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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Introduction. European agencies evaluate the adverse events (AEs) of asthma drugs in studies. The impact of these evaluations on reimbursement decisions remains unclear.

Methods. Adult asthma evaluations were accessed from initial regulatory decision by the European Medicines Agency (EMA) through reimbursement evaluations. Omalizumab and reslizumab were chosen for the comparison of an older with a newer asthma drug. A timeline was then constructed to evaluate the effect of AEs on reimbursement recommendations. Evaluations from the United Kingdom (NICE) were not used because their documents are not as complete or in depth, including those from Sweden (TLV) and Germany (IQWIG).

Results. Omalizumab was first approved as add-on therapy to improve asthma control in October 2005. Of the 6 decisions made between 2006 and 2012, safety information was found in 4 of them, all from 2006 and evaluated by either Scotland (SMC) or France (HAS). These desicions all received either a 'Do not recommend' or a 'Recommend with restrictions' decision. Reslizumab was first approved as add-on therapy for patients with severe eosinophilic asthma in August 2016. Of the 9 decisions made in 2017, safety information was found in 5 decisions evaluated by IQWiG, Germany (G-BA), HAS, or SMC, which gave them a Do not recommend, Recommend with restrictions, or Recommend decision. Of the Do not recommend decisions, both the omalizumab and reslizumab safety evaluations mentioned common AEs (worsening asthma) and less common AEs (malignant tumors). Of the Recommend with restrictions decisions, the same AEs were seen. Only reslizumab had Recommended decisions. In the safety evaluation, there were no specific AEs named.

Conclusions. The impact of AEs on reimbursement decisions could not be detected when comparing omalizumab and reslizumab reviews, as other factors may contribute to the decisions. Further research should be conducted to explore this issue.

VP35 Effectiveness and Safety of Cyanoacrylate Ablation for Varicose Veins

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Introduction. Treatment of varicose veins is currently performed by different interventionist alternatives that include surgical, endothermal and non-thermal ablation therapies. The main guidelines recommended endovenous thermal treatment as the first choice therapy; however present side effects related to thermal energy. Non-tumescent endovenous ablation techniques such as cyanoacrylate ablation (CA) started to develop to avoid these problems. The objective of this study is to assess the effectiveness and safety of CA for saphenous vein incompetence.

Methods. A systematic review with meta-analysis was carried out. The search of scientific literature was performed in Medline, Embase, Cochrane library, CDR, WoS and Scopus databases. GRADE methodology was used to assess the quality of the evidence and Cochrane risk of bias tool to assess methodological quality of randomized control trials (RCT). Pooled risk ratio was calculated using a random effects model.

Results. Two RCTs and one non-RCT comprising 1,077 participants were included. Additionally, 10 case series were included for safety assessment. Pooled analysis of closure rates by the two RCTs indicated there were not significant differences between CA and radiofrequency ablation (RFA) or endovenous laser ablation (EVLA). Improvements in venous clinical severity score were reported by all comparative studies without significant differences among groups. The most frequently reported adverse events were ecchymosis, phlebitis, paraesthesia, and thrombosis. The pooled analysis showed significant differences only in ecchymosis rates, with lower probability of ecchymosis in CA groups. CA treatment showed lower pain rates and shorter intervention times and recovery compared to endothermal therapies.

Conclusions. The effectiveness of CA devices in the treatment of varicose veins is comparable to EVLA and RFA, while the rates of adverse effects are lower. Despite the limitations of the evidence, CA may be a promising alternative to existing treatments, with the advantages of better patient comfort.

VP37 Patient Involvement In EUnetHTA Assessments (Non-Pharma Technologies)

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Introduction. Patients can provide valuable experience on living with diseases, health-related quality of life, various therapies and relevant outcomes. Their input and perspectives can be helpful in complementing health technology assessment (HTA) processes. The European Network for HTA (EUnetHTA), funded by the European Commission, aims to further advance and standardise patient involvement processes in order to add to the quality and applicability of HTAs and to allow capability building.

Methods. Different methods for patient involvement in HTAs on non-pharmaceutical technologies were tested: Patient input templates (open questions sent to relevant patient organizations, or published on EUnetHTA website); scoping meeting with patients/patient representatives; one-on-one conversation and group conversation. Applied methods depended on the scope of the HTA and other factors like timelines of HTAs and burden of disease for patients.

Results. Patients were included in eight of sixteen HTAs on non-pharmaceutical technologies. Applied methods were: group conversation (n = 2), scoping meeting (n = 1), patient input templates (n = 4), one-on-one conversation (n = 2,) and other approach (i.e. written feedback on scope n= 2). In some HTAs more than one method was used. Main reasons for not including patients were inability to identify suitable patients or tight timelines. Patients´ feedback on health-related quality of life and outcome measures proved most useful in the scoping phase.

Conclusions. The different approaches were useful for complementing HTA processes. Those need to be further tested and evaluated in order to formulate deeper understanding about the impact of patient involvement on HTA. Additionally, feedback from patients that were actively involved in the HTAs should be collected to further improve the involvement methods that should serve as basis for future recommendations post 2020.

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