SYKEHUSINNKJØP

Guidelines/ Handbook

Guidelines
for the introduction of pharmaceuticals in the specialist health care in relation to public procurements

Valid from: 01.01.2022

Version: 1.1

1. Introduction

All new methods financed by the Regional Health Authorities are introduced through the National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway (hereafter referred to with the Norwegian abbreviation "Nye metoder"). Health technology assessments (hereafter referred to with the abbreviation HTAs) constitute important parts of the decisions. The Decision Forum of the National System for Managed Introduction of New Health Technologies within the Specialist Health Services (hereafter referred to with the Norwegian abbreviation «Beslutningsforum») decides whether new methods and technologies receive public funding or not. Their decision is based on three prioritization criteria; benefit, use of resources and severity.

Procurements are conducted in parallel with processes in "Nye Metoder". These procurements may have different durations and agreement periods. Questions may therefore arise concerning how the introduction of a new method will interfere with ongoing competitions and from what time a new method can be introduced.

From a medical and a pharmaceutical political point of view, it is desirable to ensure early access to new methods for Norwegian patients. If a new method does not compete with existing treatment(s), it can be introduced without any concerns regarding the rules on public procurement. However, if a new method is partially comparable to methods comprised by a tendered agreement, the introduction may interfere with existing tendered agreements and therefore the rules on public procurement.

Guidelines, describing how decisions are implemented and procurements conducted, are necessary in order to ensure robust and effective processes when making decisions and procuring new methods.

The objective with the guidelines is to clarify the rules for different scenarios where a pharmaceutical is approved for introduction, potentially affecting a tendered agreement. The guidelines aim to provide the best possible balance between different considerations, where early access to new methods for patients is vital.

The Norwegian Hospital Procurement Trust (hereafter referred to with the Norwegian name Sykehusinnkjøp HF) was asked by the Regional Health Authorities (hereafter referred to as RHAs) to summarize the experiences with decision 45-2018 and consider the need for changes and/or clarifications. Sykehusinnkjøp HF wrote a report, which was distributed for comments during the spring of 2020. Beslutningsforum was given a summary of the comments and Sykehusinnkjøp's recommendations at the 22nd of June 2020. In decision 060-2020, it was decided that the new guidelines were applicable from the 1st of July 2020.

The guidelines do not have retroactive effect, meaning they are only applicable to procurements publicly announced after 01.07.2020. The existing guidelines apply to procurements publicly announced before 01.07.2020.

Date: 22.06.2020

Sykehusinnkjøp HF, pharmaceuticals division (the Norwegian abbreviation is "LIS")

2. Important definitions and conditions

2.1. Therapeutically equivalent pharmaceuticals

Sykehusinnkjøp relies on the South-Eastern Health Authority's (hereafter referred to with the Norwegian name Helse Sør-Øst RHF) definition of therapeutically equivalent pharmaceuticals[1]:

> *It is the members of LIS specialist group, who decide whether pharmaceuticals within a therapeutic area are therapeutically equivalent and to what extent. The assessment of equivalence may change over time, among other things based upon health personnel's experience with the pharmaceutical. Therapeutical equivalence is defined within each therapeutic area and by inclusion in the applicable procurement documents.*

2.2. A new pharmaceutical

In this context, a new pharmaceutical is defined as: a pharmaceutical which is not already a part of a tendered agreement, and therefore, the only price given is the one which is to be considered by Beslutningsforum. The pharmaceutical may have a marketing authorisation for other indications, but as long as these are not subject to public funding by the specialist health care, the pharmaceutical is defined as a new pharmaceutical.

2.3. Procurements

Open procedure – a procurement procedure which does not allow negotiations. A procedure for the award of assignments (also framework agreement) regarding the delivery of goods, performance of services or contract work for the contracting authority.

Procurement – an activity aiming at covering a need for goods, services or construction and building services.

The price offered in a procurement can be the same as or lower than the price "decided" (in Norwegian "beslutningspris") for the pharmaceutical.

2.4. "Decided" price and procurement price

There is a distinction between "decided" price (beslutningspris in Norwegian) and procurement price.

The "decided" price (beslutningspris) is a price which fulfils the cost-effective requirement, leading to Beslutningsforum deciding to introduce the pharmaceutical in the Norwegian specialist health care. The price of a pharmaceutical cannot be increased after a positive decision.

An earlier "decided" price, for an already introduced and approved indication, may not be cost-effective when a new indication is considered for introduction by Beslutningsforum. The decision to

[1] Letter of April 30th from Helse Sør-Øst RHF to Legemiddelindustrien

introduce a new indication will then require the pharmaceutical to have a lower "decided" price than before.

The date when the decided price is valid in the health care service depends on the pharmacies' supply and price system. The supply- and price system is updated at fixed dates, twice a month (the 1st and 15th every month). There are different timelines for notification of price changes, depending on whether the pharmaceutical is used for out-patient treatment (in Norwegian "H-resept") or hospital treatment.

The *procurement price* is the price offered in the supplier's tender.

The decided price will be the upper price cap for introduction of new indications. When submitting a tender in future procurements, the price must be the same or lower than this decided price. The decided price applies across all introduced indications (see also 2.6.), and a new, lower decided price replaces previous higher decided price(s).

2.5. Submission deadline

The deadline for submission of tenders, including the procurement price, in a public procurement.

2.6. The price is applicable for all approved indications

The price for a pharmaceutical is applicable for all approved indications, cf. decision 55-2016 from Beslutningsforum. This excludes the possibility of having one price when using the pharmaceutical for the treatment of indication x and another price for the treatment of indication y. Price changes will therefore affect the price within all approved indications. Alternative price agreements may be considered according to decision 059-2020 in Beslutningsforum.

2.7. Price changes relevant for tendered agreements

Price changes relevant for tendered agreements are in general not accepted. An exception is given in scenario 2, provided that the price change does not lead to changes in the tender ranking.

2.8. Participation in a procurement presupposes submission of a tender, including procurement price, within the submission deadline

A tender, including procurement price, has to be submitted within the submission deadline in order for the supplier to participate in the procurement and potentially being introduced in the specialist health care during the agreement period. This also applies to situations where the pharmaceutical/indications might receive a subsequent approval by Beslutningsforum (within the agreement period).

See the description of the different scenarios and how this affects the access to pharmaceuticals in the specific cases in sections 4-7.

2.9. Update of the ranking and recommendations

When a procurement is finalised and the results are ready, a recommendation is drafted. The managing directors of the RHAs have decided that treatment choices are based upon the recommendations from the LIS specialist groups. The pharmaceutical with the lowest price will be the preferred choice of treatment, when price is the only award criteria.

The first-ranked option is used when starting and changing treatment due to medical reasons. If the first-ranked pharmaceutical is regarded as a suboptimal option due to medical reasons, an explanation has to be stated in the patient's journal.

When pharmaceuticals are not ranked, the prescriber have a greater freedom of choice when choosing treatment than when the pharmaceuticals are ranked.

The pharmaceuticals are ranked based upon the price provided in the tenders, when price is the only award criteria. Information about the ranking will be given in the *letter of award,* which is sent to all the suppliers participating in the procurement. Pharmaceuticals, awaiting a decision from Beslutningsforum to be approved for a specific indication, will also be ranked with a reservation of approval from Beslutningsforum. The *recommendation* will include information about pharmaceuticals approved by Beslutningsforum, as well as the pharmaceuticals not yet approved. When a pharmaceutical is approved by the Beslutningsforum, it will be included without reservations in the recommendation.

All decisions made by Beslutningsforum are announced on nyemetoder.no. The LIS specialist groups will, based upon the need for information and special characteristics concerning each therapeutic area, decide how often the recommendations are updated.

3. Defining scenarios

Four main scenarios describe the introduction of new pharmaceuticals to the specialized health care.

For all four scenarios the following apply:

- The pharmaceutical is granted a marketing authorisation for an indication (regulatory approval)
- The Norwegian Institute of Public Health (in Norwegian referred to as "Folkehelseinstituttet") or the Norwegian Medicines Agency (in Norwegian referred to as "Statens legemiddelverk") have conducted an HTA and/or a price report from Sykehusinnkjøp is made.
- The pharmaceutical is presented to Beslutningsforum, which considers whether the pharmaceutical shall be approved for treatment of the medical indication in the specialist health care or not.

In case of approval, the introduction of the pharmaceutical to treat a specific medical indication, is dependent on which scenario that applies for the specific situation.

Scenario 1	A new pharmaceutical is approved for a medical indication and therapeutically equivalent treatments do not exist.
Scenario 2	A pharmaceutical is approved for an additional, new medical indication and therapeutically equivalent treatments for the indication in question do not exist.
Scenario 3	A new pharmaceutical is approved for a medical indication and there are therapeutically equivalent pharmaceuticals.
Scenario 4	A pharmaceutical is approved for an additional, new medical indication. Other therapeutically equivalent pharmaceuticals have previously been approved for the indication in question.

	NEW PHARMACEUTICAL	NOT NEW PHARMACEUTICAL
THERAPEUTICALLY EQUIVALENT TREATMENTS DO NOT EXIST	Scenario 1	Scenario 2
THERAPEUTICALLY EQUIVALENT PHARMACEUTICALS HAVE PREVIOUSLY BEEN APPROVED	Scenario 3	Scenario 4

In the case of scenario 2, 3 and 4, it is important to clarify if approval by Beslutningsforum for the new pharmaceutical or indication will affect existing procurement processes or tendered agreements.

The applicable scenario is dependent on the answers of the two following questions:

- Is the pharmaceutical included in another procurement or tendered agreement (for a different medical indication)?
- Is the pharmaceutical therapeutically equivalent to other pharmaceuticals in an existing procurement or tendered agreement regarding the medical indication in question?

Is the pharmaceutical included in another procurement or tendered agreement (for a different medical indication)?

If no (this is a new pharmaceutical which is not yet introduced to treat other medical indications)	Scenario 1 - A new pharmaceutical is approved for a medical indication and therapeutically equivalent treatments do not exist.
	Scenario 3 - A new pharmaceutical is approved for a medical indication and there are therapeutically equivalent pharmaceuticals.
If yes (the pharmaceutical is already included in another procurement or tendered agreement)	Scenario 2 - A pharmaceutical is approved for an additional, new medical indication and therapeutically equivalent treatments for the indication in question do not exist.
	Scenario 4 - A pharmaceutical is approved for an additional, new medical indication. Other therapeutically equivalent pharmaceuticals have previously been approved for the indication in question.

Is the pharmaceutical therapeutically equivalent to other pharmaceuticals in an existing procurement or tendered agreement regarding the medical indication in question?

If yes	Scenario 3 – A new pharmaceutical is approved for a medical indication and there are therapeutically equivalent pharmaceuticals.
	Scenario 4 - A pharmaceutical is approved for an additional, new medical indication. Other therapeutically equivalent pharmaceuticals have previously been approved for the indication in question.
If no	Scenario 1 - A new pharmaceutical is approved for a medical indication and therapeutically equivalent treatments do not exist.
	Scenario 2 - A pharmaceutical is approved for an additional, new medical indication and therapeutically equivalent treatments for the indication in question do not exist.

4. Scenario 1
A new pharmaceutical is approved for a medical indication and therapeutically equivalent treatments do not exist

Characteristics of Scenario 1
The pharmaceutical is new. The pharmaceutical is not included in an existing procurement or tendered agreement. Therapeutically equivalent pharmaceuticals, to treat the medical indication in question, do not exist.

There are no therapeutically equivalent pharmaceuticals available.

A new principle of treatment within a therapeutic area may be available, and alternative treatments do not exist, at the time of consideration.

The pharmaceutical is procured through a direct procurement, not an open procedure.

Rules	
Price changes relevant for tendered agreements	Price changes are not relevant. The pharmaceutical is approved at a decided price and procured through a direct procurement.
When can the pharmaceutical be introduced	The pharmaceutical is available for use soon after a positive decision by Beslutningsforum (see 2.4).
Update of the ranking and recommendations	- The pharmaceutical is not ranked - The prescribing physician can decide upon treatment in accordance with the decision made by Beslutningsforum. - The LIS specialist group will, depending on the need for information and special circumstances within the therapeutical area, consider whether and at what point of time the recommendations will be updated, presuming there are recommendations within the therapy area.

5. Scenario 2

A pharmaceutical is approved for an additional, new medical indication and therapeutically equivalent treatments for the indication in question do not exist

Characteristics of Scenario 2
The pharmaceutical is already introduced to the specialist health care for certain indications, and a new medical indication is approved by the regulatory authorities. The pharmaceutical is a part of existing procurements or tendered agreements (other medical indications). There is no competition within the new medical indication. Therapeutically equivalent treatments for the indication in question do not exist. The approval for use within the new indication may affect existing procurements.

Pharmaceuticals, already a part of an existing procurement or tendered agreement, can get a new medical indication approved. This may lead to a situation where the pharmaceutical is a part of a procurement or a tendered agreement with available therapeutically equivalent pharmaceuticals within one indication, while there is no competition within the new medical indication.

A tender, including procurement price, must be submitted within the submission deadline.

The decided price for the new medical indication must be the same as or lower than the procurement price in already tendered agreements.

The tender price should therefore seek to be at a level which enables a possible future approval of new medical indications by Beslutningsforum, in order to ensure predictability for both health personnel and suppliers.

The following rules are dependent on whether there is a need for a new, lower decided price for the new indication, and whether the new price will affect the ranking in already tendered agreements.

Rules	
Price changes relevant for tendered agreements	Price changes are in general not accepted. Price changes are only accepted if the procurement price is considered to be too high for approval for the treatment of a new medical indication. Mini competitions may be conducted if the price change affects the *ranking* in existing procurements. All the affected suppliers will then be given the opportunity to submit a new procurement price.

When can the pharmaceutical be introduced	If the procurement price is acceptable for approval within a new indication, the pharmaceutical may be approved as a treatment option immediately after the decision by Beslutningsforum. If the procurement price is not sufficient for approval, and a new, lower decided price is required, the pharmaceutical must await introduction until a positive decision by Beslutningsforum is made and the new price is updated in the supply and price system (cf. 2.4).
Update of the ranking and recommendations	- The pharmaceutical is not ranked against other pharmaceuticals for the new medical indication. - The prescribing physician can choose treatment in accordance with decisions made by Beslutningsforum. - If the procurement price is sufficient and Beslutningsforum approves the use, the pharmaceutical will be included in the LIS recommendation. - If the procurement price is not sufficient for approval of a new medical indication, and a new lower price is required, the pharmaceutical will only be included in the LIS recommendations if the new lower price does not affect *the ranking* in other procurements/tendered agreements. - However, if the procurement price is not sufficient for approval and a new lower price is required, and the new price will *affect the ranking* in existing procurements/tendered agreements, a mini competition may be conducted. - The recommendations will be updated with new prices after the mini competition is conducted, approximately 2-3 months after a decision by Beslutningsforum. The pharmaceutical may still be used for the newly approved medical indication, as described above.

Mini competitions

If an existing procurement price is considered too high for approval of a new indication by Beslutningsforum, a price reduction is required for the new medical indication to be approved. Mini competitions may be conducted if the new price affects the ranking in existing procurements/ tendered agreements.

The affected part of the tendered agreement will be subject to a new competition, and the affected suppliers will have the opportunity to submit a lower procurement price.

The suppliers are given two weeks to submit a new procurement price. The supplier of the pharmaceutical being approved for a new medical indication, may also submit a lower price than the decided price.

The date when the decided price is valid in the health care service, depends on the supply and price system, which is updated twice a month (the 1st and the 15th every month). The time for price updates depends on whether the pharmaceutical is out-patient treatment (in Norwegian referred to as “H-resept”) or used in hospitals.

The results of the mini competition will be available and new recommendations with updated prices applicable approximately 2-3 months after a decision by Beslutningsforum. The pharmaceutical in question can in the meantime be used at the new and lower decided price. The existing recommendation is applicable until a new recommendation is published.

Mini competitions will not be conducted if its less than three months left of the tendered agreement.

6. Scenario 3

A new pharmaceutical is approved for a medical indication and there are therapeutically equivalent pharmaceuticals

Characteristics of Scenario 3
The pharmaceutical is new and is not a part of any existing procurements/tendered agreements. Therapeutically equivalent treatments exist for the pharmaceutical in question. The approval for use of the pharmaceutical may affect other procurements/tendered agreements.

The supplier of a therapeutically equivalent pharmaceutical must submit a procurement price within the submission deadline in order for the pharmaceutical to participate in the procurement and being approved for use by Beslutningsforum. The pharmaceutical will be ranked based upon the procurement price, subject to a subsequent approval. Information regarding the ranking is provided in the award letter.

Therapeutically equivalent pharmaceuticals can be introduced to the specialist health care as a treatment option if the procurement price is considered to be cost effective at the time of approval.

A procurement price must be submitted within the submission deadline. In order for a new pharmaceutical to be introduced immediately after the decision, within the agreement/ procurement period, the procurement price has to be approved by Beslutningsforum.

The rules are dependent on whether the procurement price is accepted by Beslutningsforum or not. Price changes are in general not accepted for tendered agreements in this scenario.

Rules	
Price changes relevant for tendered agreements	Price changes are in general not accepted.
When can the pharmaceutical be introduced	The pharmaceutical can be introduced immediately to the specialist health care if the procurement price is approved by Beslutningsforum. Introduction is dependent on the submission of a tender, including procurement price, before the submission deadline. If the procurement price is considered to be too high for approval by Beslutningsforum, and a new, lower decided price is required, the pharmaceutical will have to await introduction until the next procurement is conducted. The pharmaceutical may only be used on exception until then. The prescribing health personnel must apply for an exception, and

	treatment is dependent on approval. The decided price will be applicable from the next agreement period and onwards.
Update of the ranking and recommendations	- The pharmaceutical is ranked against other pharmaceuticals and will be included in the recommendations after an approval by Beslutningsforum. - Prescription of the pharmaceutical is according to the applicable LIS recommendation.

7. Scenario 4

A pharmaceutical is approved for an additional, new medical indication. Other therapeutically equivalent pharmaceuticals have previously been approved for the indication in question

Characteristics of Scenario 4
The pharmaceutical is already introduced within the specialist health care for certain indications, and a new medical indication is approved by the regulatory authorities. The pharmaceutical is a part of existing procurements or tendered agreements (other medical indications). Therapeutically equivalent treatments exist for the indication in question. The approval for use within the new indication may affect other procurements/tendered agreements.

A procurement price must be submitted within the submission deadline. In order for the indication in question to be introduced immediately after the decision, within the procurement/ agreement period, the procurement price has to be approved by Beslutningsforum.

The supplier of a therapeutically equivalent pharmaceutical must submit a tender with a procurement price within the submission deadline in order for the pharmaceutical to participate in the procurement and being approved for use by Beslutningsforum. The pharmaceutical will be ranked based upon the procurement price, subject to a subsequent approval. Information regarding the ranking is provided in the award letter.

Therapeutically equivalent pharmaceuticals can be introduced to the specialist health care as a treatment option if the procurement price is considered to be cost effective at the time of approval.

In this scenario, the approval of a new medical indication may also interfere with ongoing competitions/ tendered agreements for previously approved therapeutically equivalent treatments. Price changes are in general not accepted in this scenario.

Rules	
Price changes relevant for tendered agreements	Price changes are in general not accepted.
When can the pharmaceutical be introduced	Treatment for the indication in question can be introduced immediately to the specialist health care if the procurement price is approved by Beslutningsforum. Introduction is dependent on the submission of a tender, including procurement price, before the submission deadline.

	If the procurement price is considered to be too high for approval by Beslutningsforum, and a new, lower decided price is required for the new indication the pharmaceutical will have to await introduction to the new indication until the next procurement is conducted. Until then, the pharmaceutical may only be used for the new indication on exception. The prescribing health personnel must apply for an exception, and treatment is dependent on approval. The decided price will be applicable from the next agreement period.
Update of the ranking and recommendations	- The pharmaceutical is ranked against other pharmaceuticals and will be included in the recommendations after an approval by Beslutningsforum. - Prescription of the pharmaceutical is according to the applicable LIS recommendation.

8. Application for use on exception

See the description in scenarios 3 and 4. An application for individual use on exception treatment (in Norwegian “unntaksordning”) will follow the same procedure as the unntaksordning in Nye metoder.

The application must be according to the applicable routines of the health trust in question.

Information about the decision – excluding information leading to personal identification – is sent to the Regional Health Authority and Sykehusinnkjøp (nyelegemidler@sykehusinnkjop.no).

9. Document change log

Date	Version no.	Notes
01.06.2021	1.0	New. The corresponding Norwegian version: 1.0 (22.06.2020)
01.01.2022	1.1	Corresponding to Norwegian version: 1.1. (01.01.2022)