

Nye metoder - Request for reassessment of medical product

A health technology developer seeking reassessment of a medicinal product/indication previously assessed by Nye metoder, should contact Nye metoder using this form, provided requirements detailed below are met.

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

A request for reassessment must apply to the same population as the original assessment. If the request relates to another population or a subpopulation, then the form titled "Request for assessment of medicinal product" should be used (see nyemetoder.no).

If there is no new clinical data, a request for reassessment is not warranted. If only the cost of the new method has changed since the previous assessment, contact the Norwegian Hospital Procurement Trust (Sykehusinnkjøp HF) directly¹.

This form must be completed in its entirety. Based on the request, Nye metoder will assess whether there are grounds for commissioning a reassessment. The request must be justified.

Information about Nye metoder can be found online (nyemetoder.no). 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 <i>PLEASE NOTE: For external representation, please attach an authorisation/power of attorney</i>	

¹Norwegian Hospital Procurement Trust e-mail : nyelegemidler@sykehusinnkjop.no

2 Medical product overview and assessment history

Nye Metoder ID Number	
Active substance	
Trade name	
<p>Indication</p> <p><i>A request for reassessment must apply to the same population as the original assessment. If the request relates to another population or a subpopulation, the form titled "Request for assessment of medicinal product" should be used (see nyemetoder.no).</i></p>	
<p>Current decision from Beslutningsforum for nye metoder (Nye metoder's Decision Forum)</p> <p><i>Date?</i></p>	

3 Basic prerequisites for reassessment

<p>Clinical practice</p> <p><i>Is the description of Norwegian clinical practice in the original assessment still applicable, including comparator, prior treatment etc.?</i></p> <p><i>Briefly describe.</i></p>	
<p>New data for the medicinal product</p> <p><i>Briefly describe why there are grounds for a reassessment of the method. Describe the available new data</i></p>	
<p>Expected date (quarter/year) for submission of documentation to Norwegian Medicines Agency</p> <p><i>Dates must be stated</i></p>	
<p>New data for the comparator</p> <p><i>Describe any new data for the comparator</i></p>	

Other conditions

Describe any other conditions that have changed since the previous assessment

4 Relevance of new data**New data**

Give an account of the new data compared to the original results that formed the basis for the current decision by Beslutningsforum for Nye metoder (Nye metoder's Decision Forum)

Describe how the new data can help meet the prioritisation criteria.