Guidelines for cost analyses of new medicines and indications in the hospital sector

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1. Introduction

These instructions provide the framework for the cost- and budget impact analyses that applicants must submit to the Medicine Council as a part of the application process for new medicines and indications in the hospital sector.

For all new medicines and indications which the Medicine Council categorises as being of *Major added benefit, Important added benefit, Minor added benefit* or *No added benefit* (categories 1-4) compared with current standard treatment, Amgros will evaluate the submitted incremental cost analyses for the intervention compared with the standard treatment, that is the comparator(s). A price negotiation will be based on these cost analyses and budget impact estimates in combination with the Medicine Council's evaluation of the added clinical benefit. After the price negotiation, the Medicine Council will make the decision whether to recommend the medicine for standard treatment or not.

Based on the applicant’s cost analyses Amgros will assess the validity and relevance of the submitted information. All information and choices made must be documented in a satisfactory manner.

Amgros can ask the applicant for supplementary information, if applicable, or Amgros may make its own estimates about standard clinical practice in Denmark. This supplementary information and estimates will be disclosed to the applicant, if necessary.

The template for Amgros’ evaluation of incremental cost analyses and estimates of budget impact can be found in Appendix 1.

2. Guidelines for cost analyses of new medicines and new indications in the hospital sector

All cost analyses submitted by the applicant for the evaluation by the Medicine Council must comply with a set of methodological rules. According to Amgros' definitions, an analysis that comply with these minimum requirements is known as a 'standard analysis'.

Basically, the use of a standard analysis is to:

- Clarify which elements of the cost analysis are essential for the Medicine Council's evaluation
- Make results from different medicine evaluations comparable.

The following components (sections 2.1 – 2.9) specify the requirements to the standard analysis. Table 1 below lists some of these requirements.

Table 1. Important components of the standard analysis

Components of the analysis	***Standard analysis***	***Section in the guidelines***
Intervention	The medicine applied for as standard treatment	2.2
Comparator(s)	The treatment(s) used in the final application to the Medicine Council	2.3
Perspectives of the analysis	Societal perspective, including the time spent by patients and patient caregivers (excluding productivity loss/gain)	2.4
Time horizon	The same time horizon as the one used in the final application to the Medicine Council	2.5
Resource use and costs	Direct treatment-related costs including costs for adverse events for all sectors within the relevant time horizon	2.6
Method for management of uncertainties	Relevant sensitivity analyses	2.7

The information in sections 2.1 – 2.3 must be accounted for as specified by the protocol developed by the Medicine Council. This information must correspond with the information provided in the application form to the Medicine Council.

2.1 Description of the patient population

The analysis must include a description of the patient population for which the intervention is intended, stating age and gender when relevant. The analysis must also describe the current and expected future development in population for the applied indication incidence and prevalence for the indication. Separate cost analyses are made for each sub-group defined in the protocol developed by the Medicine Council.

2.2 Description of the intervention and its area of use

The applicant must provide a brief description of the most important characteristics of the intervention, the comparator(s) and the regulatory status. If the intervention is part of a treatment sequence, this must be described in detail.

This description must include the characteristics of the intervention such as brand name, active substance(s), indication and ATC code, if applicable, and the date of approval, if these exist at the time of submitting the application. Information about the medicine and its mode of action must be based mainly on the SPC (Summary of Product Characteristics) or equivalent documentation which is available as part of the marketing authorisation application.

2.3 Comparator(s)

The Medicine Council defines the relevant comparator(s) for a given application, as specified in the Medicine Council's protocol. Consequently, a cost analysis must always use the comparator(s) specified in this protocol.

The costs of the specified comparator(s) must be listed in the same manner as the costs of the applied intervention and in accordance with the principles set out in these guidelines.

2.4 Perspective and description of consequences for different stakeholders

Applicants must use a restricted societal perspective in the standard analysis. This means that all relevant treatment-related costs must be included, irrespective of who carries the costs. This also applies to costs resulting from adverse effects and administrative expenses.

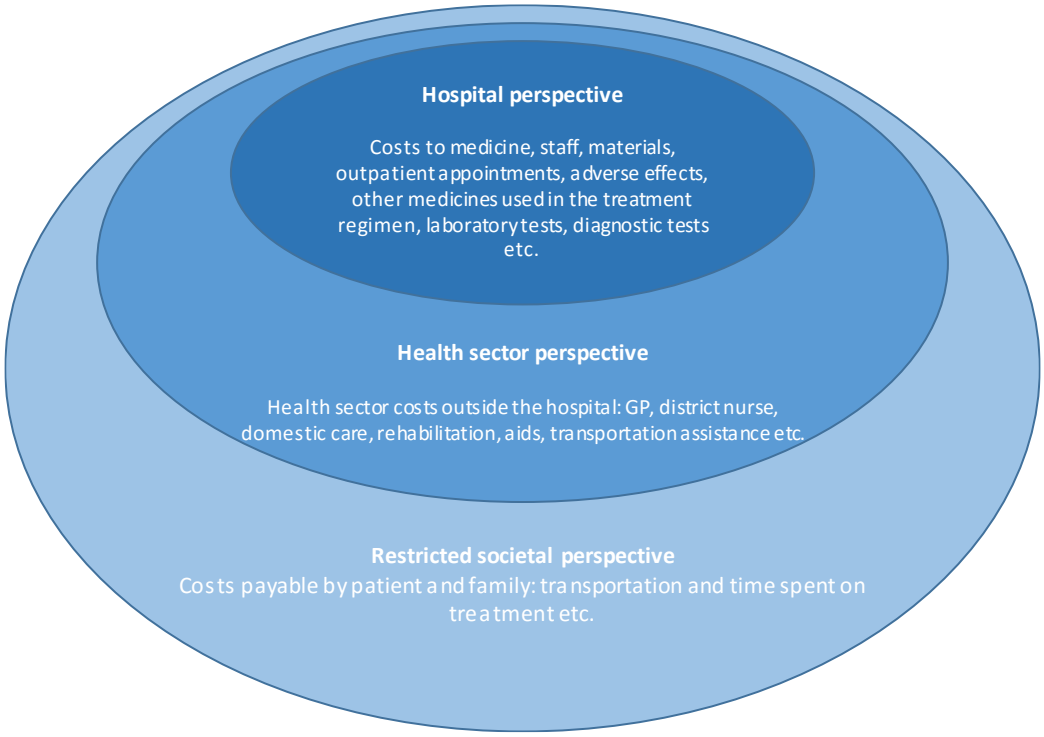
The analysis must not include productivity losses/gains attributable to the intervention (labour market gains etc.).[1]

The analysis serves to provide an overview of how the financial consequences are distributed across for the various stakeholders (hospital, primary sector players etc.).

[1] Patient functioning is part of the assessment of quality of life in the Medicine Council's evaluation of added value.

Figure 1 illustrates which costs to include in the cost analysis, provided their documentation and argumentation for inclusion are satisfactory.

Figure 1 Cost perspectives included in the cost analyses



2.5 Time horizon

The time horizon of the analysis must correspond with the time frame defined in the Medicine Council's protocol.

For time horizons exceeding 12 months, a discounting rate equivalent to the current socioeconomic discount rate defined by the Ministry of Finance must be used[2].

2.6 Resource use/quantities and costs

The use of a new intervention will most often lead to changes in the resource use, both directly and as a result of the effect and adverse effects of the intervention. In order to identify such changes the resource use for each of the included medicines must be identified and costed before any comparison can be made.

2.6.1 Use of goods and services

Medicine prices must always be stated at the pharmacy purchase price (PPP)-level, exclusive of VAT. Average costs must always be used in the cost analysis.

Arguments must be given to support the relevance and the validity of the resource use and unit costs used in the cost analysis. Cost information can be extracted from studies, expert appraisals or a mixture.

[2] This is currently 4 per cent. Please go to www.fm.dk to see the current discount rate.

For the most typical resource use, Amgros has developed the costing guideline "AMGROS Estimating unit costs" which is expected to be used by the applicant. Reasons for deviations from this must be given explicitly. Generally, the costs of using the intervention and the comparator(s) must be estimated based on the Summary of Product Characteristics (SPC), unless relevant arguments in favour of deviating from this are present.

2.6.2 Costs at municipal level

If the analysed medicines impact on the costs incurred by the municipality, the analysis must also include these costs, cf. figure 1. Validity and arguments are subject to the same requirements as applies to costs at regional level.

2.6.3 Patient costs

The costs carried by patients and patient caregivers as a result of treatment with a particular medicine (transport costs and direct time spent on receiving treatment) must be included, if relevant and there is sufficient documentation. The results of the analysis must be presented with and without these costs.

The time spent by patients and patient caregivers is valued at the average hourly wage of a salaried employee in Denmark after taxes. This figure can be found in "AMGROS Estimating unit costs".

2.6.4 Statement of unit costs and quantities

Direct costs must be divided into two components, reported separately: Quantities used, such as hospital admissions or hours for home care, and any related unit costs, as illustrated in table 2.

Table 2. Sample statement for a new medicine and the comparator

Resource type, direct resource use per time unit (hour, day, month, year etc.)	***Quantity***	***Time unit***	***Unit cost***
Medicine	X	t/d/m/y	? DKK
Staff resources	X	t/d/m/y	? DKK
Patient resources – for example time spent on transportation or treatment	X	t/d/m/y	? DKK
Home care	X	t/d/m/y	? DKK
Etc.	X	t/d/m/y	? DKK

The table is provided for illustration and is not exhaustive. Similarly, DRG/DAGS tariffs can be used as average cost estimates instead of micro costing if relevant. The analysis must include all types of relevant and documented resource use, and arguments must be made for the choices made.

The resource use and costs of treating the same patient group may vary considerably from one country to another. A cost analysis performed in another country may be of only limited relevance to the Danish setting due to differences in clinical practice,

differences in the capacity and structure of the health services and differences in reimbursement schemes. Consequently, data from another country concerning the budget impact of a treatment must be substituted by data from Denmark to ensure agreement with Danish conditions, to the extent possible. If the analysis uses non-domestic data of resource use, for example from Norway or Sweden, arguments supporting the relevance of this must be provided. Unit costs must always be substituted with Danish unit costs.

2.7 Uncertainties

Uncertainties in the cost analysis must always be addressed. Relevant sensitivity analyses must be performed and arguments supporting the choice of these analyses and inherent assumptions must be given.

2.8 Presentation of methods and outcome

The applicant must specify the methods, assumptions and data included (including references) in a manner that makes the various steps of the analysis easy to follow and making it easy to conduct re-analyses using other inherent assumptions.

The presentation of the results must clearly show the distribution of the costs per patient for the medicines evaluated (medicine costs, hospital costs, care cost etc.) for the defined time horizon. The incremental costs per patient for the intervention compared with the comparator(s) must also be presented individually. Finally, the analysis must state explicitly if discounted figures are used.

Table 3 illustrates how to present the overall results of the cost analysis. Amgros makes a standard template available to present the results of the cost analysis. This should be supplemented by tables and presentations that illustrate the remaining components and assumptions of the analysis.

Table 3. Presentation of the results of the cost analysis. Overview of average costs per patient per defined time horizon for the intervention and the comparator(s)

Cost components	**Intervention**	**Comparator(s)**	**Difference**
Direct costs, including for example:	? DKK	? DKK	? DKK
- medicine costs	? DKK	? DKK	? DKK
- hospital costs	? DKK	? DKK	? DKK
- municipal costs	? DKK	? DKK	? DKK
- etc.	? DKK	? DKK	? DKK
Costs resulting from the time spent by patient and family	? DKK	? DKK	? DKK
Total costs per patient	**? DKK**	**? DKK**	**? DKK**

2.9 Discussion of the cost analyses

General assumptions, results and uncertainties must be summed up and evaluated.

2.10 Budget impact

An estimate of the budget impact for the regions must be produced in addition to the cost analysis.

The budget impact must be estimated based on the following factors:

1. Total added costs at regional level resulting from use of the medicine as standard treatment. Both medicine costs and if possible also other treatment-related costs at regional level must be included.
2. The price of the medicine must be calculated at PPP level (pharmacy purchase price), **exclusive** of VAT.
3. The expected market share of the medicine per year for the patient population(s) which the application concerns.
4. Incremental costs for the time horizon used in the cost analysis after recommendation as standard treatment.
5. Deductions for:

- Costs of existing medicines funded by the regions that will be replaced by the new intervention, provided the medicine is recommended as standard treatment for the indication.
- Expected future costs to the medicine for the indication, provided the medicine is not recommended as standard treatment.

The estimated budget impact at regional level is calculated as the difference between these two scenarios:

1. The medicine **is recommended** as standard treatment by the Medicine Council for the indication applied for.

2. The medicine **is not recommended** as standard treatment by the Medicine Council for the indication applied for.

The estimated number of patients eligible for a treatment (prevalence and incidence) must be in agreement with the estimates given in the protocol produced by the Medicine Council. Arguments supporting any other assumptions must be given.

The following estimates may also be relevant:

1. Analyses of subgroups, for example subgroups for which use of the intervention could be recommended as standard treatment, despite a general recommendation for the population cannot be granted. The subgroups must be in accordance with the subgroups defined in the protocol developed by the Medicine Council.
2. Sensitivity analysis, if major assumptions and data changes. These calculations must be performed if

- The results of the estimates are highly sensitive to changes in the assumptions
- Critical assumptions for the estimates are highly uncertain.

2.11 References

The cost analysis and estimates of the budget impact must include a detailed list of references.

Revision log

Version	Date	Subject
1.0	2016.12	
1.1	2017.03	New time horizon for the budget consequence analysis to ensure agreement with the time horizon used in the cost analysis.