

Pharmacoeconomic Analysis Work Sheet

Product Information

Table 1, Drug Product Information

Drug Product (generic name/strength/dosage form)	Name of Manufacturer
Drug X Tablet USP Generic C 5mg Tablet	ACME Ltd.

Please complete each of the following questions:

- 1) What is the question being asked in the analysis?
- 2) What type of economic analysis was performed to answer the question?
 - i) Cost comparison
 - ii) Cost-consequence analysis
 - iii) Cost-effectiveness analysis
 - iv) Cost-utility analysis
 - v) Cost-benefit analysis
- 3) What is the justification for the approach taken?
- 4) Did the study involve a comparison of alternative treatments for patients with the same clinical condition?
- 5) Are those alternatives explicitly stated?
- 6) Is the analysis therefore an incremental analysis?
- 7) Is the view point or perspective for the analysis stated clearly?
- 8) Is it a societal perspective, third-party payer perspective, patient perspective?
- 9) Is the analysis presented in a disaggregated fashion showing these perspectives separately?
- 10) Was the evidence the evidence of the product's efficacy established through randomized trials?
- 11) Was this evidence of efficacy supplemented by evidence of effectiveness applicable to the patients covered by the Ontario Drug Benefit program?
- 12) Was the latter evidence derived from studies documenting routine use in clinical practice?

- 13) Are the methods and analysis displayed in a clear and transparent manner?
- 14) Are the components of the numerator (cost of each alternative) and denominator (clinical outcomes of each alternative) displayed?
- 15) Are clinical outcomes expressed first in natural units and then translated into alternative units such as benefits or utility? (See Section 3.4.d. of the Ontario Guidelines for Economic Analysis of Pharmaceutical Products for suggested format).
- 16) Are all important and relevant costs and consequences (outcomes), including adverse effects, for each alternative identified?
- 17) Are costs and consequences modelled as in a decision tree with information derived from a variety of sources; OR
- 18) Estimated directly from a variety of sources; OR
- 19) Estimated directly from a specific patient population?
- 20) Are capital costs and overhead costs included as well as operating cost?
- 21) How were they measured?
- 22) How were indirect costs identified and estimated?
- 23) How was quality of life measured?
- 24) What equity assumptions were made in the analysis?
- 25) For example, are QALYs gained by any individual considered equal?
- 26) If some variables were difficult to measure, how did the authors handle this difficulty?
- 27) Did they slant the analysis all in favour of one intervention in order to bias the analysis against the desired result?
- 28) Were extensive sensitivity analyses performed?
- 29) What were the ranges of values for variables in the sensitivity analyses?
- 30) Is quality of life an important component of an economic analysis of this question?
- 31) How sensitive is the estimate of cost utility to variations in quality of life?
- 32) Is there an estimate of the aggregate incremental expenditure required for the province to provide this product to patients covered by its programs?
- 33) What is the estimate of aggregate incremental costs?
- 34) Does this estimate cover all of the major indications for use of the product?

- 35) Has the incremental cost-effectiveness ratio been estimated for a special clinical indication that represents the majority or all of its expected use by those covered under the Ontario Drug Benefit program?
- 36) Do these other indications involve a large amount of utilization for which the ratio may be very different?
- 37) Who performed the analysis?
- 38) Did the authors of the report sign a letter indicating their agreement with the entire document presented?
- 39) Does the report indicate that the authors had independent control over the methods and right to publish the analysis regardless of its results?
- 40) What is the "bottom line" result of the analysis in quantitative terms? The answer to this question will be statements like the following:
 - i) The cost per QALYs gained for using this product compared to the alternative is \$X, or ranges from \$Y to Z.
 - ii) The use of this product compared to the stated alternative will result in an expected incremental expenditure of \$X per patient treated with a net reduction of Y major adverse clinical events (e.g., cardiac deaths) and Z minor clinical events (e.g., side effects).