

all scoring of drugs varied considerably, with scores ranging from 1 to 13 and with just under half of drugs (7/15) receiving a score of 1 or no score at all. In contrast, the quality of evidence provided by manufacturers varied to a much lesser extent, with the majority of drugs receiving a score of "B" which, according to the scoring system, indicates one good-quality published Phase III randomised controlled trial. **CONCLUSIONS:** Understanding the way the UK CDF makes decisions on the provision of breast cancer treatments can help pharmaceutical companies prepare evidence in order to maximise market access. Identifying strengths and weaknesses in the scoring of previous submissions to the CDF can also optimise submissions to give patients with breast cancer the best chance of access to innovative medicines.

PCN275

SIPULEUCEL-T (PROVENGE®): AUTOPSY OF AN INNOVATIVE CHANGE OF PARADIGM IN CANCER TREATMENT

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OBJECTIVES: Approved by the Food and Drug Administration (FDA) in 2010, sipuleucel-T was the first personalised "cancer vaccine" to treat prostate cancer in the metastatic, non-symptomatic population of 30,000 men in the US. Sipuleucel-T is prepared individually for each patient and infused in three sessions over one-month. In 2015, sipuleucel-T's owner, Dendreon, filed for bankruptcy. This search aimed to review how this innovative product failed to achieve commercial success. **METHODS:** PubMed and internet search focused on pricing, reimbursement and market access. **RESULTS:** Sipuleucel-T's FDA approval was delayed by 3 years, reportedly because of the vaccine's new mechanism of action. Sipuleucel-T was cleared by the European Medicines Agency two years later, but other locations were not approached. It was priced at \$93,000 for a course of treatment. The high price combined with the company's late management of reimbursement of the vaccine by the US Centers for Medicare & Medicaid Services (CMS) resulted in another year of delay in accessing the market. In spite of positive recommendation by the National Comprehensive Cancer Network, sipuleucel-T's complex administration, high price and uncertainty about the reimbursement status deterred doctors from the product. Further, the vaccine's supply was limited during the first year of launch, due to small manufacturing capacity. Two oral metastatic prostate cancer drugs with similar survival benefit reached the US market one and two years after sipuleucel-T. Even though Dendreon's market capitalization topped \$7.5 billion following FDA's approval sipuleucel-T, this value degraded gradually until the firm's bankruptcy five years later. **CONCLUSIONS:** The bankruptcy of Dendreon was largely due to the delay in reaching FDA approval and CMS coverage and the high cost that had to be incurred by providers up-front. Licensing sipuleucel-T to a Pharma company more experienced in the market access pathway may have saved the company and the product.

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A NEW PACE FOR THE SMC?

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OBJECTIVES: Access for oncology drugs can be severely constrained under obligate cost-utility HTA bodies, such as the SMC, NICE, pCODR and PBAC. Indeed the rejection rate for NICE oncology single technology appraisals is over three-times that of non-oncology ones (40% vs. 13%). In April 2014, the SMC announced it would adopt a more flexible approach in its review of end-of-life and orphan therapies. Going forwards, if the initial SMC advice is not to recommend, a Patient and Clinician Engagement Group (PACE) meeting can be convened. This meeting aims to capture the benefits of the medicine outside of the considerations of the conventional process and was anticipated to constitute a "major factor" in the SMC decision. This research aims to evaluate what effect PACE groups have had on SMC appraisal outcomes. **METHODS:** All SMC approvals from April 2014 were identified and the recommendation, indication and whether a PACE meeting was convened was extracted. **RESULTS:** 87 SMC appraisals were identified, 46 were recommended, 26 were approved with restrictions and 15 were not recommended. 25 appraisals were for oncology drugs, 28% of which (7/25) were rejected compared to 13% (8/62) of non-oncologics. PACE meetings were convened in 20 appraisals 11 of which were recommended, 4 restricted and 5 rejected. 19/20 were for oncology drugs, representing 76% (19/25) of all oncology appraisals. **CONCLUSIONS:** This new SMC PACE process is being well utilized, particularly in the appraisals of oncologics, and has resulted in many appraisals that would have been rejected being recommended instead. This has produced more timely market access for patients, without the need for multiple rounds of resubmissions, as was often the case pre-PACE. Nevertheless, rejection rates of oncology drugs still remain substantially higher than for non-oncology drugs.

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THE ITALIAN REGIONAL ACCESS OF NEW CANCER DRUGS: AN EXAMPLE IN FOUR REGIONS

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OBJECTIVES: In Italy, federalism in health system leads to an increasingly fragmented and geographically differentiated Health, often even within the same region and also leads to a long and complex process for drugs market access and to get the access of patients. We conducted a survey in four regions in order to assess the inclusion of new cancer drugs within the regional formularies evaluating the time to access. **METHODS:** Once a drug is reimbursed by the national assessment body (AIFA), a further step consists in obtaining the authorization for reimbursement by the regional health systems (RHS), many of which have their own formulary of reimbursed pharmaceutical drugs. Currently, 16 Italian regions have adopted a regional formulary. The selected Regions for this analysis are Emilia Romagna, Piemonte, Lazio and Sardegna. We considered six new oncology drugs reimbursed by AIFA in 2014, excluding three oncology drugs that bypass the regional evaluation process since they respond to the requirement of therapeutic innovation. **RESULTS:** Nowadays, only the Regions of Piemonte and Emilia Romagna have evaluated all

the 6 new oncology drugs reimbursed by AIFA in 2014 with average times from the national reimbursement decision to the regional one ranging from 3 months in Piemonte to 5 months in Emilia Romagna. The Lazio and Sardinia Regions have evaluated only 1 out of the 6 drugs with an access time of around 2.5 and 6 months, respectively. **CONCLUSIONS:** In Italy, the average times from the national reimbursement decisions to the regional evaluations aiming to the formulary inclusion vary widely between Regions.

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GEOGRAPHICAL DISPARITIES IN COLON CANCER CARE IN EUROPE: IMPLICATIONS FOR ACCESS TO INNOVATIVE MEDICINES VIA THE UK CANCER DRUGS FUND

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OBJECTIVES: To undertake a pragmatic, comparative analysis of cancer care pathways to identify drivers of improving cancer survival across Europe, using colon cancer as a case study. **METHODS:** We conducted a review of data from international, European and UK cancer databases and registries, focusing on the identification of variations in overall and colon cancer care and survival. Additionally, we investigated variation in national access to, as well as utilisation and speed of adoption of, biologic cancer treatments, a recognised source of improving cancer outcomes worldwide. **RESULTS:** Overall, outcomes for many tumour types continue to improve across Europe, including in regions with historically low survival such as Eastern Europe. Data on general cancer treatment reveal that the rate of innovative drug use in the UK has increased since 2009, just prior to the establishing of the Cancer Drugs Fund (CDF). Since the advent of the CDF, the UK has risen internationally from 11th place to 7th in terms of cancer survival rate; however, this improvement still leaves the UK as one of the lowest ranked European countries. Patients with colon cancer are ~20% less likely to receive biologics than those in other European countries; this may explain the results of other studies showing that survival rates in the UK continue to lag behind those in central Europe in the CDF/biologics era. **CONCLUSIONS:** Although survival rates continue to improve, there remain geographical disparities in some cancer types despite major advances in care pathways and treatment. The UK in particular continues to lag behind other countries. The CDF provides a vital service, giving patients access to innovative, life-extending treatments. The threat of losing this access route has serious implications for UK cancer treatment, which is already among the least successful in Europe.

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DRUG USE AMONG ELDERLY IN THE YEAR BEFORE COLON CANCER DIAGNOSIS VERSUS MATCHED CANCER-FREE CONTROLS

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OBJECTIVES: To provide an overview of drugs used by elderly in the year before colon cancer diagnosis and to compare this with a matched control group without cancer. **METHODS:** Data were obtained from the population-based Netherlands Cancer Registry (NCR) and linked to the PHARMO Database Network, which includes complete longitudinal data obtained from out-patient pharmacies. All colon cancer patients aged ≥70 years diagnosed between 2000-2011 were included. Patients were matched 1:1 with controls on gender, year of birth and postal code. Differences in the proportion of users between cases and controls of each drug on WHO ATC-3 level were calculated using Chi2 tests. Drug use was defined in the year before colon cancer diagnosis or cohort entry date and during each quarter of that year. **RESULTS:** The study population consisted of 2,735 colon cancer patients and 2,735 matched cancer-free controls. 90% of cases and 69% of controls used ≥1 drug during the study period. The top 3 most frequently used drugs, based on the highest number of users among cases during the total year, were drugs for constipation (cases vs. controls 58% vs. 10%, p<0.0001), antithrombotic agents (42% vs. 33%, p<0.0001) and drugs for acid related disorders (35% vs. 22%, p<0.0001). For all 3 drugs, the number of users in each quarter was higher among cases. Among cases, the number of users increased during the last quarter of the year for drugs for constipation (10% Q3 to 53% Q4) and drugs for acid related disorders (19% Q3 to 27% Q4). **CONCLUSIONS:** Our study demonstrates higher drug use among elderly colon cancer patients during the year before diagnosis as compared to a matched cancer-free control group, which increased even more during the last three months before colon cancer diagnosis. The effect of specific drugs on cancer treatment and outcome should be subject of further study.

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ANALYSIS OF ERIBULIN MESYLATE UTILIZATION IN PATIENTS WITH METASTATIC BREAST CANCER (MBC) BY LINE OF THERAPY AND ASSOCIATED CHANGES OVER TIME

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OBJECTIVES: Eribulin mesylate is a microtubule inhibitor FDA approved in 2010 for patients with MBC after treatment with at least two prior chemotherapeutic regimens. This study utilized real-world claims data to evaluate the utilization of eribulin mesylate by line of therapy at two and five years post launch to determine the degree to which patterns of utilization by line of therapy and payer type change over time without an associated change in labeling. **METHODS:** Using data from the Cardinal Health Specialty Solutions Revenue Cycle Management medical claims database, patients who received 2 or more eribulin administrations and completed therapy between May 2014 and April 2015 were included in the current analyses (n=368). The distribution of this study group was compared to a similar patient population identified as having completed therapy between April 2011 and