

Nye metoder - Request for assessment of medicinal product

To request an assessment of a new medicinal product or a new indication for an existing medicinal product through Nye metoder, health technology developers should complete this form. By submitting a request for assessment, the developer signals that it plans to submit documentation for such an assessment.

Please send the completed form to Nye metoder by e-mail: nyemetoder@helse-sorost.no.

A request for assessment may not be submitted prior to day 120 of the European Medicines Agency (EMA) marketing authorisation assessment process for new medicinal products under regular approval procedure, or prior to day 1 for variation/extension assessments and for medicinal products under accelerated assessment.

This form must be completed in its entirety. Nye metoder will plan the assessment process based on the information provided in the request form.

At the time of request for assessment, the health technology developer must have a plan for when it intends to submit documentation for assessment.

Information about Nye metoder can be found online (<u>nyemetoder.no</u>). Please contact Sekretariatet for Nye metoder if you have any questions.

Please note: The form will be published in its entirety.

The submitter is aware that the form will be published in its entirety (tick):

1 Contact information
Date
Health technology developer
Name
Position
Telephone
E-mail
External representation Name/Organization Phone/E-mail
PLEASE NOTE: For external representation, please attach an authorisation/power of attorney



2 Medicinal product overview	
Does the request concern a new active substance?	
Trade name	
Generic name	
Marketing authorisation in Norway	
ATC code	
Mode of administration	
Pharmacotherapeutic group and mechanism of action Briefly describe	
Expected indication relevant to the request Expected indication must be written in Norwegian	
3 Assessment history	
Has the medicinal product previously been assessed by Nye metoder for other indications? If yes, enter the Nye metoder ID number	
Are you aware of other medicinal products assessed by Nye metoder for the same indication? If yes, enter the Nye metoder ID number	



4 Expected timeline	
Procedure number for the marketing authorisation assessment in EMA	
Expected date (month/year) of CHMP positive opinion	
Expected date (month/year) of marketing authorisation in Norway	
Expected date (quarter/year) for submission of documentation to Norwegian Medicines Agency	
Dates must be stated	
5 Diagnostics and resource use Fill inn where relevant	
Will the new method require diagnostic testing for biomarker analysis?	
Which biomarker(s) are relevant and which publications describe this? Please refer to publications	
Do you know whether diagnostics can be performed by the public health service or whether it must be performed by an external supplier?	
Will introduction of the new method require establishment of other/new infrastructure? For example, custom analysis machine, digital pathology/ AI-based analysis, proteomics, functional tests etc.?	
Pre-analytical requirements For example, biopsies, other sampling, sample processing etc. are required.	

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Test execution: is there a need to establish one specific test or is a biomarker already established in the health service (e.g. in gene panels)?	
Description of reading of results including data analysis program if necessary.	
Which patient groups need to be tested, and what is the expected proportion of findings that provide treatment options?	
6 Description of the disease and o	current treatments
Description of the disease <u>Brief</u> description of the pathophysiology and clinical presentation/symptoms, possibly including references	
Therapeutic area Specify which field best describes the method	
Cancer If the method applies to the medical field of cancer, specify which type of cancer is relevant	
Current treatment Current standard treatment in Norway, including references	

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Prognosis Describe the prognosis with current treatment options, including references	
The new medicinal product's placement in the treatment algorithm	
Patient population Description, incidence and prevalence of the patient population covered by the relevant indication* in Norway, including references. Number of Norwegian patients assumed to be relevant for new method * The entire patient group covered by the indication in question is to be described	
7 Comparability to other medicina	al products and inclusion in tender
Are there existing procurements or tenders in the therapeutic area?	
Are there other medicinal products with a similar mechanism of action and/or similar effect (for the same indication)?	
Does the supplier consider the medicinal product to be comparable to other medicinal products?	



8 Relevant clinical tr (pivotal trial(s) and clini	rials ical studies relevant for estal	olishing relative efficacy)	
	Study 1	Study 2	Study 3
Study ID			
Study name, NCT number, hyperlink			
Study type and design			
Objective			
Population			
Important inclusion and exclusion criteria			
Intervention (n)			
Dosage, dosing interval, duration of treatment			
Comparator (n)			
Dosage, dosing interval, duration of treatment			
Endpoints			
Primary, secondary and exploratory endpoints, including definition, measurement method and, if applicable, time of measurement			
Relevant subgroup analyses			
Description of any relevant subgroup analyses			



	Study 1	Study 2	Study 3
Follow up time If the study is ongoing, indicate the follow-up time for the data expected to be available for assessment by the Norwegian Medicines Agency as well as the expected/planned total follow-up time for the study			
Time perspective results			
Ongoing or completed study? Available and future data cut-offs			
Publications Title, author, journal, year. Expected date of publication			
9 Ongoing and plant	ned studies		
Are there ongoing or p for the medicinal produsame indication that m further information in the state of the expectage of the	uct within the hay provide the future?		
Are there ongoing or p for the medicinal produindications?			



10 Expected health economic documentation Enter information about the expected health economic analysis	
Type of health economic analysis	
E.g. cost-per-QALY analysis or cost minimisation analysis (Justify the proposal)	
The patient population on which the health economic analysis is based, including any subgroups. The main analysis (base case) shall include the entire patient population covered by the indication sought.	
What type of documentation will form the basis for estimating relative efficacy? (Direct or indirect evidence)	
What type of documentation will form the basis for health-related quality of life data?	
Expected pharmaceutical budget impact per year, in the 5-year period following a potential approval	
11 Suitable for FINOSE?	
Can the method be appropriate for assessment through FINOSE (yes/no)	
If no, why not?	



12 Other relevant information Disclose other aspects that Nye metoder should be aware of.	
Have you been in contact with clinicians at Norwegian health trusts about this medicinal product/indication? Yes/no	
If so, who have you been in contact with and what have been their contribution?	
(Relevant information in connection with the recruitment of experts in the field at Nye metoder)	
Are there specific circumstances related to the medicinal product implying that a plain discount may not be appropriate for fulfilment of the priority criteria (yes/no)?	
If yes, a separate form must be completed and sent nyelegemidler@sykehusinnkjop. no at the same time as documentation is sent to the Norwegian Medicines Agency for a health technology assessment.	
Information and form:	
https://www.sykehusinnkjop. no/om-oss/informasjon-og- opplering/	
Any other relevant information?	