injections are lower compared to intravenous infusion due to potential lower time
increases. A shorter pharmacokinetic 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, medication costs, 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. This ensures that the difficult costs of subcutaneous MabThera,
hourly nurse and pharmacy cost is coded according to salaries, and day-care is coded
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 and additional 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
€0.35 per injection. Patients are primarily costed at the beginning of the trial.
Differences in results are primarily costed to the higher patient 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 administration. We expect that 5 years from now no expense of health, by including subcutaneous MabThera injections in the Dutch
reimbursement system. Notably, over a full course of administrations (8 cycles) cost
savings may easily surpass €100 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
european evaluation process following implementation of AMNOG in Germany. METHODS: Secondary research was used in this study. RESULTS: In
cost to other pharmaceuticals, by law, the benefit of orphan drugs (ODs) is
proven not only in terms of the pharmacological effect, but also in terms of health
benefit 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. A definitive database for G-BA is under development. Web of Science, Cochrane Library, Ill 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 consider-
able 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 Firfenidon,
with an unquantifiable benefit, a rebate of 11% was applied, while Tafamidis, with a
margin of the returned rebate of 24.5% . Therapeutic benefit were reviewed and
approved for ODs (with annual sales of less than 50 mio EUR) in terms of reduced administra-
tive burden and costs associated with the abbreviated value dossier submission.
Furthermore, the OD status and the absence of a comparative added benefit assess-
ment warrant a benefit score, whereas 60% of the non-orphans 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 ODs
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 (APLE) 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 APLE 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% dis-
count rate. RESULTS: The incremental cost-effectiveness ratio (ICER) of the APLE 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 inter-
vened in 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 APLE School program was robust against variations of program costs and model param-
eters. CONCLUSIONS: APLE 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 expanding to
the fight against epidemic obesity in Canada.

PSY79
PAYER ASSESSMENT AND REIMBURSEMENT POLICIES 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) the key payer 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
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 (49/49), and difficulties in undertaking both clinical and economic evalu-
ations given limited evidence (32/49). Several authors commented on limitations in
current health technology appraisal processes. The issue of equity and societal
preference for funding rare diseases was highlighted in almost half of the papers
(24/49). Lack of availability of alternative treatments was also considered an impor-
tant factor. Suggestions for improvements to the assessment and reimbursement
process included: greater use of registries (22/49), adjustment to preference weights used
in the HTA process and conditions for conditional approval. Several studies also
addressed risk-sharing schemes (12/49). Some authors advocated alternative pathways for assess-
ing rare disease treatments including a specific approach utilizing multi-criteria
decision analysis. CONCLUSIONS: The debate on payer policy in rare diseases has
been ongoing for 5 years and has increased about 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 OBESEITY 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. Therefore it was to assess the health care and economic effectiveness 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 out-
comes. METHODS: The review identified relevant papers from web-based searches in
emergent databases. Web of Science, Science Citation Index, Pub Med, Embase, Web of Science, Cochrane Library, Ag Econ, Ecoinet and National Agricultural library. Searching was conducted
with all possible 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 character-
istics and the results of the selected studies were extracted in a special form and
then analyzed 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 consump-
tion 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
efficacy of curbing obesity is limited 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 a 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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Agency, Stockholm, Sweden, 2Italian Medicines Agency (AIFA), Rome, Italy, 2Health Care Insurance Board (CVZ), Diemen, The Netherlands
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 reimburse-
ment processes 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 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
MEAs, followed by The Netherlands (n=8), England and Wales (n=8), Switzerland and Belgium (n=4). No MEA was identified for France and Germany
due to data unavailability. Anti-infective 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 increas-
ingly used by European payers to manage aspects of uncertainty associated with
the use of orphan drugs and the OD status will have a positive impact on future pricing opportunities after AMNOG.

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