Request for alternative agreement model

If your company wants an alternative agreement model, please complete this form and send it to Amgros at [medicin@amgros.dk](mailto:medicin@amgros.dk) and to the Danish Medicines Council at [medicinraadet@medicinraadet.dk](mailto:medicinraadet@medicinraadet.dk). Submit the form at the same time as you send your request for assessment to the Danish Medicines Council.

We will use the information in the form to assess whether the alternative agreement model is appropriate to deal with the most important uncertainties associated with the Danish Medicines Council's assessment of the medicine.

The form is dynamic up to date of application. In other words, it can be changed, for example after a dialogue with Amgros or the Danish Medicines Council.

See the Danish Medicines Council’s [guidelines for applications for alternative agreement models.](https://medicinraadet.dk/ansogning/anmodning-om-vurdering)

See Amgros’ overview of [alternative agreement models here.](https://amgros.dk/media/3598/oversigt-over-alternative-aftalemodeller-amgros-2022.pdf)

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| Facts | Applicant’s description |
| Pharmaceutical company and contact | *Name of the company and contact person, telephone number and email* |
| Name of medicine | *Generic name (trade name)* |
| Expected EMA indication | *State the expected indication as well as the date for expected positive opinion*  *State whether the indication has already been approved* |
| Expected date of application to the Danish Medicines Council | *State when you expect to submit an application to the Danish Medicines Council* |
| Has the medicine been authorised for other indications? Have they been assessed by the Danish Medicines Council? | *State whether the medicine has been approved by the EMA for other indications, and whether such indications have been assessed (are being assessed) by the Danish Medicines Council* |
| Number of expected patients (incidence and prevalence) | *State how many patients in Denmark you expect to be candidates for treatment if the Danish Medicines Council recommends the medicine. State the number of expected new patients per year.* |
| Current and future competition | *Briefly describe the current and future (< 3 years) competition. Which competing medicines do you expect to be placed on the market within the next three years?* |

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| Expectations of the agreement | Applicant’s description |
| Purpose of the agreement | *Describe the challenges/uncertainties the alternative agreement is to deal with* |
| Solution | *Describe how an alternative agreement can solve the problem* |
| Type of agreement model  Financially based agreement | *Enter a cross against the financially based agreement model(s) you propose*   |  |  | | --- | --- | | Price-volume model |  | | Budget cap model |  | | Subscription model |  | | Market-share model |  | | Added value model |  | | Combination-based pricing model |  | | Indication-based model |  | | Patient-initiation model |  | | Maintenance model |  | | Instalment payment model |  | |
| Outcome-based agreement | *Cross if you propose an outcome-based model*   |  |  | | --- | --- | | Payment by effect |  | |
| Conditional recommendation agreement | *Cross if you propose a conditional recommendation model*   |  |  | | --- | --- | | Conditional recommendation |  | |  |  | |
| Possible combination of agreements | *Briefly describe the purpose of possibly combining several models* |
| Proposed duration of the agreement | *State and give reasons for your proposed duration of the agreement* |
| Expiry of the agreement | *What do you propose should happen when the agreement expires? E.g. new agreement based on an ordinary discount model, and at which price? New alternative agreement model or other?* |

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| Agreement on payment for effect or conditional recommendation | *Must be completed if you propose an agreement on payment for effect or conditional recommendation* |
| Definition of effect measurement | *State the effect measurement(s) relevant to evaluate the effect of the medicine in Danish clinical practice*  *State the clinically relevant size of the effect in absolute figures (e.g. the absolute risk reduction, the change in number of points, months, etc.)*  *State whether the size of the effect is measured as a difference in relation to the patient's baseline value or in relation to the expected pathway in a historical control group or other*  *State the time horizon/measurement times for the effect evaluation* |
| Effect evaluation in practice | *State who is to measure and assess the effect in clinical practice*  *State who is to collect and report such data to Amgros* |
| Data collection | *State a proposal for who is to collect and analyse data* |

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| **Request for a dialogue meeting** | **Applicant’s description** |
| **Request for a dialogue meeting with Amgros** | *Cross if you want a dialogue meeting with Amgros.*   |  |  | | --- | --- | | Yes |  | | No |  |   *If you would like dialogue meeting with the Danish Medicines Council, you should usually state this in the* [*request for assessment*](https://medicinraadet.dk/ansogning/anmodning-om-vurdering) *form.* |
| **Questions** | *State here any questions regarding your proposed alternative agreement model that you would like to discuss with Amgros* |