The Norwegian processes for implementation of medicinal products and the associated tenders

Specialist Health Services
## Contents

**Executive summary** 3

**Introduction** 5

**Background**
- Funding of pharmaceuticals in Norway 7
- Pricing of pharmaceuticals in Norway 7
- Decision-making process for reimbursement by the RHAs 8
- Health Technology Assessment 10
- The negotiation and tendering process 11

**Project methodology** 13

**Discussion** 15
- “Nye metoder” 15
- Coordination between “Nye metoder” and the negotiation and tendering processes 16
- The price negotiation and tendering processes 16
- Reward for innovation in current processes 18
- Escalating list prices and confidential discounts 20
- Access to new medicinal products in Norway 21
- A trend toward European and Nordic cooperation regarding HTA and procurement 21
- Other countries have taken an interest in the Norwegian model 22
- Trends that can affect the current processes 22

**Conclusions** 25
- Suppliers with a good understanding of the Norwegian processes are likely to benefit on Nordic and European scales 25
- Value-based health care and precision medicine are likely to make new pricing models relevant 26
- Easily accessible information and predictability will further improve efficiency of the current processes 26
- Increasingly complex tenders should be met with measures to ensure treatment of high quality 27

**References** 29
The project that resulted in this article was initiated and funded by Novartis and conducted by EY professionals. In the initial phase, Novartis and EY professionals worked together to refine the scope of the article. Following this phase, in order to make the article as objective as possible, EY professionals withdrew from dialogue with Novartis. Data collection and elaboration of the article were performed by EY professionals, without involvement from Novartis.

The article aims to take a closer look at the current process for implementation of medicinal products by the Regional Health Authorities and the associated competitive tenders. By conducting in-depth interviews with representatives from various actors and stakeholders, we aim to provide insight into the processes in the light of the current environments and the road ahead. Interviews were conducted between February and April of 2018.

In Norway, several measures have been taken to accommodate increasing medical expenditures. However, such measures should be weighed against Norwegian citizens’ statutory right to equal access to healthcare services of high quality. In addition, the pharmaceutical field is changing rapidly, with development toward precision medicine and gene therapy as well as therapy for numerous narrow indications. It is likely that the supplier marked will be characterized by an increasing number of small actors, with limited knowledge about the Norwegian model.

We believe that suppliers with a good understanding of the Norwegian processes are likely to benefit on a Nordic and European scale. Several countries have taken interest in the Norwegian model, particularly in the lineup of national actors and the connected decision-making process, and negotiation and tendering processes. In addition, Norway is an active participant in several Nordic and European initiatives. Further, we believe that the governing bodies should contribute to this understanding by standardizing the processes further, and provide easily accessible and lucid information in both Norwegian and English. This is likely to simplify the dialogue between actors and suppliers, and make the processes more efficient.

EY believes that value-based healthcare and precision medicine are likely to make new pricing models relevant. Current decision-making processes are influenced by value-based health care. However, after implementation, there is limited follow-up of the implemented treatments. This could lead to a potential value gap, resulting in an uncertainty regarding the actual benefit and, consequently, the apprehension of whether the prices can be justified. It is likely that the pricing approaches in the future will require pharmaceutical companies to work together with governing bodies to gather data that can close this value gap. New pricing models will thus be an important incentive.

In conclusion, the pharmaceutical field is changing rapidly. It is important that the governing bodies be prepared for these changes, and that the processes adapt to these changes in a way that assures that the Norwegian citizens continue to have an equal access to treatment of high quality.
In the health care systems, resources are finite, and there is a global concern about the escalating health expenditures and the ability to meet the population's increasing need for health care. This is also the case in Norway, where health expenditures are escalating faster than the GDP and health expenditure per capita currently accounts for >10% of the GDP.¹

The challenge is on policymakers to balance a sustainable health sector and provide equal access to high quality health care. Policymakers have to prioritize and manage healthcare budgets against a backdrop of an aging population, introduction of increasingly advanced and expensive treatments and an enlightened population with high demands.

The expenditures on medicinal products have traditionally been fairly constant. However, with the introduction of expensive new medicinal products in recent years, this has changed, and expenditures are increasing disproportionally to total budgets.² In order to accommodate these challenges, several measures have been taken. This includes introduction of a process for reimbursement decisions and competitive tenders in the in-patient sector. The aim of this report is to take a closer look at the decision-making process for reimbursement by the Regional Health Authorities (RHAs) and the associated competitive tenders. Further, we aim to discuss relevant trends and issues that affect the processes at present or are likely to do so in the future. By conducting in-depth interviews with representatives of various actors and stakeholders, we aim to provide insight into these processes in the light of the current environment and the road ahead.
Introduction
Funding of pharmaceuticals in Norway
The Norwegian health care system is a national health service that is primarily financed through general taxation, and is obligated to cover all Norwegian citizens’ statutory right to equal access to health care services of high quality. The health care system is organized on three levels: the central government level with the overall responsibility, the four RHAs with responsibility for the specialist health care services in the respective regions, and the municipal level with responsibility for primary healthcare (Figure 1).

The funding responsibility of medicinal products in Norway is also divided among three – the National Insurance Scheme (NIS), the RHAs and the Municipalities (Figure 1).

Norwegian citizens are insured under the NIS, managed by the Norwegian Health Economics Administration (Helfo). The NIS is mainly responsible for funding medicinal products used outside of hospitals. There are two reimbursement categories under the NIS (referred to as blue prescription); general reimbursement and individual reimbursement. General reimbursement is based on a reimbursement list containing medicinal products that can be reimbursed for specific diagnoses, occasionally with additional criteria. For individual reimbursement, the prescribing doctor applies to Helfo for reimbursement on behalf of the patient, and reimbursement is granted on an individual basis.

The municipalities are responsible for funding pharmaceuticals used in institutions on the municipal level, typically nursing homes and care homes.

The RHAs are responsible for the funding of medicinal products used in hospitals and a selection of medicinal products used outside of hospitals (H-prescriptions). These are pharmaceuticals used for conditions that are managed by the specialist services. In recent times, the responsibility for reimbursement of pharmaceuticals used for several diagnoses has been transferred from the NIS to the RHAs. The RHAs are funded by the Central Government through a combination of block grants and a diagnoses-related group (DRG) system. Funding of medicinal products is to be managed within these frames, and no new funding follows a decision to implement new medicinal products.

Pricing of pharmaceuticals in Norway
The pharmaceutical market in Norway is characterized by price inelasticity. Due to third-party funding of medical costs, prices have a limited effect on the choice of drug, resulting in market demand having only a limited effect on prices. On the supply side, there are large sunk costs in relation to research and development; thus, in order to stimulate innovation, pharmaceutical companies are granted market power through patent protection. These mechanisms have provoked the need for various means to control medical expenditures.

One of the means to control medical expenditure is the use of a price reference system for medicinal products. The Norwegian Medicines Agency is responsible for setting the maximum pharmacy purchasing prices (PPP). This is estimated by calculating the average of the three lowest PPP from nine European Economic Area (EEA) reference countries (Sweden, Denmark, Finland, Germany, Great Britain, Netherlands, Austria, Belgium and Ireland). The PPP is typically reevaluated on a yearly basis; however, as of 2018, this is not the case for the H-prescriptions.
Another mean to control medical expenditure for NIS-funded medicinal products is the use of a stepped price model for generics. Once the patent expires and a generic drug enters the market, competition is created. The Norwegian Medicines Agency determines if a drug can be considered as generic. On this ground, the agency develops a list of drugs that can be considered equal and interchangeable. Based on the price of the reference drug, the price of a drug is reduced stepwise with set rates after the drug has entered an interchangeable list.\textsuperscript{5,7}

For pharmaceuticals funded by the RHAs, the decision-making process for reimbursement assures that medicinal products fulfill cost-effectiveness requirements. The Norwegian Drug Procurement Cooperation (LIS) is responsible for the procurement on behalf of all the four RHAs. Through price negotiations and tenders – yet other means to reduce medical expenditures – they achieve prices that are generally substantially lower than the official list prices, even for the patent-protected medicinal products.\textsuperscript{8} We elaborate on these processes later in this article.

**Decision-making process for reimbursement by the RHAs**

The current “National system for managed introduction of new health technologies within the specialist health services” (“Nye metoder”) was launched in 2013. The entry point into the Norwegian market is common for all new medicinal products, regardless of whether the funding responsibility lies with the NIS or the RHAs.

Suppliers who want to sell their drugs on the Norwegian market have to apply for marketing authorization. This can be done through four different procedures, the most common being a central procedure, where the supplier applies to the European Medicines Agency for marketing authorization in all EU and EEA countries.\textsuperscript{6}

When a supplier sends an application for marketing authorization, the Norwegian Medicines Agency starts preparing the Horizon Scanning (Metodevarsel) (step 1, Figure 3). The purpose of the Horizon Scanning is timely identification of new and important
medicinal products, recommending priority, and facilitating the Health Technology Assessment (HTA). Subsequently, the Norwegian Directorate of Health decides if the funding responsibility lies with the NIS or the RHAs (step 2, Figure 3). If the funding responsibility lies within the RHAs, the medicinal product is subject for the “Nye metoder” process.

The Horizon Scanning forms the basis for the order and priority of an HTA (step 3, Figure 3). This is performed by the Commissioning Forum, consisting of the medical directors of the RHAs and two delegates from the Norwegian Directorate of Health. The HTA (step 4, Figure 3) is performed by the Norwegian Medicines Agency and is conducted on all new medicinal products.

After the completion of the HTA, the Commissioning Forum evaluates whether the HTA reports are adequate and, if so, sends the documentation to the Decision Forum (step 5, Figure 3). The Decision Forum, comprising the CEOs of the four RHAs, makes the decision on whether the new drug can be reimbursed by the RHAs, and thus be implemented (step 6, Figure 3). The Decision Forum base their decision on the priority-setting criteria that forms the basis of the HTA, but also on the Patient and User Rights Act and a set of principles jointly prepared by the RHAs. Once the drug and price is registered, the health authorities can start using the new drug. As mentioned above, the new medicinal products that are to be funded by the RHAs can also be subject to price negotiations during the decision-making process (Figure 3). The Decision Forum can await decision to implement, pending a new HTA using negotiated discounts.

Provided a positive decision regarding implementation and that the new medicinal product is considered not to be significantly different from other medicinal products that are in use for the same indication, the new medicinal product can be included in a tender (step 7, Figure 3). This is the case for roughly two thirds of the new medicinal products.

Figure 3: The process of “National system for managed introduction of new health technologies within the specialist health services” ("Nye metoder"), with focus on medicinal products.

The RHAs are responsible for the funding of medicinal products used in hospitals and a selection of medicinal products used outside of hospitals.
Health Technology Assessment
The current HTA, performed by the Norwegian Medicines Agency as a part of “Nye Metoder”, is a prioritization tool in line with national guidelines. The main criteria for priority settings are 1) the severity criterion 2) the benefit criterion and 3) the resource criterion.

The pharmaceutical companies are responsible for submitting sufficient documentation prior to the HTA. During HTA, the new medicinal products are assessed based on the priority-setting criteria. In order to use these criteria in health economic analyses, they have to be quantifiable. Severity is quantified as the number of healthy life years lost as a result of not using the new medicinal product in question. Benefit of a new medicine is also measured in terms of healthy life years. Quality Adjusted Life Years (QALY) is used as a measure of healthy life years and, thus, used to quantify the severity and benefit criteria. As clinical studies have different measurements that assess the effect of a treatment, they are not directly comparable. In order to have an objective measurement that can be compared across treatments and patient groups, a generic measurement, such as QALY, has to be applied. Healthy life years have two dimensions: quality of life and length of life. Thus, the QALY measurement is a function of quality of life (H, a scale from 0 = dead to 1= perfect health) and length of life (T, time in years); QALY = H x T. Two years lived in perfect health equals 2 QALY, whereas two years lived with health-related quality of life of 0.8, equals 1.6 QALY. The resource criterion is evaluated by mapping and estimating all relevant uses of resources connected to treatment with the new medicinal product.

Further, all three criteria are to be assessed and weighted against one another. The more severe a condition or the more beneficial a new treatment is, the more acceptable the higher use of resources will be. In practice, calculation of costs and benefits are put together in a cost-effectiveness ratio, which is viewed in the light of the severity of the condition.

During the HTA, the new medicinal products are assessed based on the priority-setting criteria.
The health economic analyses are performed using the PPP and different discounts from them.

The negotiation and tendering process
The LIS is formed as a part of the Procurement Services for Health Enterprises (Sykehusinnkjøp), and is responsible for the negotiations and tenders associated with the procurements of medicinal products in the specialist health services. LIS is an actor in “Nye metoder. Their role consists of negotiating prices when there is a necessity to have a more acceptable cost compared to benefit, or when introduction of a new medicinal product has too large of an impact on health budgets. They are also responsible for the execution of tenders.¹¹

Tenders can roughly be divided into two main categories: the basic medicinal product tenders and the disease-specific tenders.¹¹ The basic medicinal product tenders are for the assortment of medicinal products needed to operate a hospital ward. These tenders are based on active pharmaceutical ingredient. The main award criteria typically include price, user-friendliness, packages and product range, delivery reliability and service.¹²

In the disease-specific tenders, there is mainly one competitive tender per indication. For some tenders, the pharmaceutical companies have to accept a minimum discount, typically in the range 5%-17%, in order to participate in the tender. The main award criteria is price, based on the prerequisite that the medicinal products are considered not significantly different in terms of regular use.¹²

Based on the offers from the pharmaceutical companies, a specialist group — typically consisting of doctors, nurses, representatives from patient organizations, representatives from the Norwegian Medicines Agency and LIS — prepares a recommendation (LIS recommendation). The health authorities are instructed to use the recommended medicinal products. If prescribing doctors deviate from these LIS recommendations, they have to document the rationale in patient records.
A look at the Norwegian decision-making process for the implementation of medicinal products
The project that resulted in this article was initiated and funded by Novartis and conducted by EY professionals. In the initial phase, Novartis and EY professionals worked together to refine the scope of the article. Through this work, as well as various in-depth interviews conducted with key subjects at Novartis, EY professionals received inputs on what suppliers saw as key issues regarding the process for reimbursement decisions and competitive tenders in the specialist health services.

In order to make the article as objective as possible, EY professionals withdrew from dialogue with Novartis after this initial phase. Data collection and elaboration of the article were performed by EY professionals, without any involvement from Novartis. Novartis do not have access to any material besides this public report.

Further, we sent out a request to the actors of “Nye metoder” and the tendering process to participate in an interview. We conducted interviews with the Norwegian Directorate of Health, the Norwegian Medicines Agency, the Commissioning Forum, the Decision forum, The Secretariat of “Nye metoder,” and the LIS. In addition, we interviewed the Norwegian interest groups for cancer and multiple sclerosis (MS). Interviews were conducted between February and April of 2018. The LIS also provided some main feedback from a roundtable conferences with external stakeholders and suppliers.

We used a semi-structured interview method where we touched upon three main topics: 1) the background of the interviewee and the role of their actor in the processes 2) current situation of “Nye metoder” and the negotiation and tendering processes 3) changes within pharma, health politics and health economics that might affect current processes. Due to limited time, differences in insight, and some actors not being able to comment on certain topics due to their position, topics varied across the interview objects. The interview objects were sent a draft of the article for them to see how their statements have been interpreted and used, and were given the opportunity to comment if they felt misrepresented.
“Nye metoder”

“Nye metoder” was launched in 2013. The involvement of numerous actors – from the time a supplier applies for marketing authorization to the point where the drug is in use within specialist health care – has led to the formation of a system that has taken some time to find its form and that is still under continuous development. In Norway, the evaluation of new health technologies is not regulated by legislation. This has made the development of “Nye metoder” challenging. In this regard, the Norwegian Medicines Agency describes that the recent White Paper on priority settings in the Norwegian health care sector has been a useful formalization and confirmation of the methodology in use. According to the Secretariat of “Nye metoder,” the development of the system has been facilitated and refined through feedback and dialogue among the actors, external stakeholders and the industry.

The actors of “Nye metoder” describe the main improvement area as efficiency. Initially, efficiency was affected by a backlog of methods that were to go through the process. Further, they describe a continuous improvement in processing time from the launch in 2013. In order to further improve processing time, they have started to quantify the time spent in various stages. This has revealed that the HTA and taking decision on whether or not to implement are especially time-consuming steps. Regarding the HTA, they report that a substantial part of the time is spent on waiting for adequate documentation from the suppliers. Thus, in addition to improving internal processes, facilitating submission of adequate documentation is also an important focus point.

“Nye metoder” has focused on building a process that is structured and transparent, with procedural steps, methodology and documentation that are consistent and verifiable. According to the Norwegian Medicine Agency, this has led to a good dialogue with the suppliers, and although they might not always agree on the outcome, they rarely dispute the methodology. This has been confirmed through conversations with the suppliers and their feedback in LIS round table conference.

However, the Decision Forum has been subject to debate. In a proposal from the Parliament to the Government, it is argued that the current situation is characterized by conflicting roles as the four CEOs are in charge of both the overall economy in their respective RHAs and deciding whether the same RHAs can fund a new medicinal product. As the RHAs have to manage within the allocations provided through block grants and activity-based funding, and no further funding follows a decision to implement a new medicinal product, they argue that this can lead to unfortunate priorities with consequences on the quality of patient care. Consequently, it was suggested to discontinue the current Decision Forum and establish a new Decision Forum, where decision to implement is not restricted to the CEOs alone. However, the proposal was declined.

We discussed this debate with the leader of the Decision Forum, Lars Vorland. He observes the current composition as appropriate. “If it is not the CEOs who make these decisions, someone that is not in charge of economy will make decisions that we have to effectuate. This will lead to an unfortunate disconnection between decisions and responsibility.” He admits that the current budget situation is challenging, and it will probably be even more challenging in the years ahead. However, priority within budgetary frames is not new to
them. Resources are finite, and current allocations reflect priorities made by the Parliament regarding how much of societies’ resources are to be allocated to the specialist health care services. Either the Parliament has to decide to allocate more funding in future, or they have to make even tougher priorities than today. This is okay, he says, but then the public needs to be aware that this is the case. He does not see a fund for implementation of new medicinal products as a solution. He argues that this funding will also need to be taken from somewhere. Consequently, drug treatment is prioritized above everything else, instead of looking at the bigger picture.

Coordination between “Nye metoder” and the negotiation and tendering processes

In a recent report from the RHAs, it was described that there was a lack of a formalized process between “Nye metoder” and the negotiation- and tendering processes. Both the Secretariat of “Nye metoder” and the Norwegian Medicines Agency described that the coordination between the actors of “Nye metoder” and the LIS is an important focus area, moving ahead. More specifically, The Norwegian Medicines Agency describes the need for improving the predictability for the new drugs that are to go through the processes. A specific measure is that the suppliers be informed at an earlier stage if they are to be included in a tender.

The suppliers in LIS’ round table conference also reported a lack of coordination between the actors. The suppliers describe a process that is somewhat unpredictable as they are sometimes included in a tender before they have gone through the process of “Nye metoder.” This has been confirmed by the LIS. The new medicinal products are included under the prerequisite that they have to be approved by the Decision Forum before the health authorities can start using the drug. The inclusion is voluntary. Suppliers do not want to miss the opportunity to compete in the tender, as this might delay market access to up to one year. On the other hand, they experience a situation where they do not know what the outcome of the decision-making process will be, which makes preconditions to compete harder. According to the LIS, they are looking closely at this arrangement, and it is yet undecided whether this should be continued or not. There are also different arrangements regarding the use of a new medicinal product – from the time the Decision Forum approves it until it is included in a tender. Some medicinal products can be used by the RHAs directly after the decision to implement has been made, while others are not to be used until they have been included in a tender. According to the LIS, the actors are currently working on specific measures in order to make the transition between “Nye metoder” and the tendering process more clear.

The price negotiation and tendering processes

The LIS was established in 1995, and was originally a collaboration among a few counties. After the transfer of specialist health services from the counties to the central government level in 2002, the LIS became a national service. In 2006, the LIS was responsible for three tenders. The number escalated considerably with the introduction of “Nye metoder” in 2013, and the transfer of reimbursement
responsibility of pharmaceuticals for several diagnoses from the NIS to the RHAs. It is estimated that the LIS will be responsible for 24 tenders in 2018. It is likely that reimbursement responsibility for even more diagnoses will be transferred in the years to come, further increasing the number of tenders.

These changes have led to the LIS having to adapt quickly. The Norwegian Medicines Agency has stated that some of the tenders have struggled to find its form. The LIS has communicated that they are in the middle of a process to develop a new strategy. In this regard, the LIS held some roundtable conferences with external stakeholders, including suppliers. The process includes a gap analysis to look at the current process up against current procurement regulations. According to the LIS, there might also be a need to change the current regulations.

As mentioned above, the tenders carried out by the LIS, can roughly be divided into two main categories: the basic medicinal product tenders and the disease-specific tenders. The actors we interviewed described the basic medicinal product tenders as well-established and working well. Consequently, the ensuing discussions will focus on the role of the LIS in “Nye metoder” and the disease-specific tenders.

Medicinal products can be included in the same tender if considered not significantly different in terms of regular use. The Norwegian Medicines Agency performs this evaluation. According to the LIS, the tenders are growing in complexity and it can sometimes be difficult to evaluate whether the medicinal products can be included in the same tender. The oncology tenders have especially grown in complexity, and some diagnoses have different LIS recommendations for different subgroups of patients.

Suppliers perceive that the tendering process lacks transparency as the clinical considerations made during the different tenders are not made available. When talking to the LIS, they expressed an understanding toward the suppliers’ experience; however, transparency is complicated partly due to the confidential discounts. Furthermore, suppliers perceive that a thorough evaluation of cost-effectiveness is conducted in “Nye metoder,” but is not sufficiently considered as a part of the tender. In the roundtable conference with the suppliers, they also called for a consideration of the effect of the treatment in addition to costs. Their experience is that the current process is not sufficiently rewarding incremental innovations. The Norwegian Directorate of Health states that the differences in effect or side effects that are advocated by the pharmaceutical companies are often not significant on a group level. Further, The Norwegian Medicines Agency states that small differences in effects can be acceptable, given a substantial discount. Furthermore, evaluation of differences in effect is often difficult due to a low number of comparable studies at the time of the tender.

The LIS confirms that there are no routine evaluations of other factors than costs. However, the LIS specialist groups are established
to safeguard that other factors are taken into consideration, if necessary. According to the Norwegian Medicines Agency, the TNF/bio and the MS tenders are examples of tenders where differences in effects or side effects have affected the recommendation. The LIS underlines that the prescribing doctors’ right to make an individual evaluation based on the patient in question further safeguards the quality of treatment.

The MS interest group problematizes a lack of consistency between the LIS recommendations and clinical guidelines. Their perception is that the clinical guidelines are rarely discussed in the preparation of the LIS recommendation. The MS interest group fears that this can cause confusion among clinicians, and that the use of LIS recommendations can lead to less-aggressive treatment than recommended in clinical guidelines. A lack of coordination between the work with clinical guidelines by the Directorate of Health and the LIS recommendations was also highlighted in a report from the RHAs. However, updating clinical guidelines is time-consuming, and experiences from Denmark suggest that waiting for such updates before a new tender is unfortunate, as this leads to local guidelines being susceptible to influence by market forces. The LIS however, states that although the main award criteria is costs, clinical guidelines are considered, and that LIS specialized group generally includes clinicians involved in the elaboration of clinical guidelines for the same indication.

The LIS confirmed that the great diversity and complexity in the current tenders have made it obvious that one size does not fit all. In developing the new strategy, an evaluation of factors that need to be taken into consideration and the use of the LIS specialized group are being considered. One tender per active substance has been mentioned as one of the options under consideration.

Reward for innovation in current processes
Facilitating innovation and research is an important objective in the Norwegian policy for medicinal products. As mentioned above, suppliers perceive that the Norwegian model is not sufficiently awarding innovation. Actors of “Nye metoder” report a difference between governing bodies and the suppliers on the perception of what should be defined as innovation. The reduced willingness to pay for the so-called incremental innovation is a global phenomenon that is well-known. Some of the new medicinal products are the so-called “me too drugs” that focus on targets that are already thoroughly documented by others. They base their documentation on not being significantly different from the reference drug and, thus, use less resources. In addition, they often do not submit sufficient documentation to perform full-cost efficiency analyses. The Government has asked “Nye metoder” to develop a fast track for the evaluation of these drugs in order to increase efficiency. Consequently, these medicinal products are rapidly included in tenders with the reference drugs where they mainly compete on price. The Norwegian Medicines Agency understands that this might seem unjust for the pharmaceutical companies with the reference drugs.

In previous revisions of principals for priority settings, evaluations have been done on whether there should be a separate priority criteria to evaluate whether a new method contributes to innovation. The conclusion has been that this is not advisable and that this can lead to other outcomes than what follows the main priority criteria; for example, treatments for less-severe conditions can get higher priority due to higher innovation potential. In line with these investigations, the Norwegian Medicines Agency advocates that innovative drugs be safeguarded by the HTA, as their benefits become apparent. This, in turn, will increase the willingness to pay. When a new medicinal product demonstrates an effect that is significantly better than the existing treatment for the same condition, or is a treatment for a condition where no previous treatment is available, price can be negotiated through direct negotiations. This was the case for the widely discussed and newly implemented drug, Spinraza.

Suppliers also call for the possibility of indication-specific pricing. As it is today, a medicinal product can only have one price. Since the effect of a medicinal product can vary based on indication, cost-efficiency can also vary based on indication. Therefore, suppliers argue that indication-specific prices can be relevant. The actors of “Nye metoder” are critical as regards to indication-specific pricing, as they believe that this will lead to increased administration and will be difficult to reinforce.

A new medicinal product can be subject to price negotiations through several steps, such as during the decision-making process for reimbursement, including negotiations with the Decision Forum and the Norwegian Medicines Agency, and through participation in tenders with mandatory discounts. Suppliers perceive this as a complex process that does not sufficiently reward the cost-effectiveness of a medicinal product, demonstrated in an HTA. Further, suppliers describe the process as arbitrary as, for instance, approvals in the
A look at the Norwegian decision-making process for the implementation of medicinal products | 19
Decision Forum can be dependent on price submissions in tenders. In this regard, suppliers perceive that the mandate of the different actors is somewhat unclear. In addition, although the HTA is perceived as transparent by the suppliers, the Decision Forum base their decision on additional criteria. The evaluations made by the Decision Forum that lead to their decision, are not made public. The suppliers therefore report that the outcome is not always intuitive based on the accessible documentation.

An increase of minimum discounts for participation in the TNF BIO tender from 9% in previous years to 17% this year received critique from several of the pharmaceutical companies. The LIS stated that they are currently evaluating whether minimum discount is a practice they should continue. The Norwegian Medicines Agency states that the steep increase in list prices in the recent years cannot be defended by the increases in research and development costs, but has to do with the pharmaceutical companies’ strategy to fulfill commitments made to shareholders by maintaining high profit margins. They believe that the evaluation in “Nye metoder” system is to be considered as an absolute upper limit, and negotiations are necessary in order to bring prices down to acceptable levels.

Escalating list prices and confidential discounts

As stated in the White Paper on Medicinal Products, actors from “Nye metoder” describe that there is a trend in the pharmaceutical industry for setting what they see as exorbitant list prices for certain new medicinal products, but that the industry is willing to negotiate on discounts, given that the official list prices stay the same. One of the motives of the industry might be that this prevents knowledge about discounts being spread across countries and thus being used in price negotiations in other countries.

Confidential discounts and unit prices were implemented in Norway in 2016, based on the legal assessment that unit prices are regarded as trade secrets pursuant to the Public Administration Act. Confidential prices has later been subjected to extensive opposition and debate in the public hearings connected to changes of the Act related to medicines, the White Paper on priority settings, and recently in the public hearing related to the report about the handling of unit prices. Opponents argue that confidential unit prices are not in line with the principals of transparency and trust within the Norwegian health care sector and that such transparency is crucial to legitimize the decision and compare priorities across patient groups to confirm that priorities are fair. The Government has decided that as of now, the potential disadvantages of missing substantial discounts outweighs the advantages. Further, they argue that transparency regarding discounts will require coordination at Nordic and European levels, and that this is one of the incentives for Norway’s participation in several initiatives.

Official list prices that are not representative of actual prices have decreased the opportunity to control medical expenditures through the price reference system. Consequently, as of 2018, the yearly reevaluation of PPP is no longer applicable for H-prescriptions. Talking to the Norwegian Medicines Agency, there is an ongoing process to further evaluate the use of price reference system for the
Discussion

A look at the Norwegian decision-making process for the implementation of medicinal products

The limited benefit of the price reference system has made the negotiation and tendering processes necessary in order to achieve discounts, bringing the prices down to an acceptable level. If the list prices were close to the acceptable levels, the tendering process would not be necessary, as stated by the Norwegian Medicines Agency. Given this development in list prices, the Norwegian Medicines Agency argues that the LIS has to become tougher and more strategic than they are today in order to achieve a desired negotiation position.

Access to new medicinal products in Norway

The actors of “Nye metoder” state that they are not under the impression that pharmaceutical companies choose not to prioritize the Norwegian market. Their view is that pharmaceutical companies see the Norwegian market as attractive because of new medicinal products being rapidly implemented with a generally high willingness to pay. In addition, with centralized decision-making with regards to implementation, access to the whole market is given at once.

Further, the actors are under the general impression that Norway is relatively quick to implement new medicinal products, compared to the rest of Europe. However, the Secretariat of “Nye metoder” underlines that no formal investigations have been performed in recent years. The MS interest group shares this impression, as Norway often has more rapid access to new MS treatment compared to the rest of the Nordics. However, The Norwegian Cancer Society has had some experiences where it has taken a long time from granting of marketing authorization until implementation of the medicinal product. This has led to a situation where other Nordic countries have access to medicinal products that are not yet available in Norway. The Norwegian Cancer Society has suggested a temporary funding arrangement for medicinal products pending decision on implementation. The Norwegian Medicines Agency and the Commissioning Forum argue that such an arrangement is not advisable, as it will weaken the governing bodies’ negotiation position and undermine the decision process. The Norwegian Cancer Society further underline that the national model has led to more equal access to treatment, and that the processes have become increasingly more efficient. Further, they emphasize that the implementation rate is high, giving Norway access to advanced cancer treatment of high quality.

A trend toward European and Nordic cooperation regarding HTA and procurement

At EU level, there has been an ongoing HTA cooperation since the 1980s. A third joint action (EUnetHTA Joint Action 3) was launched in 2016, with the focus on developing a common methodology and piloting joint clinical assessment and HTA reports. Norway is an active contributor in this project. In January 2018, the EU Commission published a proposal for an EU regulation of HTA. The proposal suggests common European assessment methods and common procedures within the EU. More specifically, the proposal suggests that clinical assessments of benefits compared to existing treatment be jointly performed by the Member States, while economic, social and ethical aspects, as well as pricing and reimbursement be performed on a national level.
A Nordic cooperation has been discussed with regards to priority issues for some time, and a report elaborating the possibilities was released back in 2013. In January, The Norwegian Medicines Agency announced that the Medicines Agencies of Norway, Sweden and Finland are going to perform common HTAs. The collaboration is called FINOSE and is considered a pilot.

The process workloads of “Nye metoder” are high today, and are going to be even higher moving forward. According to the Norwegian Medicines Agency, the main goal is to distribute the workload between the collaborating countries. The hope is that the collaboration will increase efficiency and make it easier for suppliers, as they will have to submit documentation in only one country instead of three. Further, the description of the pilot states that if a clinical assessment is performed within EUnetHTA, and can be used as a basis for the health economic analysis. Decisions are still to be taken on a national level. Thus, it is likely that this is similar to the way HTA can be performed after the application of EU regulations, provided that the Nordic collaboration persists. The Norwegian Medicines Agency and the Commissioning Forum underline that such collaborations also aims to improve governing bodies’ negotiating positions.

The Norwegian Medicines Agency states that collaboration on HTAs is applicable for rare conditions primarily. It is likely that the number of drugs for rare conditions will increase. The Decision Forum adds that such a collaboration will be good for exchanging ideas, as recently done in the process with the drug Spinraza for the rare condition spinal muscular atrophy (SMA). In addition, they believe that such a collaboration will be crucial for developments within precision medicine, as a larger workforce and academic community are needed to deal with the challenges that might occur.

According to the Norwegian Medicines Agency, the challenge is, however, on recognizing each other’s methodology and agreeing on a common report. Differences in methodology are also the main reason why Denmark as of now is not a part of the collaboration – the main difference being that they do not use QALY as a standard measurement. However, according to the Secretariat of “Nye metoder,” the methodologies across the Nordics are converging, and so inclusion of Denmark might occur.

A Nordic collaboration is also emerging for tenders. In 2015, Amgros, the pharmaceutical procurement service for the regional authorities in Denmark, initiated “Nordisk Lægemiddel Forum” (NLF), a community created for knowledge-sharing and providing opportunities for common tenders. The community has representatives from Iceland, Norway, Sweden and Denmark. There have already been some common tenders with Denmark and Iceland. According to the LIS, collaborations with Iceland and Denmark are currently more relevant due to the fragmented organization of procurement processes in Sweden. At Amgros, the focus is currently on three areas: 1) Common tenders for new and expensive drugs, 2) Horizon scanning, and 3) Delivery reliability. As of now, three specific tenders are discussed.

Other countries have taken an interest in the Norwegian model

Several of the actors we interviewed referred to an international interest in the Norwegian model. The HTA in itself is not unique, says the Secretariat for “Nye metoder,” but the interest lies in the national lineup of actors, and the coordination and collaboration among the actors – from the point where the supplier applies for marketing authorization to the point where the drug is in use in the health authorities. Further, the LIS describes that a national service for both procurement and tendering is unique. Countries around Europe are contacting them to learn more about how they are organized.

Trends that can affect the current processes

Value-based health care is about achieving the best outcomes for the resources spent. Norway has a long tradition of working systematically with priority issues within the health care sector, and five public investigations has been conducted during the last 30 years. The Norwegian Medicines Agency believes that the current decision-making process for reimbursement, with priority criteria that aim to ensure high-quality treatment at an acceptable cost, is in line with a development toward value-based health care. However, after implementation, there is limited follow-up of what effect the new treatment has on the population. After “unreserved” implementation, the pharmaceutical companies have limited incentives to follow up treatments. One such incentive could be through new types of pricing models.

In general, Norway seems to have a relatively low maturity level for new types of pricing models. The actors’ main concerns about new types of pricing models, such as risk-sharing models or “pay for value” solutions, are that they require too much administration. Resources are limited as it is today; hence additional monitoring of contracts would potentially put too much pressure on the system. In addition, the prescribing doctors are resistant to perform additional work, and the systems are not developed in a way that allows for simple extraction of relevant data. The Norwegian Directorate of Health observes that management of the principle of transparency and equality of treatment will be challenging with the introduction of
such models. If the governing bodies are to be open to new types of pricing models, the contracts and terms will have to be undisputable and easy to manage. In addition, there needs to be a real potential benefit in accepting such models.

In Norway, there are some examples of contracts that included detailed terms of use or outcome measures, which led to additional follow-up. One example is the contract for general reimbursement for the use of the diabetes drugs Actos and Avandia in combination. The drugs could only be prescribed in combination and there were clear terms for when this combination could be prescribed. If the treatment was prescribed outside of these terms, the pharmaceutical companies were obligated to refund some of the costs. The general experience from this contract was that it was difficult to enforce these terms. The start and stop criteria that is a part of the terms of use for Spinraza, is another example of contracts that can lead to additional monitoring. The Norwegian Directorate of Health expects increased use of such criteria, moving ahead.

The Norwegian Cancer Society believes that new types of pricing models are likely to become relevant. They see this as a way to facilitate rapid access to new treatment, and an incentive for suppliers to follow up the effect of new medicinal products after implementation. In general, they believe that Norway should be participating more in the testing and monitoring of new medicinal products. This can contribute to strengthening the documentation that the HTA is based on, and contribute to a better understanding of who benefits from the medicinal products. This, in turn, can lead to more personalized and cost-efficient treatment. The Secretariat of “Nye metoder” agrees that monitoring of new methods after implementation is an important focus point.

In the horizon, the actors are aware of medicinal products that are granted approval based on mechanisms of actions instead of indications. This is a challenge for a process that is based on indication-specific treatment. They have already seen an increase in treatment for rare conditions, and narrow indications, and expect to see more of this in the future. This can potentially lead to a volume challenge. The actors expect that the development within precision medicine, the use of several medicinal products in combination and as well as gene therapy can also affect the current processes in the years to come. They also expect a development toward more holistic solutions where suppliers offer solutions that include treatment and follow-up. The Norwegian Directorate of Health stated that there is a risk that the models can become so complex that the processes may collapse.
Suppliers with a good understanding of the Norwegian processes are likely to benefit on Nordic and European scales

For suppliers, EY professionals believe, an extensive knowledge about the Norwegian processes will be valuable, not only in the Norwegian market, but also in the Nordic and European markets. There are several reasons for this. Regarding the HTA, the actors report that a substantial part of the time taken for a new medicinal product to go through an HTA is spent on waiting for adequate documentation from the pharmaceutical companies. The comprehensive HTA sets the standards high for documentation. The quality of the documentation delivered will affect the cost-efficiency analyses and, thus, the willingness to pay. Timely delivery of adequate documentation will shorten the time it takes for the medicinal product to go through the HTA. This, in turn, will lead to quicker access to the market and more time to prepare for a potential tender.

Further, the actors are responsive to inputs from stakeholders, including suppliers. The tendering process is currently being evaluated and several aspects are in focus. By knowing the process and giving constructive feedback, suppliers can influence the process.

Several countries have taken an interest in the Norwegian model as Norway has developed a process that effectively evaluates new medicinal products’ efficiency, safety and cost-effectiveness requirements, while managing to achieve substantial discounts. A number of visits from other European countries to gain insight into the model reflect this. They are particularly interested in the lineup of national actors the connected decision-making process, and negotiation and tendering processes. Therefore, knowledge about the Norwegian model is important in order to be prepared for possible developments in other countries.

Norway is an active participant in several Nordic and European initiatives. They are currently involved in collaborations within both HTA and tenders. The HTA collaborations have included the possibility of making use of the clinical assessments performed as a part of the ongoing EUnetHTA pilot. Thus, it is likely that this is similar to the way HTAs are to be performed after the application of the proposed EU regulations.

Finally, mastering the Norwegian processes has obvious benefits as Norway is often among the first in Europe in implementing new medicinal products. In addition, Norway has a relatively high implementation rate and a decision to implement leads to simultaneous implementations in all health authorities.

Norway is an active participant in several Nordic and European initiatives.
Value-based health care and precision medicine are likely to make new pricing models relevant

Regarding the process of “Nye metoder,” there is clear influence of value-based health care, where the focus is on producing the best patient outcomes with the allocated resources. This is clearly demonstrated by the current priority criteria used in the decision-making process for new medicinal products.

However, after implementation, there is limited follow-up on the implemented treatments. The issue with this kind of setup is that the return of investment needs to be decided upon up front, while the actual benefit on the population is often not measurable until years later. A majority of medicinal products now coming to the market will be classified as having potential value instead of proven value due to the documentation being based on clinical trial data and not population-based data. For instance, current principles for priority settings state that medicinal products for rare conditions should have less comprehensive demands for documentation, in order to stimulate research and development. It is expected that the number of medicinal products for rare conditions will increase in the years to come. Consequently, stakeholders are unsure if the high prices can be justified. This has been referred to as a “value gap.”

EY believes that pricing approaches in the future will require the pharmaceutical companies to work together with the stakeholders to gather data that can close this value gap – i.e., gather data based on the actual population. In Italy, for instance, access to some high-priced oncological products requires some form of pay-for-performance agreements based on follow-up through patient registries. This type of follow-up can also contribute to identifying subgroups within the population that has limited effect, or substantially better effect, of the treatment. Closing the “value gap” is also addressed in the recent EU proposal for regulation on HTA, stating that countries should take advantage of the outputs of research on HTA, including real-world evidence, in order to reduce uncertainty on effectiveness.

As for the Norwegian market, if such new pricing approaches are to be accepted, they will have to be based on clear and undisputable agreements, be easy to administer; and there has to be a clear possibility that the state will gain from these agreements. Finally, it is likely that Norway has to see clear examples from other countries, before accepting such agreements.

Easily accessible information and predictability will further improve efficiency of the current processes

In this article, we have used publicly available sources to gain knowledge about the current processes. Although the process of “Nye metoder” has developed an informative webpage that gives a good overview, we had to ask the actors to clarify the process. In our regard, the most common process for a new medicinal product should be explained without complicating it with, for instance, steps used for non-medicinal products or the more rarely used full HTA.
The information in English is limited. Further, the information about the connection between “Nye metoder” and the tendering process is also limited. The governing bodies should continue to focus on making the processes more standardized and predictable for the suppliers. This will be especially important for suppliers with limited knowledge about the Norwegian processes, and so an important measure to assure more equal terms. We also believe that these measures will increase efficiency, and simplify the dialogue between the actors and the suppliers.

**Increasingly complex tenders should be met with measures to ensure treatment of high quality**

The White Paper on Medicinal Products underlines the focus on quality treatment: “All treatment with medicinal products must be of good quality. This includes the best possible effect and the fewest possible adverse reactions.” Due to lack of transparency, it is difficult to know what considerations are taken today. However, on a general basis, EY professionals believes that the increasing complexity of the disease-specific tenders should be met with measures to confirm that the processes lead to treatment of high quality.

The tenders vary in complexity; so we agree with LIS evaluation that “one size does not fit all.” However, one should have measures that ensure that significant differences in effect or side effects are taken into account. In addition, one can consider whether to make use of the cost-efficiency analysis, and routinely evaluate if there are clinical guidelines that should be taken into account. Conflicting clinical guidelines and LIS recommendations will most likely lead to uncertainty among clinicians. We are aware that updating clinical guidelines before the tender is likely to lead to unfortunate delays, but the LIS specialist group could be used to consider if there are clinical guidelines that should be taken into consideration for the specific tender.

Further, transparency has been a key success factor for “Nye metoder” but the same transparency is not the case for the tendering process. The lack of transparency is probably due to confidential prices, as well as due to LIS’ need to maintain its negotiation position. However, the possibility that a lack of transparency regarding clinical considerations made during the elaboration of the LIS-recommendations, could lead to mistrust among patient groups and clinicians should also be considered. Uncertainty regarding considerations made, might make clinicians more susceptible to not use the LIS-recommended drug. This might especially be the case if pharmaceutical companies advocate that their medicinal products have properties that have not been considered.


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