to reimbursements, causing a significant growth in costs. Expenses for oncology in 2010 were increased by 8.5% (from €15.4 billion in 2009 to €16.8 billion in 2011), a cost/QALY threshold was introduced to legislation, creating a barrier to the inclusion of oncology drugs to the Reimbursement list. Following adoption of this legislation, of the 12 drugs registered by the EMA, only 3 oncology drugs were included. The total number of drugs which were withdrawn from the list, which was limited to 2011/2012. Uncertainty was introduced in the availability of innovative oncological treatment. The health system in Slovakia needs to introduce efficient and transparent mechanisms that enable the treatment of oncology patients in line with the latest medical findings, while keeping expenses for treatment within economic possibilities.

PCN229

INNOVATION MAY DRIVE STREAMLINED ACCESS TO NEW BIOPHARMACEUTICALS ACROSS SOME EMEA MARKETS

Gardiner EB, White R
Access Partnership, London, UK

OBJECTIVES: Biopharmaceuticals, approval, pricing and reimbursement of pharmaceuticals take place under varying timelines with different outcomes. There are some countries that may obtain access to new pharmaceuticals through early access schemes. Breakthrough and innovative products that are thought to have a profound impact on current standard of care are often eligible for quicker routes to access. This research sought to investigate how these schemes worked, where they were prevalent, and the outcomes of such schemes. METHODS: The research was conducted through in-depth interviews with payers and clinicians across 10 EMEA markets. RESULTS: Of the 10 markets studied, 5 countries were identified to have either easier or quicker routes to access for new biopharmaceuticals (e.g. ATU in France and Italy). Germany is the only country that includes all European Union member states (and the “white list” in Norway). Most often, these routes were reserved for products with orphan indications or products that were believed to significantly impact current standard of care. Breakthrough and innovative companies are often able to get increased access in certain markets. DISCUSSIONS: Access partnerships (with payers and clinicians) may provide increased access in countries where access is normal. The innovation route in Germany may provide increased access for companies in Europe where access is limited. CONCLUSIONS: Access partnerships may provide an opportunity for companies to increase access to innovative treatments and could be a key to accessing markets. As payers and clinicians are increasingly driven by data and evidence, companies must ensure they have a robust package of evidence to support their claims.

PCN230

HEALTH ECONOMIC IMPACT OF VOLUME DOUBLING TIME AS BIOMARKER IN LUNG CANCER: A CASE STUDY

Brinkhoff J¹, Groen HJM², Siesling S³, Izerman M²
¹University of Twente, MIRA Institute for Biomedical Technology & Technical Medicine, Enschede, The Netherlands, ²University Medical Center Groningen, Groningen, The Netherlands, ³Cancer Registry of the Netherlands, the Netherlands.

OBJECTIVES: Lung cancer has a continuously bad prognosis in terms of survival and quality of life, usually because of late detection of malignancies. Given an expected increase in the incidence, overall mortality will increase. Early detection and efficient diagnostic planning may offer additional gain in survival. The purpose of this study was to estimate the impact of lung cancer diagnosis by pathology on patients with suspected lung cancer is characterized by a cascade of different imaging and diagnostic modalities. The main objective of this study is to estimate the health economic impact of diagnostic procedures and the expected outcome in terms of volume of product is lower. Frequently, if products opt for the faster route to access, this will serve as additional evidence for getting the product reimbursed at a later date for use in a wider population. CONCLUSIONS: New pharmaceutical products that are likely to dramatically change the treatment of landscape or are active in orphan diseases should take advantage of these schemes. Physicians grasp at the opportunity to use efficacious products as easily as possible and companies need to leverage the opportunity for streamlined access to products.

PCN231

HOW SUCCESSFUL HAVE PEDIATRIC INVESTIGATION PLANS BEEN IN STIMULATING RESEARCH FOR PEDIATRIC CANCERS?

Miller KL
University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

OBJECTIVES: The European Pediatric Medicine Regulation was created in 2007 to further encourage drug development for pediatric diseases, by requiring pharmaceutical companies to submit pediatric investigation plans (PIPs) when submitting the marketing application for a new drug. The objective of this study was to determine how successful this legislation had been in stimulating research in pediat-}

rnic cancers. METHODS: Current oncology PIPs were manually extracted from the EMA database. From January 2004 to December 2010, all PIPs were reviewed. Data were collected, including the number of applicant, decision, date, and date of expected completion. Indications for approved PIPs were classified into five categories: brain tumors, diagnostics, leukemias, lymphomas, side effects, and solid tumors. RESULTS: A total of 105 PIPs were found distributed across 12 periods of which 38 (36%) were approved. The study found that 39% (27) of approved PIPs were indicated for solid tumors, including melanomas and malignant tumors; 30% (21) of approved PIPs were indicated for leukemias or lymphomas; 12% (8) were indicated for side effects, such as anti-nausea and neurotopriming medications; 12% (8) of approved PIPs were indicated for brain tumors; and one oncology diagnostic PIP was also approved. The ramp-up of the PIP program was significant. PIPs approved in 2013 and first half of 2014 accounted for 54% (37) of all PIPs approved during the study period. CONCLUSIONS: Approved PIPs covered a wide range of pediatric cancers, and the number of approved PIPs increased significantly over time. While the ramp-up of the program indicated success, there were serious concerns in this area, serious concerns remained regarding the feasibility of the program. For example, there were currently four trials planned for completion between 2015-2020 for extremely rare high grade gliomas. This limitation may complicate the integrity of the PIP program.

PCN232

TREATMENT PATTERNS AND OUTCOMES OF PATIENTS DIAGNOSED WITH OVARIAN CANCER IN THE NETHERLANDS: A REGISTRY STUDY

Houben E¹, van Haalen HGM², Sparaebow W³, Overbeek JA⁴, Enzema ND⁴, Pijnborg H⁴, van der Slik K⁴
¹Leiden University Medical Center, Leiden, The Netherlands, ²University Medical Center Groningen, Groningen, The Netherlands, ³Erasmus MC, Rotterdam, The Netherlands, ⁴Lumière Ziekenhuis, Tilburg, The Netherlands

OBJECTIVES: This study is to estimate the health economic impact of diagnostic procedures and the expected outcomes of patients with suspected lung cancer is characterized by a cascade of different imaging and diagnostic modalities. The main objective of this study is to estimate the health economic impact of diagnostic procedures and the expected outcome in terms of volume of product is lower. Frequently, if products opt for the faster route to access, this will serve as additional evidence for getting the product reimbursed at a later date for use in a wider population. CONCLUSIONS: New pharmaceutical products that are likely to dramatically change the treatment of landscape or are active in orphan diseases should take advantage of these schemes. Physicians grasp at the opportunity to use efficacious products as easily as possible and companies need to leverage the opportunity for streamlined access to products.

PCN233

THE FDA BLACK BOX WARNING DOES NOT REDUCE THE USE OF ERYTHROPOIETIC STIMULATING AGENTS AND INCREASES BLOOD TRANSFUSIONS IN INSURED, LOW INCOME CANCER PATIENTS

Noonan V¹, Bennett CT², Wu J³
¹South Carolina College of Pharmacy – USC Campus, Columbia, SC, USA, ²University of South Carolina College of Pharmacy, Columbia, SC, USA, ³University of South Carolina, Greenville, SC, USA

OBJECTIVES: Erythropoietin stimulating agents (ESAs) are useful drugs for treating chemotherapy related anemia to reduce the number of blood transfusions. However, there were unrecognized toxicities of ESAs. These toxicities were finally recognized in 2007 when the FDA issued a black box warning for ESAs. The objective of this study is to determine the effect of the FDA black box warning on ESA use patterns and associated outcomes in insured, low-income cancer patients in South Carolina. METHODS: The merged South Carolina Central Cancer Registry-Medicaid database was used to determine the trend of ESA use from 2001-2010. Female Breast, Colorectal and Non-Small Cell Lung cancer patients were identified from the registry. Of those, their chemotherapy status was identified along with ESA use from Medicaid medical claims. The major outcome measures were claims for use of ESAs after chemotherapy and the blood transfusion rate. Logistic regression was used as a quantitative method to determine if the likelihood of receiving ESA treatment was reduced after FDA black box warning. RESULTS: Among 1,645 patients treated with chemotherapy from 2002-2010, the proportion of chemotherapy patients receiving ESA treatment increased from 56.47% before the black box warning to 63.09% after black box warning (p < 0.001). The blood transfusion rate per year during 2002-2007 remained around 10.15% and increased to 31% in 2009. The likelihood of ESA use was reduced by 35% after black box warning issued by FDA after adjusting for demographic and clinical variables. CONCLUSIONS: The black box warning may have negative effect in reducing overall ESA utilization in cancer patients taking chemotherapy.

PCN234

TREATMENT PATTERNS AND COSTS OF NEOADJUVANT SYSTEMIC THERAPIES (NAT) FOR EARLY BREAST CANCER (EC): A RETROSPECTIVE CLAIMS ANALYSIS

Houben E¹, Santos E², Antao V³, van der Slik K³, Portera C³, Wang V³, Ramath T³, van der Sluis O³, Leenstra AA³, Santos E², van der Slik K³, Portera C³, Wang V³, Ramath T³, van der Sluis O³, Leenstra AA³
¹Leiden University Medical Center, Leiden, The Netherlands, ²University Medical Center Groningen, Groningen, The Netherlands, ³Lumière Ziekenhuis, Tilburg, The Netherlands
OBJECTIVES: NAT for eBC have potential benefits in reducing tumor size, permitting biopsies, and identification of the adenocarcinoma, and providing prognostic information. This study investigated the characteristics of eBC patients' real-world utilization patterns of NAT, and health care costs from diagnosis to primary surgery (neoadjuvant phase) using a US claims database. METHODS: A cohort analysis was conducted. The Medica Plus database included female patients 18+, with the first (index) breast cancer (BC) diagnosis (ICD-9-CM 174. x, 233.0) between July 2006 and September 2012, primary surgery (mastectomy or lumpectomy) after index, continuous enrollment from 180 days before index (pre-index) to 90 days after surgery, no pre-index diagnosis for BC or other primary cancer, and no secondary malignancy from pre-index to surgery. Systemic therapies used by this cohort in neoadjuvant phase were assumed as NAT. Patients with eBC trastuzumab use were presumed HER2+.

RESULTS: Of 57,032 eligible eBC patients (median age 56), 2,011 (3.3%) received NAT. Patients who received NAT had primary surgery in a median of 166 days after index diagnosis vs. 21 days for patients who were not treated with NAT. There were no statistically significant differences between patients with and without NAT in terms of the number of approved off-label regimens by year and cancer type, and the regimen of the most widely used. RESULTS: From Dec. 2006 to 2013, total 203 off-label regimens were approved for their use in 63 hospitals (number of cumulative cases: 16,566). From 2006 to 2012, the number of approved off-label regimens was increased (1, 3, 3, 14, 39, 37, 67, respectively). In 2013, only 38 regimens were approved. Compared with the other cancer, non-Hodgkin lymphoma (50 regimens, 15%), ovarian cancer (10 regimens, 3%), and hematopoietic disorders (10 regimens, 3%), fewer regimens were approved off-label for the number of approved off-label regimens by year and cancer type, and the regimen of the most widely used.

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