2013 Be
453 DALY/100,000 women.
In Portugal 6.938 new cases of female BC were estimated. A total 1,646 deaths were
1Center for Evidence Based Medicine, Faculty of Medicine, University of Lisbon, Lisbon, Portugal,
GfK, San Francisco, CA, USA
Li J, Asabere A, Kelly S, Cho Y, Dua D, Bastian A
based on data from the Portuguese Institute of Statistics using a social weighting
software. The Years of Life Lost (YLL) due to BC premature mortality were calculated
The average total disease duration by age groups was approximated using DisMod II
DRG Database was queried in order to identify incident cases undergoing surgery.
with specific disutility weights. Data from the Portuguese National and Regional
Economics, Lisbon, Portugal
Li J, Asabere A, Kelly S, Cho Y, Dua D, Bastian A
The study aimed to evaluate the application of the ASCO framework for all recently
approved oncology therapies, including barriers and challenges that may be encoun-
tered. METHODS: Oncology drugs approved from January 2013 to May 2015 (N = 19)
were reviewed to determine if non-randomized trial design, resulting in 22 trials
were excluded due to lack of publication in peer-reviewed journals. An additional
1 trial was rejected due to lack of publication. The findings were applied systematically
corresponding to 16 drugs. OS data was used for scoring in 59% of the remaining trials.
FSS was used in 27% of the trials, and RR in 14% of the trials. Toxicity data was scored
in 95% of the remaining trials, palliation data in 95% of trials, and clinical data in
95% of the trials. The most common scoring issues included measured OS or
PFS not reached (8/22) and incomplete palliation or treatment-free interval data
(5/22). CONCLUSIONS: Lack of peer-reviewed publications, non-randomized trial
design, and clinical data missing lend support to the detriment of application of the
ASCO framework for some oncology drugs. Lack of appro-
priate data may result in lower scores than could be recognized from the available
evidence at time of market authorization.

PCN331
HOW HAS THE SMG PATIENT AND CLINICIAN ENGAGEMENT (PACE) PROCESS BEEN USED IN ASSESSMENTS OF END-OF-LIFE MEDICINES AND MEDICINES TO TREAT VERY RARE CONDITIONS?
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1PRMA Consulting, Fleet, UK, 2PRMA Consulting, Hampshire, UK
OBJECTIVES: To identify decisions by the SMG using the PACE process since the
scheme was introduced, to identify and assess the influence of its success.
METHODS: Assessments that used the PACE process were identified from
SMG briefing notes between May 2014 and June 2015. Key points expressed were
classified into categories for action or added value for the patient or the
clinicians. Twenty assessments were identified that used the PACE process: 17 in oncology
indications and one each in hypertension, infection in cystic fibrosis, and myelofi-
brosis/myelodysplastic syndrome. Ten were accepted (two with rejections) – three that met
orphan criteria, one that met end-of-life criteria, and six that met both. Five products were accepted with restrictions (four with a PAS) and five were
rejected (one with a PAS). All assessments discussed clinical issues, including
effectiveness, cost-effectiveness, adverse events, and the impact on the patient and family.
Fifteen of the assessments were considered to be positive for the disease. Targeted therapies represented 77% of all drugs.
CONCLUSIONS: PAC assessments to date have largely focused on clinical issues and patient's quality of life, with limited attention as yet to the
assessment of severity; 9 characterized the unmet need; 13 considered
data on the severity of the condition (impact on patients, carers and families,
to symptoms (13/20), and reduction in adverse events (11/20). Sixteen provided
research evidence. Ten were accepted (seven with a patient access scheme (PAS)). All assessments discussed clinical issues, including
to symptoms (13/20), and reduction in adverse events (11/20). Sixteen provided
research evidence. Ten were accepted (seven with a patient access scheme (PAS)). All assessments discussed clinical issues, including

PCN352
FEMALE BREAST CANCER: BURDEN OF DISEASE IN PORTUGAL
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Economics, Lisbon, Portugal
OBJECTIVES: This study estimates the burden of breast cancer (BC) on population
health in Portugal in 2013. METHODS: The impact on health status was measured using
the Disability Adjusted Life Years (DALYs). Years Lost due to Disability (YLD) were
estimated following Kruijshaar and Barendregt (2004) and the European
National Burden of Disease Study (2012) for the year 2010. YLD were presented
as a measure of disease burden on the population.
CONCLUSIONS: Breast cancer is a major cause of
disease burden for Portuguese women and should be an important target for health
policy interventions.

PCN333
APPLICATION OF ASCO VALUE FRAMEWORK EVALUATIONS OF NET HEALTH BENEFIT FOR ONCOLOGY DRUGS LAUNCHED IN THE UNITED STATES BETWEEN 2013 AND 2015
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OBJECTIVES: As the emphasis on value of oncology agents grows, ASCO has released
tools to help quantify net health benefit. This study aims to evaluate the application of the ASCO framework for all recently
approved oncology therapies, including barriers and challenges that may be encoun-
tered.
METHODS: Oncology drugs approved from January 2013 to May 2015 (N = 19)
were reviewed to determine if non-randomized trial design, resulting in 22 trials
were excluded due to lack of publication in peer-reviewed journals. An additional
1 trial was rejected due to lack of publication. The findings were applied systematically
corresponding to 16 drugs. OS data was used for scoring in 59% of the remaining trials.
FSS was used in 27% of the trials, and RR in 14% of the trials. Toxicity data was scored
in 95% of the remaining trials, palliation data in 95% of trials, and clinical data in
95% of the trials. The most common scoring issues included measured OS or
PFS not reached (8/22) and incomplete palliation or treatment-free interval data
(5/22). CONCLUSIONS: Lack of peer-reviewed publications, non-randomized trial
design, and clinical data missing lend support to the detriment of application of the
ASCO framework for some oncology drugs. Lack of appro-
priate data may result in lower scores than could be recognized from the available
evidence at time of market authorization.

PCN334
FRENCH HEALTH TECHNOLOGY ASSESSMENT OF ANTI-INFLAMMATORY DRUGS INDICATED IN THE TREATMENT OF SOLID TUMOURS: PERSPECTIVE FOR FUTURE TRENDS
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3Janssen, Issy-les-Moulineaux, France, 4Creativ-Ceutical, Paris, France, 5Aix-Marseille University, Marseille, France
OBJECTIVES: The French system is one of the European countries that spends the most on oncology
drugs. In the context of a cost-constraint environment, Health Authorities highly
scrutinize market access pathways for potentially costly medicines. This study aimed
to conduct a review of the Transparency Committee (CT) opinions on antiinflam-
atory drugs indicated for the treatment of solid tumours to assess current trends in
French health technology assessment (HTA), to confront experts with outcomes of this
review and discuss foreseen challenges for HTA of future antiinflammatory medi-
cines in France. METHODS: A review of CT opinions issued for all antiinflammatory drugs indicated in the treatment of solid tumours and approved between 2009 and 2014 was performed to assess current trends in French HTA. An expert board consultation
was also conducted to capture critical issues on the future of antiinflammatory drugs HTA.
RESULTS: Thirty-one CT assessments were identified. Targeted therapies represented 77% of all drugs. Initial CT assessments
were available for 26 drugs. Efficacy/safety ratio predicted actual benefit (SMR), but
not improvement in actual benefit (ASMR) ratings. Early access scheme for innova-
tive medicines did not impact ASMR score. Four key items in CT assessment were identified: (1) Clinical trial methodology; (2) Acceptance of progression-free survival as a valuable endpoint; (3) Transferability of clinical trials in clinical practice; (4) Lack of proof of efficacy of CT decisions. Future French HTA assessment of personalized medicine in oncology raising many challenges in terms of strategic posi-
tioning, ethics and clinical trial design, to generate information expected from HTA
perspective. CONCLUSIONS: The French system remains committed to its values and phi-
osy (access of all innovations for everybody) which are threatened by the increas-
ing launch of innovative therapies and budget constraint. French HTA decision model
will have to evolve to cope with new challenges raised by oncology drugs.

PCN335
DIFFERENCES AND SIMILARITIES IN HTA: A COMPARATIVE ANALYSIS OF THE DECISION-MAKING PROCESSES FOR CANCER DRUGS ACROSS 4 COUNTRIES
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OBJECTIVES: To identify similarities and differences in HTA decision-making pro-
cesses and outcomes, and explore the criteria driving these decisions in different
settings analyzing a sample of cancer drugs. METHODS: This study applied a vali-
dated methodological framework built on a mixed methods approach to system-
atically compare HTA recommendations for a sample of 15 cancer drugs in four
countries (England, Scotland, Sweden and France). All decision-making criteria were
identified and compared at each stage of the decision-making process: the evidence
appraised, its interpretation and influence on the final decision. Qualitative data
collection and analysis was conducted using the NVivo software.
RESULTS: Across the sample, the same primary trials were generally appraised to determine the treatment's clinical efficacy (93% common to all). From the same trials, heteroge-

ey seen in the subgroup analyses (nsubgroupNICE=25, nsubgroupHAS=15, nsubgroupSMC=11, nsubgroupTIV=7) and number of endpoints considered (nend-
pointNICE=20, nendpointsSMC=23, nendpointsTIV=7). All trials were phase III, 57% of which were open-label. Direct comparators were the most commonly used (73%), the remainder being placebo (28%), standard
care (13%), none (13%) and drugs (sequence=8%). The trials that were presented
cross the 4 agencies, where 53% used the same direct comparator. When interpreting the same trials, NICE classed the highest number of cancers (nuncertainNICE=94 uncertainties), of which 76% were addressed by various means (74% stakeholders input). SMC, HAS and TIV raised a lower number of uncer-
tainties with fewer being addressed (16% of nuncertainSMC=80, 8% of nuncertain-
HAS=38, and 9% of nuncertainTIV=11). CONCLUSIONS: This study enables to better understand the reasons for differences across countries, and whether we can learn from the different ways seen to assess value in different settings. Identifying those