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Title **Guidelines for Pharmacoeconomic Evaluations in Belgium**

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Reference Report no 78C, 2008. Cleemput I, Van Wilder P, Vrijens F, Huybrechts M, Ramaekers D. Joint work by KCE and the Belgian National Sickness and Disability Insurance Institute

Aim

To develop methodological and reporting guidelines for pharmacoeconomic evaluations submitted in the context of a reimbursement request for pharmaceutical products.

Conclusions and results

Twelve guidelines are built around a reference case that defines the recommended methodology for each component of the economic evaluation: literature review, perspective of the evaluation, target population, comparators, analytic technique, study design, calculation of costs, estimation and valuation of outcomes, time horizon, modeling, handling uncertainty, and testing robustness of results and discount rate. Each pharmacoeconomic submission should at least contain a reference case analysis. Additional analyses are allowed, but cannot replace the reference case.

Recommendations

Access to and provision of Belgian resource use data should be facilitated for pharmacoeconomic analyses aimed to serve Belgian pharmaceutical policy.

The Royal Decree of December 21, 2001 may benefit from integration of guideline 2 of the Guideline for Pharmacoeconomic Evaluation. Pharmacoeconomic analyses should include the costs to the healthcare payer, including governmental payers and the patients.

To increase the credibility and usefulness of pharmacoeconomic evaluations for drug reimbursement decisions, both the applicants and RIZIV/INAMI should systematically apply these guidelines.

Methods

The guidelines were developed in two phases:

Phase 1: A set of draft guidelines were developed by 8 health economists from Belgium and abroad, 2 pharmacists, 1 medical doctor with training in health economics, and 1 statistician.

Phase 2: The guidelines were implemented during a 6- to 12-month test period, which led to conclusions concerning their practicality, usefulness, and potential for improvement. The guidelines were adapted and finalized based on the practical experience of 1 company and extensive feedback from about 20 pharmaceutical companies through the organization representing the pharmaceutical industry in Belgium, *Pharma.be.*

Further research/reviews required

The field of economic evaluation in health care is still evolving. Hence, the guidelines will need to be revised regularly to include new insights and improved methods of economic evaluation.

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