

## COMPARATORS IN HTA GUIDELINES

**Podgaina M. V., Skril A.**

*National University of Pharmacy Kharkiv, Ukraine*

*economica@nuph.edu.ua*

Huge progress of the health technology assessment (HTA) has place today in all over the world and in Ukraine. Quality health technology assessment includes selection of comparator(s) as one of important stage. It is crucial to select the appropriate comparators for the analysis, as the choice will be important in determining the cost-effectiveness of the intervention and the relevance of the study to decision makers. In principle, the comparator is the alternative that is most likely to be replaced in clinical practice should the intervention be adopted. Consider the study question, the indication or purpose of the intervention, and the target audience for the study. Selecting comparators may be complicated when there is a range of approved alternatives for the same indication, or if there is variation in clinical practice across jurisdictions or patient subgroups (e.g., patients in nursing homes versus the general population).

In the Reference Case, the comparator should be “usual care,” which is the most common or most widely used treatment in clinical practice for the condition. This is also referred to as “existing practice,” “current practice,” “typical care,” or “status quo.” The most commonly used treatment that the intervention is intended to replace can be the one used for the largest number of patients, based perhaps on utilization data and clinical expert opinion. In addition, there may be the most prevalent type of care that dominates clinical practice or there may be two or three prevalent alternatives, in which case, all should be individually compared to the intervention being studied. The comparator need not be an alternative drug listed in the formulary of the relevant jurisdiction. As a starting point, it may be useful to consider alternatives in the same therapeutic class (i.e., drugs with the same indication). This may include drugs with the same chemical composition or mechanism of action as the new drug. For example, the comparators for a new quinolone antibiotic may not be limited only to other quinolones (as all quinolones may not be approved for the same indications), but rather all other antimicrobial agents that are clinically used to treat the infections the new quinolone is intended for. If the new drug is in a new therapeutic class, then the comparator is usual care (and recommended care, if appropriate), which may involve treatment with a drug from another chemical class, if available, or a nondrug treatment.

The regimen used for costing should reflect the dose and duration supporting the efficacy or effectiveness data for the product used in the evaluation. State whether the dosing regimens that are used clinically differ from those used in the clinical efficacy trials. Actual (versus recommended) dosing can be determined by reviewing the literature, by examining utilization data, or by conducting a survey of clinical experts. Where appropriate, use the dosage of each individual comparator required to achieve the same therapeutic effect, and justify the dose equivalencies used.

It is established that correctness in comparator selection provides correctness of HTA results.