focused around more scrutiny in the reimbursement assessment of orphan drugs.

**Conclusions:** All twenty stakeholders gave recommendation to strengthen the stronger European cooperation for the value assessment of orphan drugs, with eleven stakeholders suggesting a European reimbursement system for orphan drugs.

**PSY73**

**CONSIDERATION FOR RARE DISEASES IN DRUG REIMBURSEMENT DECISION-MAKING**

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**OBJECTIVES:** Reimbursement processes have been implemented to inform which therapies should be funded in light of scarce health care resources. However, the applicability of standard processes to drugs for rare diseases is heavily debated. As a result, the assessment of orphan drugs is affected by various processes for prescription pharmaceuticals both within the current system and internationally, with the objective of assessing how drugs for rare diseases are considered within existing processes. **METHODS:** Using the C20 countries as a sampling frame, a review of published and grey literature was conducted to identify the reimbursement processes used in 28 countries, and in Canadian provinces/territories. A search for peer-reviewed publications was conducted using Medline, Scopus, CINHAL, EconLit, and PsychInfo. The relevant literature includes pharmacoeconomic studies, and literature on the reimbursement of drugs for rare diseases. **RESULTS:** Drugs for rare diseases are considered uniquely for reimbursement within three Canadian provinces and seven countries. Reimbursement frameworks focused specifically on the reimbursement of drugs for rare diseases are limited. In some jurisdictions, drugs for rare diseases are considered uniquely within the established decision-making process for drugs. Varying decision criteria are applied within the identified processes for the reimbursement of drugs for rare diseases. **CONCLUSIONS:** This review identifies approaches for making resource allocation decisions for drugs; explicitly considering funding decisions related to drugs for rare diseases. An understanding of these frameworks and the decision criteria applied when making resource allocation decisions may help inform the development of more standardized approaches for the reimbursement of drugs for rare diseases.

**PSY74**

**THE ECONOMIC AND HUMANISTIC BURDEN OF RELAPSED/REFRACTORY (R/R) INDOLENT NON-INDOLENT NON-HODGKIN'S LYMPHOMA (iNHL): AN EVIDENCE-BASED ANALYSIS**

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**OBJECTIVES:** To identify research studies that examine the economic and/or humanistic burden of R/R iNHL, and identify evidentiary gaps which could be informed by future research. **METHODS:** iNHL refers to a group of largely incurable lymphomas. The term has been used in a relapsed/refractory context, and can lead ultimately to life-threatening complications. Although many therapies are available, patients eventually relapse and become refractory to existing therapies. As such, additional treatment options with improved response rate, durability of response and more manageable toxicity are needed to treat patients with R/R iNHL. A structured literature search was performed to assess the economic and patient burden of iNHL. English-language articles published since 2009 were systematically reviewed in Pubmed, Embase and Cochran databases. Additionally, searches from global HTA organizations and conference abstracts were performed. Research was considered relevant to the economic and humanistic burden of iNHL based on reported outcomes such as resource utilization costs, or relevant patient-reported outcomes associated with relapsed/refractory iNHL. **RESULTS:** Few cost-of-illness studies or HTAs address iNHL. Evidence was limited to hospital-based direct treatment costs, omitting societal and indirect costs of the disease. Multiple cost-effectiveness analyses were identified focusing on Rituximab; however, few studies evaluated the cost-effectiveness of alternative 2nd- or 3rd-line therapies in the case of R/R iNHL. The majority of identified patient reported outcomes (PRO) research exists as concept abstracts. No studies were identified that examine PRO in a R/R iNHL population. **CONCLUSIONS:** The economic and humanistic burden of R/R iNHL has not been widely reported in the literature. Areas of future research may include evaluating both direct and indirect costs in R/R iNHL. PROs are not well understood in iNHL, and future research should focus on QoL and related factors that may help evaluate any trade-off between progression-free survival and the severity/duration of adverse events.

**PSY75**

**HTA ASSESSMENT COMPARISON OF ORPHAN DRUGS IN FRANCE AND GERMANY**

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**OBJECTIVES:** In the context of Health Technology Assessment (HTA) decision framework, some countries (e.g. Germany) have a specific regulation for orphan drugs (OD), whereas others aim to adapt the reimbursement of the same drug to compare the HTA decisions, prices and reimbursements for the OD that have been evaluated in France and Germany. **METHODS:** We selected OD assessed under AMNOG law in Germany and reviewed HTA assessments from the Transparency Committee (TC) for France and from IGWc/G-BA for Germany, and extracted prices and reimburse-