

implemented that will widen innovative contracting opportunities and thus facilitate access, but may also limit pricing. The ability to anticipate payer behaviour and navigate an increasingly complex access pathway will be critical for achieving optimal access for C&T therapies.

PCN284 PRESCRIBING TRENDS ACROSS EPIDERMAL GROWTH FACTOR RECEPTOR TYROSINE KINASE INHIBITORS IN NON-SMALL CELL LUNG CANCER IN IRELAND

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Objectives: Afatinib, erlotinib and gefitinib are epidermal growth factor receptor tyrosine kinase inhibitors (EGFR-TKIs). They are indicated for the treatment of non-small cell lung cancer (NSCLC) with activating EGFR mutations. Erlotinib is also indicated for pancreatic cancer. Erlotinib, gefitinib and afatinib have been reimbursed in Ireland since 2006, 2011 and 2014 respectively. This work aims to describe prescribing trends across EGFR-TKIs in Ireland. It is anticipated that the patent for erlotinib will expire in 2020; the potential cost saving implications of this are examined. **Methods:** Anonymised prescription claims data obtained from the Primary Care Reimbursement Service (January 2006 to April 2019) were analysed using R. The following variables were examined: market share (MS), treatment sequencing and number of patients treated per year. **Results:** Until 2011 erlotinib held 100% of the MS for EGFR-TKIs. Following the launch of gefitinib in 2011 the MS of erlotinib decreased to 91% by 2013. In 2014, afatinib reduced the MS held by erlotinib and gefitinib by 3% and 5% respectively. In 2017 the MS for erlotinib was 71% and the annual expenditure was reported to be €1,218,666. It was found that only 3% patients received sequential EGFR-TKIs, with afatinib followed by erlotinib the most common sequence (N=40). The lowest number of patients (N=150) were treated with an EGFR-TKI in 2018. **Conclusions:** Erlotinib was found to dominate the market share each year despite the subsequent launch of gefitinib and afatinib. A limitation of this study is that the MS reported included patients prescribed EGFR-TKIs for conditions other than NSCLC. The availability of generic erlotinib is likely to result in significant cost savings with the price expected to fall to 50% of the original ex-factory price. However, the upcoming availability of third generation EGFR inhibitors as first-line treatment in NSCLC may have substantial impact on the majority MS currently held by erlotinib.



PCN285 THERAPEUTIC BENEFIT OF ORPHAN DRUGS IN ONCOLOGY: EVIDENCE AT THE POINT OF EUROPEAN MARKETING AUTHORISATION

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Objectives: We analysed evidence on therapeutic benefit of orphan oncology medicines approved in the past five years, at the point of marketing authorisation by the European Medicine Agency (EMA). **Methods:** Orphan oncology medicines authorised in 2014–2018 were identified from the EMA website. Data on trial design, overall survival (OS), progression free survival (PFS), adverse events (AEs) and health related quality of life (HRQoL) were extracted from the European Public Assessment Reports. **Results:** In the last five years, 23 products were approved in 38 rare oncology indications, eight of which were granted conditional marketing authorisation (CMA). Evidence was based on single-arm studies in 67% and 31% of CMA and full approvals respectively, with the remainder based on final or interim results of randomised controlled trials (RCTs). Included were three potentially curative advanced therapies for rare blood cancers which showed a significant increase in complete response rates compared to historical controls. Of those medicines evaluated through RCTs, prolonged PFS (1.2 to 19.9 months) was demonstrated in 64%, prolonged OS (1.0 to 49.2 months) in 36%, and increased number of serious AEs in 77%. Data on HRQoL was available in 64% of RCTs, of which 18% demonstrated improvement. All drugs were subject to post-approval evidence generation or surveillance. **Conclusions:** In rare oncology, particularly in potentially life-saving personalised treatments, demonstration of therapeutic benefit through RCTs is not always feasible, and nearly a half of approvals is based on single-arm studies. Most drugs evaluated in randomised settings demonstrated improvements in progression free survival, however there were frequent increases in serious adverse events. Evidence of overall survival gain was available in less than half of indications. Commitments to post-approval evidence generation were required for all medicines. Further efforts aimed at adaptive approaches to evidence generation are warranted, to ensure timely patient access and to stimulate innovation in medical practice.



PCN286 HEALTH TECHNOLOGY ASSESSMENT DECISIONS OVER THE LAST DECADE IN THE UNITED KINGDOM AND THE NETHERLANDS - A FOCUS ON NON-SMALL-CELL LUNG CANCER

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Objectives: To analyse reimbursement trends by evaluating Health Technology Assessment (HTA) submissions and appraisals made for non-small-cell lung cancer (NSCLC) over the last decade between the United Kingdom (UK) and the Netherlands. **Methods:** A search was conducted in the databases from UK (NICE) and the Netherlands (Dutch Health Care Institute (ZIN)) between January 2008 and December 2018 for NSCLC treatments. Exclusion criteria concerned: 'treatments for small cell lung cancer' and 'treatments available before 2008 or HTA submissions after 2018'. HTA decisions were evaluated by drug class, indication, decision, economic- and budget impact outcomes. **Results:** 29 HTA submissions were appraised for 15 unique NSCLC treatments between 2008–2018. In the UK 76.9% of all HTA appraisals received a positive recommendation for reimbursement, of which 61.5% were conditional on a patient access agreement (PAS). In the Netherlands 25% initially received a negative recommendation for reimbursement by ZIN, however after negotiations with the Dutch government 93.7% of all submissions received reimbursement. The average duration for full HTA appraisals until final decision was significantly shorter for the Netherlands in comparison to the UK: 198 versus 313 days. During this 10 years period the budget impact regulations changed as in 2015 the Netherlands implemented an annual budget impact cap of €2.5 million per year, and the UK implemented in 2017 a cap of £20 million in any of the first 3 years. When exceeded, negotiations for PAS agreements are mandatory for reimbursement in the UK regardless of the incremental cost-effectiveness ratio (ICER), while in the Netherlands the lock procedure for expensive medicines will be started. Both procedures can lead to a longer appraisal process. **Conclusions:** Both countries show an increasing challenging reimbursement environment for NSCLC treatments. The amount of positive recommendations for reimbursement were similar in both countries, whereas the Netherlands showed a higher reimbursement rate after negotiations.

PCN287 THE ROLE OF EFFICACY AND EFFECTIVENESS ANALYSES IN HEALTH TECHNOLOGY ASSESSMENTS IN DETERMINING TENDERING RANKS FOR ONCOLOGY DRUGS IN DENMARK & NORWAY

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Objectives: The Danish Medicines Council and Norwegian Medicines Agency appraise pharmaceuticals on clinical and economic grounds. Following recommendations from these institutions, manufacturers enter tendering processes which result in rankings of drugs within an indication. The influence of clinical outcomes on these ranks in oncology in practice has not been assessed. This review aims to determine whether efficacy/effectiveness assessments from HTAs are a key driver of the rankings in Denmark and Norway. **Methods:** Tendering ranks for oncology indications in both countries as of May 2019 were extracted. Indications where at least two different drugs/regimens were ranked were included. HTA reports for the included regimens were identified from agency websites, and preference orders presented by the appraisers based on clinical outcomes and other reported decision criteria (e.g. cost-effectiveness) were extracted, if reported. Where these not available, overall survival and progression-free survival outcomes were extracted and rank orders generated using surface under the cumulative ranking (SUCRA) method in network meta-analyses. Rank orders based on clinical data and HTA reports were compared to tendering rank orders and reasons for differences explored. **Results:** Across both countries, 26 multiple-regimen ranks were being used in oncology where at least one corresponding HTA had been conducted. In most cases, the most efficacious medicines were included in tendering ranks, but in 38% of indications, efficacy ranks were not aligned with tendering ranks. Possible justification for differences relates to added uncertainty in indirect comparisons and interpretation of clinical evidence. **Conclusions:** The HTA processes in Denmark and Norway allow market access for the most effective drugs, however it appears to have less of a role in treatment prioritisation in oncology. Tendering presents one method for cost containment for pharmaceuticals, but the impact this has on patient access to efficacious treatments in oncology and other indications needs to be evaluated further.



PCN288 HOW IS METASTATIC MELANOMA TREATED IN THE PUBLIC HEALTH SYSTEM IN BRAZIL?: A CALL FOR CHANGE

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Objectives: - To undertake an exploratory analysis of the patients with metastatic melanoma and the treatment they received at SUS between the years 2015 and 2017. **Methods:** - We evaluated the data available at DATASUS, which were originated from the Ambulatory Chemotherapy Information Systems - SUS (SIASUS). In order to retrieve the data, we used the International Classification of Diseases C43 (the ICD for melanoma) and the period comprised between January 2015 and December 2017. These were then reviewed in order to be correctly assigned to treatment groups related to different levels of efficacy. We excluded those APACs that recorded ICD C43 but were related to supportive medications (such as bisphosphonates for bone

