PCN251  THE CANCER DRUGS FUND: A SYSTEMATIC ANALYSIS OF THE REQUIREMENTS FOR INCLUSION ON THE ENGLISH NATIONAL LIST OF DRUGS FOR PRIORITY FUNDING
McNamara L, McNamara S  Roche Products Ltd, Weylin Garden City, UK

OBJECTIVES: The Cancer Drugs Fund (CDF) was set up in 2011 in England to enable patients to access therapies that are not routinely available on the National Health Service (NHS). In April 2013, NHS England became responsible for the management of the CDF with a single national list of drugs for prioritised funding. As the CDF has recently been extended to 2016, it is increasingly important to understand the key clinical attributes of each oncologic that influences the CDF’s decision-making process. This research aims to define.

METHODS: CDF appraisal reports were sourced from the NHS England website (April 2013 – March 2014) and the date, decision, and key rationale were extracted. RESULTS: 56 CDF decision summaries were available, 14 (25%) received full appraisal, 10 (18%) received conditional/restricted appraisal, 28 (50%) were rejected, and 4 (7%) were referred to commissioning. The key clinical attributes of each oncologic were given a numerical scoring that sum to a possible maximum +21 and minimum -4. The maximum score of any drug appraised was +8 and the minimum was -1. Excluding appraisals referred to commissioning, 16/18 appraisals scoring ≥2 were rejected (89%) compared to only ≤2/5 (20%) scoring ≤-2 (4/5 primarily due to trial comparator choice). 9 were not scored due to a lack of appropriate (SACT) data. Appraisals were rejected if only an aspect of oncologic (submissions, efficacy scores were halved), 5 of which were approved. CONCLUSIONS: A score of >-2 seems to be the key clinical threshold above which most drugs are rejected, while below which most are accepted. Given that 43/47 scoring appropriate evidence. 11 submissions were only based on Phase II data (for such positive assessments by IQWiG and G-BA. Beside the study design (H2H vs. indirect comparison) and the format of briefly summarising the decision and drug, with the majority of the article comprising reactions from various sources. However, there was an overall numerically higher number of sources in each article criticizing NICE (38, mean 5.0 per article) than those defending the NICE decision (21, mean 1.1 per article). CONCLUSIONS: NICE decisions not to fund oncology drugs still seem to be predominantly faced by a hostile media reception that focus more on patient restrictions than the difficulties of how to allocate finite health care resources to best optimise care in the NHS.

PCN252  TESTING THE UTILITY OF THE NHS’S SYSTEMIC ANTI-CANCER THERAPY DATA SET FOR MULTINDICATION PRICING
McNamara L, McNamara S  Roche Products Ltd, Weylin Garden City, UK

OBJECTIVES: The price of a medicine should reflect the value it offers to patients, the health care system and society more broadly. However, with current pricing, manufacturers can only set the price of a product based upon the cost per unit of that product. This may result in a price being set which society considers as being too high. This is where a reference price, or value and cost can lead to patients being denied access to medicine in certain indications. METHODS: The implementation of a pricing model where there is differentiated value of a medicine across indications, line of therapy or if used as a mono/combination therapy requires the use of real world drug utilisation data. The Personalised Reimbursement Models project is at the forefront of the development and implementation of innovative pricing approaches in the UK. This project includes identifying and developing the indication specific criteria in order to introduce Multi-Indication Pricing (MIP) into the NHS in the UK. We have worked alongside NHS Trusts and national bodies in a joint working project to validate and test the utility of the Systemic Anti-Cancer Therapy (SACT) dataset.

RESULTS: This joint working project demonstrates that SACT has the potential to allow implementation of MIP in England. CONCLUSIONS: Following completion of this work we hope SACT will be used to introduce MIP in England – this will eliminate the administrative pharmacy burden of data collection for commercial schemes and for cancer medics will enable them to set the value for the product. TYPICAL ADDITIONAL BENEFIT IS GRANTED. CONCLUSIONS: Therefore, the success rate of oncologic products is 80% and much higher than the success rate of non-oncologic products (29%). METHODS: An analysis of all oncologic assessments will reveal key drivers responsible for the positive assessments by IQWiG and G-BA. Beside the study design (R2H vs. indirect comparison), and comparator choice the analysis will focus on submitted end-points. It will be evaluated which endpoints contribute most in oncologic indications to additional benefit. RESULTS: Additional benefit is assessed based on patient relevant endpoints (mortality, morbidity, quality of life & safety). More than 55% of submitted endpoints fall in the safety category, followed by morbidity (approx. 30%), mortality (approx. 10%) and quality of life (approx. 5%). The most important endpoints are ’progression-free survival’ and ’overall survival’. The G-BA granted additional benefit in 18 out of 20 dossiers primarily based on OS data. In terms of morbidity, PFS, ORR, and “Time to Progression” are the top three most submitted morbidity endpoints; however, only “Time to Progression” led to additional benefit in 2 out of 3 cases (progression-free survival in the remaining case). In total, 3 criteria with similar endpoints (% change from baseline) were recommended for all drugs in order of preference: 1) statistical significance of one of the endpoints; 2) specifying the benefit; 3) the line of therapy. However, many agents had additional restrictions on top of this, including 20/80 (25%) specifying the performance status (14 good or better; 6 bad or (2) and 12/80 (15%) to be used within the treating Trust’s governance framework as these drugs were not licensed in the specified indication.

PCN254  COMPARING HOW SINGLE ARM PHASE II TRIAL DATA CAN SUPPORT APPROVAL OF ONCOLOGIES BY EUROPEAN HEALTH TECHNOLOGY ASSESSMENT BODIES
Macaulay R  HERON Commercialization, London, UK

OBJECTIVES: The National Institute of Health and Care Excellence (NICE) makes recommendations on which drugs the National Health Service (NHS) should fund, with cost-effectiveness being a key criterion. There have been critical media reactions toward NICE appraisals that recommend against funding drugs (particularly oncology) that are the most memorable example of which relates to the funding of Herceptin in early-stage breast cancer in 2005. This research aimed to evaluate how the media currently report NICE decision-making, focussing on the NICE appraisal consultations documents during which the media was involved. METHODS: A selection of regional and national newspaper websites, UK broadcasters, press agencies, pharmaceutical industry websites and other websites were included. RESULTS: 7/19 articles were from British newspapers, 6 regional newspapers, 3 broadcasters, and 4 other. 7/19 articles primarily focussed on the reaction of a patient/driver, all of whom were particularly critical of the NICE decision. 3/19 focused on the high proposed cost of the new drug, 2 of which were critical of the pharmaceutical company. 9/19 followed the format of briefly summarising the decision and drug, with the majority of the article comprising reactions from various sources. However, there was an overall numerically higher number of sources in each article criticising NICE (35, mean 6.0 per article) than those defending the NICE decision (21, mean 1.1 per article). CONCLUSIONS: NICE decisions not to fund oncology drugs still seem to be predominantly faced by a hostile media reception that focus more on patient restrictions than the difficulties of how to allocate finite health care resources to best optimise care in the NHS.

PCN255  COMPARING HOW SINGLE ARM PHASE II TRIAL DATA CAN SUPPORT APPROVAL OF ONCOLOGIES BY EUROPEAN HEALTH TECHNOLOGY ASSESSMENT BODIES
Macaulay R  HERON Commercialization, London, UK

OBJECTIVES: The National Institute of Health and Care Excellence (NICE) makes recommendations on which drugs the National Health Service (NHS) should fund, with cost-effectiveness being a key criterion. There have been critical media reactions toward NICE appraisals that recommend against funding drugs (particularly oncology) that are the most memorable example of which relates to the funding of Herceptin in early-stage breast cancer in 2005. This research aimed to evaluate how the media currently report NICE decision-making, focussing on the NICE appraisal consultations documents during which the media was involved. METHODS: A selection of regional and national newspaper websites, UK broadcasters, press agencies, pharmaceutical industry websites and other websites were included. RESULTS: 7/19 articles were from British newspapers, 6 regional newspapers, 3 broadcasters, and 4 other. 7/19 articles primarily focussed on the reaction of a patient/driver, all of whom were particularly critical of the NICE decision. 3/19 focused on the high proposed cost of the new drug, 2 of which were critical of the pharmaceutical company. 9/19 followed the format of briefly summarising the decision and drug, with the majority of the article comprising reactions from various sources. However, there was an overall numerically higher number of sources in each article criticising NICE (35, mean 6.0 per article) than those defending the NICE decision (21, mean 1.1 per article). CONCLUSIONS: NICE decisions not to fund oncology drugs still seem to be predominantly faced by a hostile media reception that focus more on patient restrictions than the difficulties of how to allocate finite health care resources to best optimise care in the NHS.

PCN256  COMPARING ACCESS TO DRUGS THROUGH THE CDF AND BY NICE – THE CDF STIPULATES STRICTER CLINICAL CRITERIA BUT WILL ALSO APPROVE DRUGS FOR LABEL USAGE
Macaulay R  HERON Commercialization, London, UK

OBJECTIVES: The Cancer Drugs Fund (CDF) was set up in 2011 in England to enable cancer patients to gain access to therapies that are not routinely available on the NHS. However, this fund has been criticised for providing funding for therapies that have not been shown to be cost-effective by the National Institute for Health and Care Excellence (NICE). This research aims to compare how such data can further support approval between different European Health Technology Agencies (HTAs). METHODS: Relevant National Institute of Health and Care Excellence (NICE), Scottish Medicines Commission (SMC), Commission de la Transparence (CT), Institute for Quality and Efficiency in Health Care (IQWiG), Federal Joint Committee (G-BA), and Swedish Dental and Pharmaceutical Benefits Agency (TLV) reports were sourced for any oncologic approved by the EMA on the basis of pivotal Phase II data (up to March 2014) and the decision and key rationale were analysed. RESULTS: CT fully recommended 14/14 (100%) oncologies appraised on the basis of pivotal Phase II data, with 10/14 obtaining ASMR I (100%); IQWiG, 6/6 (100%) oncologies appraised on this basis were deemed to offer some added benefit, avoiding reference pricing (5/6 were orphan drugs which are not subject to a benefit assessment). NICE approved 5/7 (71%), SMC 6/11 (55%), and TLV 7/10 (70%) of oncologies appraised on Phase II data. For NICE/SMC/TLV rejected drugs, the lack of comparative data was critiqued as introducing considerable uncertainty to submissions. CONCLUSIONS: for any oncologic approved by the EMA on the basis of Phase II data, favourable ASMR and benefit ratings can be awarded on this basis by the CT and IQWiG/G-BA, respectively. NICE, SMC, and TLV recommendations are conditional on cost-effectiveness being adequately demonstrated with a differential price discounts required to offset inherent uncertainties in cost-utility modelling from such limited clinical data.