

Company contact person (name, email, telephone)

A. General

Name of medicine:

Name of active substance:

ATC code:

Date for approval:

Protected by patent (yes/no):

Approved indications:

Table 1: Products

Good	Administration form	Dosage	Size of package	Price (SEK, AIP)

B. Indication

Table 2: Indication*

Indication	Average used dosage per day	Average treatment time	Average cost of treatment (SEK)	Estimated share (DDD) of total sales

* Answer with the best possible information you have access to. In other words the source does not have to be a scientific publication.

C. Medical effects (Answer the six questions below separately for the different indications. Preferably not more than three pages per indication, table not counted.) Older products are often without documentation of an acceptable quality, or changes in clinical praxis have rendered the efficacy measures used in existing studies clearly irrelevant to LFN reviews. In such cases, the resume of the responses to questions 1-6 may be replaced by an “expert report” containing a summary of present knowledge and written by clinical specialists with experience of the field.

1. Which are the most important and well-executed studies which have been conducted on your medicines? Account for each study in Table 3.

Table 3: Medical effect – summary of study and structure*

Name of study	
Type of study	
Comparator (comp.)	
Number of participating patients	
Length of study	
Dosage	
Dosage comp.	
Primary effect measure	
Effect of treatment (incl. Standard error)	
Comp. effect (incl. Standard error)	
Difference (incl. conf. interval)	
P-value	
Secondary effect measure	
Effect (incl. Standard error)	
Comp. effect (incl. Standard error)	
Difference (incl. conf. interval)	
P-value	
Share of patients (pat.)not to completion due to too little effect	
Share of pat. not to completion due to side-effects	
Share of pat. not to completion due to other reasons	
Share of pat. not to completion due to too little effect comp.	
Share of pat. not to completion due to side-effects comp.	

Share of pat. not to completion due to other reasons comp.	
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*Fill in the information in the first place according to *intention-to-treat*, in the second place according to *per-protocol*.

2. How would you summarise your medicine's medical effect based on these studies?
3. What is the effect of the treatment on the patient's quality of life?
4. What is the effect of the treatment on the patient's life expectancy?
5. Regarding side-effects is there anything which speaks for or against your medicine compared to other medicines in this class of pharmaceuticals?
6. What known variations are there in the medical effect of the medicine? (For example, in respect to the gravity of the disease, patient's sex and age, existence of other diseases.)

D. Cost-effectiveness (Please answer the six questions below separately for differing indications. Preferably not more than four pages per indication.)

1. What are the best carried out and for Swedish conditions most relevant cost-effectiveness studies which have been done on your pharmaceutical? Account for each study if possible in accordance with Table 4. If the nature of the study makes this difficult then account for it in normal text form.

Table 4: Cost-effectiveness – summary of the most important studies

Author's name and year of publication	
Product	
Comparator (comp.)	
Prices (own medicine and comp.)	
Perspective	
Country	
Patient group	
Model study (yes/no)	
Assumptions on clinical effect*	
Assumptions on clinical effect for comp.	
Effect**	
Cost	
ICER***	
Comments	

*Eg. mmHg

**Eg. QALYs gained

***Incremental cost-effect quota

2. How would you summarise the cost-effectiveness of treatment with your pharmaceutical based on Table 4?
3. Which factors are most decisive for the cost-effectiveness of the medicine; price, other costs, effect on quality of life, effect on life expectancy, or something else?
4. Which factors, crucial for the cost-effectiveness of the medicine, are most uncertain?
5. On which points does existing health economic documentation clash with the guidelines published by the LFN?
6. How does the medicine's cost-effectiveness vary with respect to, for example, gravity of the disease, sex, age, other risk factors, primary or secondary prevention?

E. Miscellaneous

Is there any other aspect of your pharmaceutical or medical treatment within this therapeutic group which you would like to highlight? (Preferably not more than one page per indication.)