endpoint was impacted by a nEnG study, we classified the study as non-relevant to the HTA's conclusion and specified a reason for this.

Results. Of seventy-two HTAs, twenty-nine (40 percent) included a total of eighty-three nEnG publications). Three HTAs were impacted by the inclusion of altogether seven Chinese publications. For one HTA on systemic therapy, five endpoints' conclusions were changed; for the other two HTAs, the statistical significance would have changed for one endpoint each. The remaining seventy-six publications (included in sixty-nine HTAs) were judged as non-relevant to the HTA's conclusion, the most prominent reason being "meta-analysis would have had the same result without respective study" (44 percent of nEnG publications).

Conclusions. Only three of seventy-two HTAs (4 percent) were impacted by nEnG publications, the changes being minimal for two of these. When faced with limited time or personnel resources, searching only for English and German publications may be sufficient, especially when generalizability issues are a possible concern.

VP32 Incorporation Of The Only Drug For Primary Biliary Cholangitis Brazil

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Introduction. Primary biliary cholangitis (CBP) is a rare autoimmune cholestatic liver disease, inflammation and progressive destruction of small and medium-sized interlobular ducts, progressing to fibrosis, cirrhosis, and death. Currently, the Brazilian public health system (SUS) offers treatment of the symptoms of cirrhosis, and has no medication with indication for CBP.

Methods. Scientific technical opinion with systematic review (SR) of available evidence in the databases MEDLINE (Pubmed), LILACS and Cochrane Library (accessed July 2017) on ursodeoxycholic acid (AUDC). Methodological quality was evaluated with AMSTAR and Newcastle Ottawa tools. Meta-analyses were performed in Review Manager® 5.2 in the random effects model. Analysis of the budget impact calculation deterministic model, from the perspective of five years for the SUS.

Results. Ten SRs and three cohorts were included. There was no statistically significant difference between AUDC and placebo in outcome. Overall survival was significantly (P <0.001) higher in the AUDC group compared to that predicted by the Mayo model or placebo. Treatment with UCD showed an increase in the long-term transplant-free survival time from the fifth year of treatment, with statistically significant results for years five, eight and ten (p <0.01). There were no statistically significant differences for safety outcomes. Based on the assumptions adopted, the incremental budgetary impact with the incorporation of the AUDC into SUS would be BRL 11.77 million (EUR 2.68 million) in the first year and BRL 98.52 million (EUR 22.45 million) in the accumulated five years, considering a market share of 10 percent per year.

Conclusions. Despite the uncertainties in the evidence of effectiveness of the AUDC and the probably underestimated budgetary impact, AUDC was incorporated into the SUS because it is the only alternative with indication for CBP and in use for more than two decades, allowing everyone access to the medicine

VP33 Pharmacoeconomic Submission Requirements: Africa Compared With England

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Introduction. The South African Pharmacoeconomic Submissions Guideline (SAPG) is currently voluntary for medicines in the private health sector but may become mandatory and more widely used under the proposed National Health Insurance system. To make recommendations on evidence generation and areas where the SAPG could be strengthened, the study compared the SAPG requirements with other African pharmacoeconomic guidelines and the National Institute for Health and Care Excellence Methods Guide (NICE MG).

Methods. The World Health Organisation, International Network of Agencies for Health Technology Assessment (INAHTA), HTA International, and the International Society for Pharmacoeconomics and Outcomes Research websites were consulted, and email requests sent to named individuals from retrieved source material. The European Network for HTA Core Model® (version 3.0) (the Model®) provided the evaluation and comparison framework, using three criteria: completely, partly or not completely requiring the same or similar information as the Model®.

Results. Of the forty-five countries identified, only Egypt had a publicly available pharmacoeconomic guideline (Egyptian Pharmacoeconomic Guideline (EPG)). The guidelines varied considerably in their intended audience, size and content. All three guidelines' primary focus was the cost and economic evaluation, and health problem and current use domains. Safety, organisational, ethical and legal aspects were poorly covered by the SAPG and EPG guidelines (less than thirty percent of issues in each domain completely / partly covered). The SAPG completely or partly required the same or similar information in the Model® for thirty-nine percent of total issues, the EPG thirty-three percent and the NICE MG sixty-six percent

Conclusions. The SAPG was not as comprehensive as the NICE MG and poorly covered some key aspects of HTAs, suggesting that the SAPG could be developed to be more informative for decision-makers. Evidence generation should focus on describing the health problem the technology is targeting and on evidence that can be synthesized into cost-effectiveness analyses.

VP34 Impact Of Adverse Events On Reimbursement Recommendations

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