inclusion of more qualitative criteria in tenders may increase the risk of complaints from competitors.

6 Discussion

6.1 Significant steps towards value-based procurement

Denmark has taken significant steps towards a procurement system that recognises multiple dimensions of pharmaceutical value. Over the past years, several attempts have been made to stimulate competition on other parameters than price, covering a range of market situations.

With the establishment of an evaluation model for hospital medicines in 2016, which combines HTA with price negotiations, newly marketed products and products with new indications are qualified by the Danish Medicines Council based on their added therapeutic value compared to their incremental treatment costs. The evaluation model sets the stage for an encompassing conception of pharmaceutical value that includes clinical effectiveness, safety, quality of life or other patient-relevant outcomes, in addition to treatment costs pertaining not just to hospitals but also healthcare providers outside the hospital sector and patients and their relatives. In practice, however, methodological constraints seem to limit the actual impact of patient-relevant outcomes. Constraints include a lack of clarity about what constitutes acceptable outcome measures and documentation requirements imposed by evidence assessment tools. On the cost side, a range of aspects can be counted in, but the drug price will typically drive most of the incremental costs for newly marketed products, in effect making price the most influential parameter.

The vast majority of hospital medicines are procured through tenders. Since 2007, there has been one national set-up for the procurement and supply of hospital medicines. Whereas tendering has traditionally been used only as a mechanism for stimulating price competition, it has increasingly come to encompass also other dimensions of value than price. In some cases, this is done directly in the process of tendering through the application of MEAT (Most Economically Advantageous Tender) as the award criterion, allowing for competition on parameters such as the storage life of products and safe drug administration. Still, lowest price constitutes the award criterion in the vast majority of tenders. Importantly, this does not mean that tendered medicines are not qualified in other ways. Since 2009, traditional tenders have been coordinated with the development of clinical guidelines for treatment areas with important budget implications – a practice that is continued by the Danish Medicines Council. This implies that tender prices are included in an encompassing cost analysis (restricted societal perspective), which in turn informs a ranking of products in groups of treatments deemed therapeutically equivalent. While a more indirect mechanism, this procedure does allow for the rewarding of several dimensions of pharmaceutical value.

6.2 Incremental development rather than systemic changes

Overall, the existing set-up for procurement of hospital medicines enjoys support from political and administrative actors at the regional level as well as the pharmaceutical industry associations. At the national political level, the overall tenets for the assessment of hospital medicines have been sanctioned by the unanimous approval of seven principles of priority setting. Therefore, the development of the procurement practices will most likely be incremental rather than involving more fundamental systemic changes.

These are not merely technical choices, as the methodological framework for the assessment of hospital medicines in the context of the Danish Medicines Council is still in the making. Since the specific methodological choices greatly impact on which dimensions of pharmaceutical value are

brought to bear on the assessments. To understand the actual valuation of pharmaceuticals, the devil is in the detail.

Value addition constitutes a key part of the competitive strategies of pharmaceutical companies, and the agenda of value-based procurement can be a strategic option for manufacturers to try to broaden the possibilities for product differentiation. Still, the pharmaceutical industry associations are unlikely to advocate the inclusion of specific assessment criteria or drive particular methodological changes, as the associations organise companies with competing interests. Larger patient organisations, such as the Danish Cancer Society, are more likely to provide specific input to the methodological development, as far as quality of life and other patient-relevant outcomes are concerned.

From the regional political level, support was expressed for potential future widening of assessment criteria to encompass more dimensions of pharmaceutical value in the evaluation practices of the Danish Medicines Council and Amgros. Due to an arm's length principle, however, the ongoing methodological development is to be driven from within the Danish Medicines Council of Medicine and Amgros. Any substantial changes are likely to be decided upon following the announced evaluation of the Danish Medicines Council early 2019.

In relation to the ongoing discussions about a model for value-based procurement in the market for medical devices, more general discussions about organisational and methodological approaches to HTA can be expected, along with renewed debate about the pros and cons of specific outcome measures, such as quality adjusted life years (QALYs). At the European level, the recent proposal for strengthened HTA cooperation also constitutes a basis for renewed discussion of Danish evaluation and procurement practices[35].

6.3 Administrative boundaries up for debate

As is the case in several other aspects of healthcare organisation, the procurement of pharmaceuticals is organised in a way that maps onto existing administrative boundaries. Current political priorities and ongoing developments in the market for medical technologies bring this mode of organising up for debate.

Pharmaceuticals are but one of a range of technologies used in hospitals, and added expenses for pharmaceutical treatment may lower expenses for other treatments involving other types of technologies, such as medical devices used for surgery. Moreover, in line with political-administrative ambitions of enabling still more specialised treatments to be undertaken in the home of patients products are increasingly developed that allow for self-administration of medicine through combinations of pharmaceuticals and devices (e.g. injection pens for insulin or growth hormone). These developments contribute to blur the line between pharmaceuticals and medical devices, and also raise questions about the distinction between hospital medicines and practice sector medicine. In the longer run, the administrative distinctions among different categories of medicine and various types of medical technologies therefore warrant attention. Related to this, it appears relevant to examine how product combinations are handled within the existing regulatory framework (EU and national level), and which incentives for innovation, e.g. of safety-by-design solutions, the existing procurement system provides.

[35] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A51%3AFIN

6.4 Value-based healthcare: political momentum but weak alignment with practical possibilities

Visions for value-based healthcare have gained political momentum, and, in some measure, the current discussions about value-based procurement in the pharmaceutical market reflect these more general reform ideas. Importantly, the notion of value-based healthcare does not refer to one distinct program of reform (Frederiksson, Ebbevi & Savage 2015; Rud Petersen & KORA 2015). Rather, it constitutes a gathering point for actors with distinct but somewhat overlapping reform agendas.

If value-based healthcare is viewed as a financial management model that is to encourage cohesion through performance-based payment across administrative boundaries, there are clear points of convergence with new types of purchasing agreements in the pharmaceutical market. Most notably, perhaps, with regard to ideas of performance-based risk-sharing and indication-based pricing – but with the important addenda that these forms of payment are regulated within a framework of contract management that establishes clear limits for the scope of action for public authorities. Akin to other ambitions of outcome-based payment, practical constraints also limit the feasibility of the discussed procurement agreements, including lacking consensus about acceptable outcome measures and limited possibilities for documenting outcomes in a valid way. Therefore, performance-based risk-sharing agreements do not seem to enjoy support from national and regional healthcare authorities in Denmark, at the moment. More positive attitudes are expressed by the healthcare authorities regarding volume-based risk-sharing agreements, but still with some concern about administrative costs related to data generation. Indication-based pricing is currently not accepted in the Danish healthcare system, but discussions have been initiated to explore the possibilities.

With the cost analyses that Amgros performs for the Danish Medicines Council, the regional authorities in Denmark have set the stage for a more encompassing costing perspective than that supported by the existing financial divisions, as they also include municipal costs. However, as the regional budget is not adjusted accordingly it is really a reallocation of resources from the regional level. This limits the potential scope for an even broader costing perspective in a Danish context.

6.5 Looking forward

In sum, there appears to be consensus among the interviewed stakeholders that, ideally, the purchasing power of public institutions should be used actively to spur demand for pharmaceutical treatments that generate added value on a broad range of dimensions. In practice, however, there are several challenges that makes widespread use of value-based procurement a long-term prospect rather than a current possibility.

Since there are only few examples of performance-based procurement agreements internationally and none in Denmark, the debate on performance-based procurement tends to be centred on risk perceptions rather than any concrete experiences. In case the stakeholders wish to move in this direction, concrete examples are warranted.

Moreover, while significant steps have been taken by the Danish Medicines Council and Amgros to conceptualise and operationalise the added value of pharmaceutical products, methodological challenges remain. These challenges particularly pertain to the inclusion of patient experiences and the principles for weighing together different dimensions of value. In the Danish context, a relevant first step would be to obtain an overview over the current practices for the inclusion of patient-relevant outcomes in the evaluations undertaken by the Danish Medicines Council: Which outcome measures are requested by expert working groups, how are these requests met by data provided

by applying manufacturers, and what are potential lines of development given current methodological developments in relation to patient-relevant outcome measures? Moreover, dialogue with research environments about possible outcome measures is warranted. For instance, it appears relevant to follow the Danish Cancer Society's development and testing of composite outcome measures that take into account patient experiences.

Besides the methodological challenges, the infrastructure for data generation also needs attention. In Denmark, forthcoming national registries may provide some opportunities for following up on treatment outcomes. Meanwhile, it can be relevant to explore in more detail the types of documentation requirements imposed by various forms of risk-sharing agreements and the possibilities for using the Danish regions' existing patient registries and patient administration systems to monitor the use of hospital medicines and associated treatment outcomes.

Importantly, for companies that operate globally, evidence production is not a national but an international matter. It creates challenges for companies as well as national HTA institutes when there is a mismatch between documentation requirements and the existing evidence base. Therefore, it appears relevant to examine more closely the interplay between EU-level marketing approval requirements for pharmaceuticals and documentation requirements imposed by national level procurement policies: When do discrepancies arise, and how are they dealt with? How do national level authorities follow up upon EMA recommendations of clinical monitoring to document the effectiveness of new products?

Finally, the implementation of procurement agreements warrants further attention, since this is a precondition for the agreements to contribute to value generation. In Denmark, the decentralisation of budget responsibility and the somewhat different financial control models applied by the regions makes it relevant to explore further what the funding models imply for the uptake of new hospital medicines at the hospital level.

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Appendix 1: Project design and methods

This project has been designed as a qualitative study based on semi-structured interviews and document analysis. The informants were sampled purposefully (Palinkas et al. 2015) by the authors to represent key stakeholders with detailed knowledge about pharmaceutical procurement and the regulation of the pharmaceutical market.

Empirical material

In preparation of the analysis, two background interviews were conducted with Novartis representatives, Director of Governmental and Public Affairs Europe Elke Grooten and WorldWide Associate Brand Director Brice Mahe. These interviews were undertaken to learn about industry perspectives on value-based procurement and EU-level initiatives pertaining to the valuation of pharmaceuticals.

To inform the mapping of current procurement practices in the Danish hospital sector, we drew upon previously published reports and publicly available documents, such as notes from the Danish Regions and the Ministry of Health, methods guidelines published by the Danish Medicines Council and Amgros, and tender documents published on the website of Amgros. In addition, we conducted five semi-structured interviews with:

- Tommy Kjelsgaard, vice director, Danish Regions
- Flemming Sonne, director, Amgros
- Jørgen Clausen, chief economist, Lif – the industry association for research-active pharmaceutical companies in Denmark
- Peter Jørgensen, director, IGL – The Danish generic and biosimilars medicines industry association
- Søren Lund, head of office, and Rasmus Fynbo Aagaard-Jensen, chief consultant, Danish Ministry of Finance.

To identify which challenges and opportunities stakeholders recognise in relation to value-based procurement, we drew upon semi-structured interviews. In addition to the informants listed above, we also conducted three interviews with:

- Anna Skat Nielsen, head of office, and Liv Nordin Christensen, administrative officer, Centre for Pharmaceuticals and International Affairs, Danish Ministry of Health
- Karin Friis Bach, pharmacist, vice president of the Regional Council in the Capital Region of Denmark, chair of the Danish Regions' Health Committee, board member in Amgros and president for the Danish Society for Patient Safety
- Jes Søgaard, chief economist, the Danish Cancer Society.

We also invited two representatives from regional pharmaceutical committees, a representative from the umbrella organisation for Danish patient organisations and a representative from the Danish Medicines Council to participate in the study. Two of these declined due to time constraint, while the others found it incompatible with their position to participate in a study funded by a pharmaceutical company. This means that we have not been able to include other considerations regarding the methodological choices of the Danish Medicines Council than those included in the publicly available methods guidelines. Furthermore, it means that the perspectives of patient organisations are constrained to viewpoints presented by the Danish Cancer Society, which is the largest patient organisation in Denmark. Representatives from other patient organisations, e.g. those who organise

smaller groups of patients, may hold other views about value-based procurement. Since no representatives of the regional pharmaceutical committees were able to participate, we have had to build upon existing reports when describing the implementation of procurement agreements and treatment recommendations. Hence, we have been unable to include any specific considerations of the committee members about the prospects of value-based procurement in general, and the perceived challenges of implementing risk-sharing agreements and other forms of procurement agreements. Finally, a member of the Health Committee of the Danish Parliament declined participation arguing that the assessment of value in relation to pharmaceutical procurement is a regional responsibility; thus reconfirming the formal division of responsibilities between national and regional level authorities. After the data were generated for this analysis, political debate about the prioritisation of hospital medicines was renewed bearing witness to the interest of national level politicians in these matters. While we mention this in the report, the data material has not allowed for more detailed exploration of the interaction between the national and the regional political administration.

In the comparison with the device market, we drew upon three semi-structured interviews with:

- Peter Huntley, Director, Medicoindustrien – the industry association for companies that develop, manufacture, sell or otherwise take an interest in medical devices
- Jeppe Parving, Head of Sales & Commercial, Coloplast
- Rune Orloff Pedersen, Field Market Access Manager - Denmark & Norway, Alcon.

The interviews were guided by a generic interview guide designed to yield insight into the overall attitude of stakeholders towards the existing set-up for the procurement of hospital medicines; which aspects they find important when assessing the value of pharmaceuticals; their views upon which assessment criteria a value-based tendering model should ideally include (including views on a cost per QALY-based model); and which pitfalls and potential gains they see in relation to a potential broadening of criteria for the assessment of pharmaceutical value. For the interviews with the representatives from the medical device industry, the interview guide was amended to cover the specificities in the device market. The generic interview guide is attached in appendix 2.

The interviews were conducted during spring 2018. They lasted 30-90 minutes and were recorded with the permission of the informants. Based on the recordings, detailed transcripts were produced by the first author for each interview. All data have been kept confidential at VIVE and no one but the authors has had access to the data.

Data analysis

The first author went through all interview minutes systematically and extracted text excerpts relating to the three parts of the analysis. Subsequently, a content analysis (Hsieh and Shannon 2005) was undertaken to condensate key points from the interviews and identify contrasts and agreements between different stakeholders. In cases of differing viewpoints among stakeholders, we have strived to reflect the diverging perceptions in the text.

Before publication, the informants were given the opportunity to review and correct any factual errors in the report sections that build directly on their interviews. This led to some revisions in the comparison between the market for hospital medicines and medical devices; most notably in the description of the documentation requirements for product approval of medical devices. None of the informants prohibited the use of any of the information with which they were presented.

Appendix 2: Generic interview guide

Introduction to the project and the interview

- Along with ambitions of using procurement practices to maximise health outcomes per money spent, new questions arise about the organisation of procurement processes and the application of evaluation criteria.
- Novartis has approached VIVE to obtain a mapping of Danish experiences with the inclusion of other evaluation criteria than price in the procurement of hospital medicines.
- VIVE does not seek to forward a certain agenda in relation to value-based procurement. Our interest is to understand which conceptions of value are expressed in the current regulation of pharmaceutical procurement.
- The purpose of this interview is to learn about your perspectives on the procurement of hospital medicines in Denmark and experiences of combining price with other criteria. We expect the interview to last maximum one hour.
- Ok to record the interview? Data are stored confidentially and neither the sponsor nor any other person will have access to any of the data. The results of the study will be published in a report on the website of VIVE.
- Go through consent documents together and reach agreement on the use of interview data.
- Any questions before we start?

General perceptions of pharmaceutical value

1. Viewed broadly, which parameters do you/your organisation find relevant when assessing the value of hospital medicines? Which parameters do you find most important?

   For instance, clinical efficacy, adverse effects, tolerability, safety, ready-to-use formulations, security of supply, environmental impact, innovation, health economic benefits, patient preferences, quality of life, functional ability, PRO/PROM, risk reduction (e.g. reduced spread of an infection).

Use of value-based pricing in Denmark

2. To your knowledge, what is the current state of affairs in Denmark when it comes to the inclusion of other criteria than price in the evaluation of hospital medicines/medical devices?

   a. How much does the price typically weigh, when other criteria than price are included in tenders? Do you know of any examples of price weighing less than 50%?

3. Can you provide an example of a tender in which other parameters than price were included in a way that you found beneficial?
   a. What contributed to make it beneficial? Is the example exceptional or widespread?
   b. Which other parameters were included? How were they decided upon?
   c. Which documentation requirements? Did you find them relevant and fair?
   d. Any monitoring of the contract? How?
   e. Any challenges in the tendering process?

Perceived challenges in relation to value-based procurement

4. In your view, which challenges are related to the use of other criteria than price, when the value of hospital medicines / medical devices is evaluated? For instance, considerations about:
    a. Risk of discrimination?
    b. Documentation demands and possibilities?
    c. Risk of evidence requirements crowding out 'softer' aspects of product value?
    d. Risk of evidence requirements being disadvantages for some patients groups (e.g. due to small population sizes)?
    e. How to ensure funding for products with added value? Re-allocation within the existing budget?
    f. How to handle situations when potential savings or costs fall outside the realm of the regional payers?
    g. Economic disincentives for procurers or hospitals to give weight to other criteria than price?
    h. Any experiences of resistance from clinicians or others?

Looking forward

5. Which possibilities do you see for more systematic efforts to stimulate competition on other parameters than price in the procurement of hospitals medicines / medical devices? Which pitfalls?
    a. Which parameters could be relevant to include, and how could they be translated into assessment criteria?
    b. Any parts of the market that appear particularly suitable for value-based procurement?
    c. Are the possibilities here now, or is there anything that needs to be changed?
    d. Where do you look for inspiration?
    e. Any potential for conflicts among various actors on the market?

Specifically about the Danish Medicines Council (only relevant for some informants)

6. How are patient experiences included in the assessments undertaken by Danish Medicines Council?
    a. Which possibilities do you see for including patient experiences?
    b. Which challenges?

7. Do you see any risk of ignoring important differences among products with the current assessment methods? What are your considerations in this regard?

8. How is the added clinical value being compared with the incremental treatment costs?

    a. Any indications of political acceptance of cost effectiveness analysis (CEA)?
    b. Your / your organisation's perception of CEA and use of cost per QALY?

Specifically about the medical device market (only relevant for some informants)

9. Please explain how the procurement of medical devices is organised in Denmark.
    c. Who buys?
    d. Which procurement mechanisms?
    e. Which criteria applied?
    f. What documentation requirements?

10. What do you see as the main differences compared to the pharmaceutical market?
    g. In your view, what do these differences reflect?

11. Any experiences from the device market that you think could be of relevance to the pharmaceutical market?

Rounding off

- Anything else you would like to add?
- Anything you would like to ask us about?
- We would also like to interview political decision makers about their views. Whom would you suggest we talk to?
- Thank you for your participation and for your provided information about the publication process.

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