

Template for reporting of Amgros' evaluation of costs analyses for new medicines and new indications in the hospital sector

The following framework describes the overall structure of Amgros' evaluation of the cost analyses which is a part of the Medicine Council's assessment of new medicines and indications. The extent of the sections may vary from analysis to analysis. But it is a minimum requirement that Amgros addresses the below listed items for every assessment.

1. Background (a brief summary of the Danish Medicine Council's clinical assessment)
 - i. Description of the problem
 - ii. Description of the patient population (**P**opulation)
 - iii. Description of the medicine and its area of use (**I**ntervention)
 - iv. Choice of comparison alternative(s) (**C**omparator)
 - v. Description of the treatment procedure including the time horizon over which the added clinical value will be assessed
2. Assessment of the submitted cost analysis
 - i. Model, method and assumptions
 - a. Perspective of the analysis
 - b. Patient population
 - c. Intervention
 - d. Comparator (treatment alternative)
 - e. Time frame (as in the Medicine Council's assessment of added clinical value)
 - f. Costs (input data)
3. Results
 - i. Sensitivity and scenario analyses
 - ii. Critical assessment of the submitted cost analysis
 - a. Relevance of the analysis compared with the population, intervention and comparator defined by the Medicine Council
 - b. Structure of the economic model
 - c. Cost data
4. Amgros' own calculation, if applicable
 - i. New scenarios with adjusted assumptions
 - ii. Results of adjusted analyses
5. Assessment of submitted budget impact analysis
6. Summary of results and assessment of submitted cost- and budget impact analyses