OP59 The Tunisian Guidelines For Pharmacoeconomic Analysis: What We Need To Know

Nabil Harzallah (nabil.hrz@gmail.com), Jaafar Chemli, Hela Grati, Marie Jebali, Mouna Jameleddine and Chokri Hamouda

Introduction. As a new milestone in health technology assessment (HTA) implementation in Tunisia, L'Instance Nationale de l'Evaluation et de l'Accréditation en Santé (INEAS)—the Tunisian HTA body—published a set of methodological guidelines to support HTA dossier submission by the pharmaceutical industry. Including, 'guide for submitting clinical data for an HTA at INEAS', 'methodological choices guide for pharmacoeconomic analysis at INEAS', and 'methodological choices guide for budget impact analysis at INEAS'. We aim to report the major methodological recommendations of the pharmacoeconomic analysis guideline.
Methods. The 'methodological choices for pharmacoeconomic analysis at INEAS' guideline was reviewed and the major recommendations were retrieved and reported.
Results. The reference analysis required by INEAS is the cost-utility analysis systematically combined with a cost-effectiveness analysis (cost per life-year gained) from the public payers' perspective. The choice of any other type of analysis must be duly justified. Comparators should include alternative treatments which are considered to be 'the standard of care' (i.e., interventions routinely used in Tunisia for the same indication) and in which public resources are invested. The time horizon should be sufficiently long to reflect all differences in costs and outcomes. Additionally, a discount rate of 5 percent per year is recommended. The best available evidence for efficacy, safety and quality of life is required. An indirect measure of patient preference, through a validated measurement instrument is preferred for utility calculation. Cost inputs should be identified from Tunisian sources. Health resource utilization should reflect the care pathway in Tunisia. INEAS favors the use of a recognized model. Uncertainty and impact of the input parameters on the results should be assessed and reported through probabilistic and deterministic sensitivity analyses. Model validation tests to assess face validity and internal validity should be performed, and a discussion of the methods used provided. Demonstration of external validity is required. Results should be presented in incremental cost-utility and cost-effectiveness ratios.
Conclusions. The recommendations of 'methodological choices for pharmacoeconomic evaluation at INEAS' is an important step to facilitate and harmonize pharmaceutical companies' submissions and to enhance the use of these analyses in decision-making.

OP60 Methodological Guidance And Doctrine Of The French National Authority For Health For Economic Evaluation

Véronique Raimond (v.raimond@has-sante.fr) and Commission for Economic and Public Health Evaluation

Introduction. The French National Authority for Health (HAS) "defines and issues guidelines and medico-economic opinions on prevention, healthcare, prescription, and best care strategies, and contributes to their comparison or ranking to support public health and optimize health insurance spending." Based on a decade of producing cost-effectiveness evaluations, the Economic Evaluation and Public Health Committee (CEESP) issued two documents to frame its activity related to the economic evaluation of health products: (i) the new guidance highlights the expectations of the CEESP regarding cost-effectiveness evaluations; (ii) the doctrine elucidates the grading of methodological reservations expressed during the technical appraisal of manufacturers' submissions, the CEESP's statements regarding its findings, and the key messages it wishes to convey to public decision-makers, especially to negotiate healthcare product prices.
Methods. We aim at sharing the content of these documents and describing the willingness of the CEESP to support decision-makers in implementing evidence-based pricing policies.
Results. The new guidance provided an opportunity for HAS to stress the importance of interpreting the evaluations, which are often perceived as highly technical. In this perspective, several guidelines call for more reasoned reflection on the objectives of the evaluation upon its conception, along with a constant effort to justify the methodological choices made and an extensive interpretation of the results produced.
The doctrine highlights two steps taken by the CEESP, mainly built on analyzing the cost-effectiveness evaluation's uncertainty. First, the ability to characterize the level of the ICER in a context where no thresholds for willingness-to-pay exist in France; second, the suggestion of specific regulation schemes to increase the cost-effectiveness of the products.
Conclusions. The CEESP developed the new guidance and its doctrine as conditions to ensure the usefulness of the economic evaluation for decision-making.

OP62 Patients' Opinion On Health Technology Assessment Reports: An Analysis Of Brazilian Health Technology Assessment In 2021

Denis Satoshi Komoda (deniskomoda@gmail.com), Carlos Roberto Correa, Marilia Berlofa Visacri, Daniela Santos and Flavia Maia

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