OBJECTIVES: The analysis was conducted to compare trends in recommenda-
tions for orphan products reviewed by the Scottish Medicines
Consortium (SMC), the National Institute of Health and Care Excellence (NICE)
and the Gemeinsamer Bundesausschuss (G-BA), and identify disease areas that
may be particularly challenging for manufacturers planning European product
launches. METHODS: The analysis followed 3 objectives: (i) assessing SMC,
and NICE positive and restricted recommendations, G-BA major, minor and con-
siderable additional benefit decisions, and ‘unable to recommended’; NICE nega-
tive recommendations, SMC negative recommendations and non-submissions,
G-BA no-benefit or unquantifiable benefit. Analysis of products by disease area
was conducted by classification into British National Formulary (BNF) catego-
ries. RESULTS: SMC, NICE and G-BA have published 1160, 147 and 100 recom-
mandations since their formation. Positive recommendations from NICE/SMC
have increased in 2012-2014 (58% to 74%) but decreased from G-BA (50% to 43%).
Treatments for malignant disease and immunosuppression formed the largest
categories of submissions (SMC 244, NICE 70, G-BA 34) with higher recommenda-
tion rates in Germany (65%) than the UK (50%). Significant differences in recom-
mendations between the UK and Germany were found in endocrine treatments
(73% vs. 24%, p=0.00035) and eye treatments (74% vs. 20%, p=0.012). In 2011-2014,
G-BA and SMC recommended 16 orphan products, respectively. Overall, NICE
has recommended more orphan products (67%) than G-BA (63%) or SMC (49%).
NICE and SMC recommendations for orphan products have increased in
2014 compared to previous years. CONCLUSIONS: This analysis illustrates that
the UK market may be easier to access than the German market but the scale of
the challenge depends on the BNF category of the treatment. The next stage of
analysis will consider trend analysis when accounting for SMC submissions and
the review of NICE technology appraisals and multiple technology appraisals.

PHP145
USE OF REAL WORLD EVIDENCE IN GERMAN AMNOG APPLICATIONS
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OBJECTIVES: The German statutory health insurance in Germany comprises 90% of
the German population covering nearly all healthcare services with only little co-
payments. German health insurance claims data therefore constitute an important
basis for real world evidence (RWE) on epidemiology and cost information. Aim of
this study was to investigate to which extent RWE was used for estimation of
prevalence and incidence in German AMNOG assessments since introduction 4
years ago and also its impact on price discounts. METHODS: German AMNOG
assessments submitted until December 2014 were evaluated. They were screened
for use of RWE in assessing prevalence and incidence and also target populations.
After description and discussion of methods and data sources used, statistics
were applied to explore a potential influence of use and quality of RWE data on price
discounts. RESULTS: In total, 108 AMNOG dossiers were included. Real world
evidence was used in 42.6% of these dossiers to assess prevalence and incidence
as well as target populations. German claims data were employed in 8 dossiers
(7.4%), registry data in 7 dossiers (6.5%), other data sources like Delphi panels
in 37 dossiers (34.3%). The impact of quality of RWE evidence on negotiated dis-
counts is inconclusive with limited data available. German claims data comprise
comprehensive information such as demographics, outpatient and inpatient care,
prescription data, inpatient and outpatient hospitalization data, inpatient and out-
patient claims data, laboratory data within an electronic health record (EHR) system.
Additionally, routine documentation of diagnoses, procedures and prescriptions as well as
the ability to evaluate patient histories are particularly useful for prevalence
and incidence analysis. Therefore we hypothesize that the use of real world data
which are of paramount importance in price negotiations following the
AMNOG assessment. CONCLUSIONS: German claims data constitute a valuable
and valid data source for assessing epidemiologic evidence in German AMNOG
assessments. Integrating real world claims data analyses are a meaningful comple-
ment to literature research.

PHP146
THE VALIDITY OF THE PROPORTIONAL HAZARDS ASSUMPTION FOR THE META-
ANALYSIS OF TIME TO EVENT DATA TO SUPPORT SUBMISSIONS TO HEALTH
TECHNOLOGY ASSESSMENT (HTA) AUTHORITIES
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OBJECTIVES: Meta-analysis (M-A) of time to survival data are most commonly
performed using the individual summary statistic hazard ratio from each study, as
an appropriate measure of effect. Currently there is no clear guidance regarding
alternative novel methodologies of evidence synthesis using survival data which
violates the proportional hazards (PH) assumption. The aim of this study was to
assess: (i) the guidance from HTA bodies in relation to the MA of time to event
survival data; (ii) technology assessments (TAs) submitted to NICE to determine
the level of supporting information relating to the PH assumption accompanying
MAs of time to event data in manufacturer submissions, and the response of
reimbursement authorities. METHODS: HTA authorities guidelines (NICE, PBAC,
IQWiG, CADTH, NCEPO) were searched to identify information relating to the MA
of time to event data used in evidence synthesis. CONCLUSIONS: The guiding
principles for reviewers of the validity of evidence synthesis may result in clinical decisions based on
inappropriate methods.

PHP147
ANALYSIS OF RECENT HTA DECISIONS IN TAIWAN AND KOREA: INFLUENCE
FROM AUSTRALIA AND THE UK
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OBJECTIVE: It was to analyse recent HTA decisions in Taiwan and Korea, and
determine the influence on the outcome by HTA decision in Australia and the UK.
METHODS: This study examined 30 high-cost drugs that were FDA and EMA approved
between 2011-2014. Two-thirds of the sample were oncology drugs, while the remaining one-third included drugs treating multiple sclerosis,
chronic hepatitis C and type 2 diabetes. The HTA decisions of these products in Taiwan
and Korea were analyzed as well as in their frequently referenced countries, Australia
and the UK. RESULTS: Of the 30 products, 24 products were assessed by FRAC.
In Australia and 15 products were evaluated by NICE in the UK, while only 9 products
received HIRA assessments in Korea and 5 products were assessed by the CDE in
Taiwan. The difference in favorable HTA outcomes among these countries was even
greater. Only 2 products received positive HTA decisions in Taiwan and Korea, while
8 and 11 products were recommended in Australia and the UK respectively. Among
the 8 products evaluated by HIRA, and previously assessed by FRAC and NICE, 6 prod-
ducts received positive recommendations, SMC negative decisions and/or NICE, the corre-
lative coefficient between HIRA and FRAC decisions was 0.75. Similarly, all 5 products assessed
by the CDE received similar evaluations to those of FRAC and/or NICE, and the correla-
tion coefficient between CDE and FRAC decisions was 0.8. CONCLUSIONS: Access to
treatment in Asia, even in wealthy countries like Taiwan and Korea, still largely
lags behind Western countries like Australia and the UK. In Taiwan and Korea, where phar-
macoeconomic assessment is a key component in the HTA evaluation, HTA decisions may
be greatly influenced by the HTA outcomes in countries like Australia and the
UK where pharmacoeconomic evaluation is well-established.

PHP148
AN ANALYSIS OF NICE RECOMMENDED IN LINE WITH CLINICAL PRACTICE
HEALTH TECHNOLOGY ASSESSMENT DECISIONS
O'Neill P.1, Chapman AM, Devlin O1

OBJECTIVES: Between January 2007 and September 2014 NICE report that they
have made 65 health technology assessment decisions categorized by them as a ‘recommendation’ (RILwcDFP), of which 35 (53.8%)
were explained and implications for patient access are not clear. Using a previously
developed method, we calculate the degree of recommended access for these deci-
sions. In order to test our methodology, we also develop a taxonomy for the fac-
tors underlying these decisions. METHODS: In a previously published paper we
developed a measure, M, to summarize access associated with NICE technology
optimized appraisal decisions: This was defined as M=pr/F(D,F), where M is a mea-
sure of the proportion of patient access. RESULTS: In total, 108 AMNOG dossiers were
included. Real world evidence was used in 42.6% of these dossiers to assess prevalence and incidence
as well as target populations. German claims data were employed in 8 dossiers (7.4%), registry data in 7 dossiers (6.5%), other data sources like Delphi panels
in 37 dossiers (34.3%). The impact of quality of RWE evidence on negotiated dis-
counts is inconclusive with limited data available. German claims data comprise
comprehensive information such as demographics, outpatient and inpatient care,
prescription data, inpatient and outpatient hospitalization data, inpatient and out-
patient claims data, laboratory data within an electronic health record (EHR) system.
Additionally, routine documentation of diagnoses, procedures and prescriptions as well as
the ability to evaluate patient histories are particularly useful for prevalence
and incidence analysis. Therefore we hypothesize that the use of real world data
which are of paramount importance in price negotiations following the
AMNOG assessment. CONCLUSIONS: German claims data constitute a valuable
and valid data source for assessing epidemiologic evidence in German AMNOG
assessments. Integrating real world claims data analyses are a meaningful comple-
ment to literature research.

PHP149
A COMPARISON OF G-BA'S ADDITIONAL BENEFIT SCORE TO NICE ICERS
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OBJECTIVES: G-BA and NICE are two influential HTA agencies: both are large mar-
kets for pharmaceuticals, many countries look to Germany for reference pricing,
and NICE decisions are referred in other agencies’ assessments. Both agencies
review clinical efficacy versus a comparator. NICE also evaluates the cost-effect-
iveness behind the output of a G-BA review is the “additional benefit” score, while for
NICE it is an incremental cost-effectiveness ratio (ICER). Because both outcomes
are dependent on the clinical evaluation, we hypothesize that G-BA’s additional
benefit score and NICE’s ICER are inversely related. The relationship between NICE
and G-BA is useful for manufacturers trying to predict reimbursement in these
markets and globally. Our objective is to examine how G-BA’s additional benefit
decision correlates with NICE’s ICER decision and to the most probable
incremental cost-effectiveness ratio (ICER). METHODS: G-BA assessments
were matched to NICE final guidelines. G-BA’s additional benefit was extracted and
compared to the NICE ICER using the approach identified: the ICER reported in the
associated ERG/FAD reports in the oncology setting (published 2011–2014) report-
ning MAs of time to event data. RESULTS: Of the guidelines searched, the NICE,
PBAC and DIA guidelines: For evidence synthesis refer to the consideration of
the proportional hazards assumption when performing MA of time to event data.
Of the most recent 60 NICE TAs, seven included the analysis of time to event
data, however none commented upon the PH assumption. CONCLUSIONS: The
impact of the additional benefit score on the validity of evidence synthesis may result in clinical decisions based on
inappropriate methods.