injections are lower compared to intravenous infusion due to potential lower time investments, shorter pharmacy preparation time, less patient chair time and less spillage. **METHODS:** We use a prospective, observational, bottom up, micro-costing approach aiming at the inclusion of 50 patients with hematological disease. Primary cost outcomes comprise the labor costs for nurses and pharmacists/pharmacy technicians, materials, hourly daycare costs and drug spillage costs. Exact timings are measured using stopwatches, dosing and spillage is measured using registered MabThera volumes in the Hospital Pharmacies' registrations and materials are exactly numbered and labeled. List prices are used for materials and MabThera costs, hourly nurse and pharmacy time is costed according to salaries, and day-care is costed using the Dutch guideline for costing research in health care. Anticipating positive outcomes of the currently ongoing non-inferiority study, efficacy of MabThera along both administration routes was implicitly assumed similar; additionally parity pricing is assumed. **RESULTS:** Interim results based on 24 patients included so far indicate that extra costs of intravenous infusion over subcutaneous injections are on average €175 per administration. This difference is primarily constituted by €100 lower daycare costs related to shorter chair time for subcutaneous as compared to intravenous administration. **CONCLUSIONS:** Our interim cost-minimization analysis suggests that subcutaneous injection of MabThera involves lower administration costs than intravenous infusion. With similar efficacy assumed, cost savings can be achieved at no expense of health, by including subcutaneous MabThera injections in the Dutch reimbursement system. Notably, over a full course of administrations (8 cycli) cost savings may easily surpass €1000 per patient per year.

PSY77

IS IT WORTH HAVING ORPHAN DRUG STATUS IN GERMANY POST-AMNOG?

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OBJECTIVES: To review the assessments of benefit for orphan drugs within the early benefit assessment process after implementation of AMNOG in Germany. **METHODS:** Secondary research was used in this study. **RESULTS:** In contrast to other pharmaceuticals, by law, the benefit of orphan drugs (ODs) is proven by market authorization. No assessment vs. an appropriate comparator as defined by G-BA will be conducted, provided the revenue is less than 50 mio. EUR based on pharmacy retail prices including VAT over the past twelve months. IQWiG only assesses the accuracy of the number of patients and the therapy costs stated in the value dossier, while GB-A defines the extent of the benefit based on the Phase III data submitted with the abbreviated dossier. Seven ODs have been assessed by G-BA since implementation of AMNOG in 2011. Only one OD has received considerable benefit status in one patient subgroup, whilst two ODs have been classified as not quantifiable, and the other ODs assessed so far have been granted only a minor benefit. Prices have been negotiated for only 2 ODs so far: For Pirfenidon, with an unquantifiable benefit, a rebate of 11% was applied, while Tafamidis, with a minor benefit, received a rebate of 24.5%. **CONCLUSIONS:** There is a clear benefit for ODs (with annual sales of less than 50 mio EUR) in terms of reduced administrative burden and costs associated with the abbreviated value dossier submission. Furthermore, the OD status and the absence of a comparative added benefit assessment warrant a benefit score, whereas 60% of the non-orphan pharmaceuticals failed to prove an additional benefit vs. the defined comparator. As only two orphan drugs have completed price negotiations, it is very difficult to estimate, whether OD status will have a positive impact on future pricing opportunities after AMNOG.

PSY78

COST-EFFECTIVENESS OF SCHOOL-BASED HEALTH PROMOTION IN CANADA: A LIFE-COURSE MODELING APPROACH

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OBJECTIVES: The Alberta Project Promoting active Living and healthy Eating (APPLE) Schools has been recognized as a "best practice in preventing childhood obesity. To inform decision making on the expansion and resource allocation for such school-based program like the APPLE Schools, we evaluated its cost-effectiveness and return-on-investment following a life-course approach. **METHODS:** We developed a state transition model to represent the life-time progression of weight status of three groups of children who were obese, overweight or normal weight at 11 years. The model quantified impacts of the intervention in terms of prevented excess weight cases, improved quality-adjusted life years (QALY), and avoided health care costs. Both costs and QALYs were estimated to their present value using 3% discount rate. **RESULTS:** The incremental cost-effectiveness ratio (ICER) of the APPLE Schools program was CA$ 15,833 per 1 QALY gained, and CA$ 24,359 or 11,047 per 1 obese or overweight case prevented in adult population. Every 1,000 children intervened; the program costs CA$190,000, and the estimated saving in the health care costs is about CA$ 2.3 million, that is equivalent to a benefit-cost ratio of 13:1. The sensitivity analyses showed that the incremental cost-effectiveness of the APPLE Schools program was robust against variations of program costs and model parameters. **CONCLUSIONS:** The APPLE Schools program is a cost-effective intervention for obesity prevention, and promises substantial return on investment. Expanding the coverage and allocating resources towards school-based programs is central to the fight against obesity epidemic in Canada.

PSY79

PAYER ASSESSMENT AND REIMBURSEMENT POLICY FOR RARE DISEASES: A REVIEW OF THE LITERATURE

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OBJECTIVES: To review the published literature to identify: a) the most frequently cited challenges relating to payer assessment and reimbursement of rare disease treatments (including orphan drugs), and b) to review author recommendations to improve the assessment of these treatments. **METHODS:** A systematic literature review of Medline and EMBASE databases was conducted for the period 2000 - 2013. The search sought to identify papers on the topic of assessment and reimbursement policy for rare diseases. Health policy studies, commentaries, and review articles were included. Clinical or economic studies of specific drugs or diseases were excluded. Information was extracted on assessment and reimbursement challenges and author recommendations for addressing these issues. **RESULTS:** The literature review identified 726 papers; 49 met the inclusion criteria. The most frequently identified issues included multiplicity of orphan indications (34/49), high per-patient cost (32/49), and the difficulty in undertaking robust clinical and economic evaluations given limited evidence (32/49). Several authors commented on limitations of current health technology appraisal processes. The issue of equity and societal preference for funding rare diseases was highlighted in almost half of the papers (22/49). Lack of availability of alternative treatments was also considered an important factor. Suggestions for improvements to the assessment and reimbursement process included: greater use of registries (22/49), adjustment to preference weights used in cost effectiveness analysis (19/49) and conditional reimbursement and risk-sharing-schemes (12/49). Some authors advocated alternative pathways for assessing rare disease treatments including a specific approach utilising multi-criteria decision analysis. **CONCLUSIONS:** The debate on payer policy in rare diseases has grown in the last 5 years as concerns have increased about patient access to new medicines. While there is some consistency in the literature, there is as yet little consensus on how policy should be changed to address these issues.

PSY80

A SYSTEMATIC REVIEW OF THE EFFECTIVENESS OF TAXES IN PREVENTING OBESITY TRENDS

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OBJECTIVES: Obesity prevalence is increasing worldwide, a worrying trend as it relates to many diseases and imposes significant direct and indirect health care costs. The purpose of the present study was to assess the impact of taxation policies upon the consumption of Sugar Sweetened Beverages (SSBs) and High in Fat Sugar and Salt (HFSS) foods and ultimately caloric intake and weight outcomes. **METHODS:** The review identified relevant papers from web-based searches in comprehensive databases such as: Pubmed, Web-of-Science, Cochrane Library, Ag Econ, Econlit and National Agricultural library. Searching was conducted with all potential combinations of various relevant for the purposes of the study financial, nutritional, and outcome terms. Thereafter, abstracts were reviewed and studies were selected based on predefined criteria. The search included studies published from 1990 up to February of 2013 in English language. The characteristics and the results of the selected studies were extracted in a special form and consequently were reviewed and synthesized, based on the methodological design. **RESULTS:** A total of fifty five studies were finally included in the review. Several different types of studies showed a reduction in purchases and consumption of SSBs or HFSS foods when prices increase due or not due to taxation, but the subsequent effect upon total caloric intake was much smaller. A few studies which report weight outcomes, indicate that they are either insignificant or very small in magnitude to cause any public health improvements. **CONCLUSIONS:** The effectiveness of taxation policies to curb obesity levels is doubtful and the desired objectives not easily attainable, mainly because of the complex nature of consumer behavior and the impact of substitution effects, for which there is limited evidence to date. There is need to investigate in more depth the potential underlying mechanisms and the links between price increase policies, obesity and public health outcomes.

PSY81

MANAGED ENTRY AGREEMENTS AND ORPHAN DRUGS: A EUROPEAN COMPARATIVE STUDY (2006-2012)

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OBJECTIVES: To identify, describe and classify managed entry agreements (MEAs) applied to orphan drugs by national payers and to analyse their practice in Europe. **METHODS:** To identify and describe MEAs, national HTA and reimbursement decisions on orphan drugs across seven European countries were reviewed and their main characteristics extracted. To fill data gaps and validate the accuracy of the extraction, collaboration was sought from national payers. To classify MEAs, a bespoke taxonomy was implemented. Identified MEAs were analysed and compared by focusing on five key themes, namely by describing the MEAs in relation to: drug targets and therapeutic classes, geographical spread, type of MEA applied, declared rationale for setting-up of MEAs, and evolution over time. **RESULTS:** Forty-two MEAs for 26 orphan drugs, implemented between 2006 and 2012 and representing a variety of MEA designs, were identified. Italy was the country with the highest number of schemes (n=15), followed by The Netherlands (n=10), England and Wales (n=8), Sweden (n=5) and Belgium (n=4). No MEA was identified for France and Germany due to data unavailability. Antineoplastic agents were the primary targets of MEAs. 55% of the identified MEAs were performance-based risk-sharing arrangements; the other 45% were financial-based. Nine of these 26 orphan drugs were subject to MEAs in two or three different countries, resulting in 24 MEAs. A total of 60% of identified MEAs focused on conditions whose prevalence is inferior to 1 per 10,000. **CONCLUSIONS:** This study confirmed that a variety of MEAs were increasingly used by European payers to manage aspects of uncertainty associated with the introduction of orphan drugs in the health care system, and which may be of a clinical, utilisation, or budgetary nature. It remains unclear whether differences in the use of MEAs reflect differences in how 'uncertainty' and 'value' are perceived across health care systems.