Template for submission of information for managed entry agreements

## Introduction

Reference is made to section III in the [Framework for Price Agreements](https://sykehusinnkjop.no/seksjon/nyheter/Documents/Informasjonsm%C3%B8te%20beslutningsforum/Framework%20for%20price%20agreements.pdf)  applicable from the 23rd of June 2020:

The RHAs, represented by The Norwegian Hospital Procurement Trust (hereafter referred to as Sykehusinnkjøp HF), assess whether there should be an alternative price agreement and the contents of it.

The description below should be precise, both regarding the proposed concept (type of agreement and structure, practical workflow and follow-up) and contents (sufficient for Decision Forum to consider whether the principles for priority setting can be met). If the proposal is considered by Sykehusinnkjøp HF to present at potential solution for introduction of the pharmaceutical in question, it may be presented to the medical directors in the RHAs or the Decision Forum for pre-approval. The template should be sent to: [nyelegemidler@sykehusinnkjop.no](mailto:nyelegemidler@sykehusinnkjop.no).

***The submitted proposal is not binding, but it may serve as a basis for finalising an agreement that could contribute to finding a solution if a simple discount cannot be applied.***

## Overview

|  |  |
| --- | --- |
| Name of the pharmaceutical: |  |
| Order ID-number in New methods (in Norwegian Nye metoder): |  |
| Title of the method in Nye metoder: |  |
| Number of patients per year within the relevant indication: |  |
| Is there a Conditional approval for the MA? | Yes/No |
| Are other indications approved for introduction in Nye metoder (please specify): |  |
| Number of patients per year within the other indications approved for introduction: |  |

## Could a managed entry agreement be appropriate?

1. Please explain why a standard financial agreement, with a simple discount, is not appropriate in this case?
2. Please provide a brief description of the existing and expected competition (2-3 years ahead in time):
3. Please describe the challenges or uncertainties which could be addressed by the proposed agreement, and how the proposed agreement can meet these challenges.

## The proposed type of agreement

1. Please provide a description of the type of agreement (short text):
   1. Volume discount
   2. Budget cap
   3. Coverage with Evidence Development
   4. Payment by Result
   5. Other type of agreement
2. Please describe the degree of uncertainty related to the cost-effectiveness and what the uncertainty is mainly related to? (e.g., uncertainty related to long-term efficacy of the intervention, uncertainty regarding efficacy of the standard treatment, uncertain number of patients/budget impact, etc.)
3. Please describe how the proposed agreement will ensure that the treatment in question is cost-effective, hence making introduction to the specialist health care services possible and in line with the priority criteria?

## Operationalization

Please describe possible practical challenges:

#### For financial agreements

1. Which parameters are measured and how will they be documented (data /documentation sources)?
2. Please describe the uncertainty associated with measuring these parameters:
3. Which price should be the basis for future competition, e.g. in tender?
4. How can a possible agreement handle future competition, e.g. in case of a different winner of the tender than your company?

#### For outcome based agreements

1. Which parameters are measured and how will they be documented (data /documentation sources)?
2. Who will register the data?
3. Please describe the uncertainty associated with measuring these parameters.
4. How can the relevant outcomes be registered and reported?
5. What would be appropriate times or time periods for reporting and follow-up?