PHP228
THE IMPACT OF LABEL EXTENSIONS ON THE REIMBURSED PRICE OF PHARMACEUTICAL PRODUCTS ASSESSED ACCORDING TO §35A SGB V IN GERMANY - ONCOLOGICAL AND METABOLIC DISEASES
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OBJECTIVES: In Germany, with each label extension the additional benefit of a product is assessed according to §35a SGB V and the reimbursed drug price is renegotiated with the National Association of Statutory Health Insurance Funds (GKV-SpiBu). With this study, we aimed to investigate the price development of pharmaceuticals with at least one label extension and potential factors for price decreases in the therapeutic areas oncology and metabolic diseases. **METHODS:** First, the data from all AMNOG dossiers evaluated by the Federal Joint Committee (G-BA) from January 2011 until December 2017 were extracted. Information on the active substance, product name, therapeutic area, orphan status, decision date, for all dossiers including the initial submission and label extension dossiers, were included in the analysis. In a second step, the product prices of the SmPC recommended packages were taken from the official German database for drug prices (LAUER-Taxe). The initially negotiated prices and negotiated prices after each label extension were then linked to each dossier. Finally, the correlation between price development after label extension and size of patient populations as well as extent of additional benefit was analyzed. **RESULTS:** Altogether, n=102 (oncology: n=77 and metabolic diseases: n=25) dossiers were included into the analysis. Of those, n=80 were non-orphan dossiers and n=22 were orphan dossiers. Mean decrease of product prices after first label extension was -17.8% among all products, -19.5% among oncological and -13.5% among the metabolic disease products. The most common price reduction after first label extension was in the category between 0% and -20.0%. **CONCLUSIONS:** The analysis shows that the negotiated prices decrease with each label extension. Hereby, the price decrease per label extension is directly correlated with the amount of increase in the number of patients and indirectly with the extent of additional benefit. However, it remains unclear which other factors may influence this development.

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EU5 MARKET ACCESS FOR MEDICINES WITH CONDITIONAL MARKETING AUTHORISATIONS
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OBJECTIVES: To examine market access timelines and HTA assessments for medicines authorized via European Commission (EC) conditional approval pathway between January 2009 and December 2017. **METHODS:** Evaluated 17 of the 27 EC approved medicines that still have conditional approval. Analysis does not include 10 medications that have been converted to 'standard' marketing authorization. Data gathered from EMA, national HTA agencies and P&R bodies. Cut-off date for data collection was March 1, 2017. **RESULTS:** 17 drugs approved by the EC between January 2009 and December 2017 currently have conditional approval status. 94% (n=16) of these are new active substances including 2 new ATMPs. 88% (n=15) have an orphan designation and 59% (n=10) are indicated for oncology. ~47% (n=8) have an orphan designation and are indicated for oncology. Only 24% of drugs (n=4) with conditional approval have completed P&R negotiations in Spain and only 41% in France (n=7). Time to market for drugs with conditional approval is substantially longer in France and Spain compared to all drugs (France: 101 weeks vs. 67 weeks, Spain: 135 weeks vs 67 weeks). Analysis of HTA assessment for 7 drugs available in France, Germany and the UK suggest that France and German HTA decisions are not consistent/aligned. For the 2 drugs that received ASMR III in France and were reviewed in Germany, no additional benefit rating or non-quantifiable benefit rating was assigned. In the UK, for drugs assessed by NICE, positive recommendations were issued based on simple discounts or managed access agreements. **CONCLUSIONS:** It is important to recognise that, while conditional approval pathway may result in quicker regulatory approval, it may also result in greater market access challenges, in countries like France and Spain. Engaging HTA bodies at an earlier stage could help speed up patient access.

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EU5 MARKET ACCESS FOR MEDICINES APPROVED UNDER EXCEPTIONAL CIRCUMSTANCES
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OBJECTIVES: To examine market access timelines and HTA assessments for medicines approved under exceptional circumstances by the European Commission (EC) between January 2009 and December 2017. **METHODS:** Analysed medicines approved by the EC that are still authorized under exceptional circumstances. Data gathered from EMA, official national HTA agencies and P&R bodies. Cut-off date for data collection was March 1, 2017. **RESULTS:** 15 drugs approved by the EC between January 2009 and December 2017 under exceptional circumstances. Less than 50% (n=7) are new active substances, including 1 ATMP. 80% of drugs have an orphan designation, whereas only 1 drug (dinutuximab beta) has an oncology indication. Only 20% of drugs (n=3) approved under exceptional circumstances have completed P&R negotiations in Spain and only 40% in France (n=6). Time to market for drugs approved under exceptional circumstances is substantially longer compared to all drugs across the EU5 countries. Analysis of HTA assessment for 6 drugs available in France, Germany and the UK suggest poor appraisal outcomes. Two thirds of the drugs assigned ASMR IV in France. In Germany, of the four post AMNOG drugs, 2 had a non-quantifiable added benefit. Drugs with high ASMR ratings in France (asfotase alfa and cholic acid) assigned non-quantifiable added benefit rating in Germany. Only 1 drug assessed by NICE and recommended with managed access agreement. **CONCLUSIONS:** Unlike conditional marketing authorisation, authorisation under exceptional circumstances is granted when comprehensive data cannot be obtained even after approval. Although this may be a possible pathway for regulatory approval for certain drugs, significant access challenges are likely across the EU5 countries given immature data.

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ADOPTION OF INNOVATIONS IN THE GERMAN DRG-SYSTEM – A QUANTITATIVE ANALYSIS
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OBJECTIVES: Since 2005 the NUB program has been available in the German inpatient sector for introduction of innovative medical technologies. It allows providers to apply for funding in early market phases, after submitting an application for the respective method and appraisal by an independent institute (InEK). Ultimate goal of the process should be transfer into the regular DRG system. Aim of this study was to evaluate the rate of successful transfer of NUB methods into the regular DRG system and investigate patterns of transfer. **METHODS:** NUB applications of the years 2005-2018 were obtained from the InEK database (www.g-drg.de). Data was analyzed according to time from application to integration, number of applying hospitals and final integration route. **RESULTS:** Since 2005, NUB applications for 3110 medical methods were submitted. Out of these, 78 interventions were transferred in the regular DRG catalogue (54 pharmaceuticals, 20 medical devices, 3 surgical procedures, 1 diagnostic). The majority (96.15%) had been classified NUB status 1 before transfer. Mean time between initial application and inclusion was 38.7 ± 22.2 months. Successfully integrated methods had on average 522.6 ± 485.6 hospital applications. Pharmaceuticals had significantly more applications than medical devices (634.88 ± 482.25 vs. 211.87 ± 287.84 applying hospitals, $p < 0.005$) and transfer time was significantly longer (40.70 ± 20.86 vs. 24.45 ± 20.88 months, $p < 0.05$). Most methods were integrated as an add-on fee (88.46%), while the rest received a DRG code. **CONCLUSIONS:** Though the NUB program was introduced to enable market entry for innovations, the permeability of the DRG system is low and rarely leads to long-term funding. Innovators should investigate alternate pathways for sustainable reimbursement. Even among methods with highest status, only 20.66% are transferred into regular reimbursement (75/363). Further investigation is required to improve understanding on the role of demand and therapy diffusion in the transfer process.

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A COMPARISON OF COST-EFFECTIVENESS ASSESSMENTS BETWEEN NICE AND SMC TECHNOLOGY APPRAISALS
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OBJECTIVES: England and Scotland have separate health technology assessment (HTA) programs, usually requiring independent submissions with jurisdiction-specific cost-effectiveness estimates. The objective of this research was to compare cost-effectiveness assessments for National Institute for Health and Care Excellence (NICE) submissions with those for Scottish Medicines Consortium (SMC), and how these affected submission outcomes. **METHODS:** All publicly-available technology appraisal advice was extracted from the NICE and SMC websites from January-2010 to January-2018. Superseded, suspended, terminated, and non-submissions were excluded. Both manufacturers' base-case ICERs and agencies' preferred ICERs were extracted for products assessed by both NICE and SMC, where available. **RESULTS:** As of January-2018, 129 products had been appraised by both agencies across 174 indications. Where reported, manufacturers' base-case ICERs for NICE were generally similar to base-case ICERs submitted to SMC (median: £24,280 versus £24,215, respectively, excluding cases of dominance), but did vary substantially in some appraisals, such as where a different patient-access scheme or subgroup was submitted. Committee-preferred decision-making ICERs were on average 29% higher than the manufacturer's base-case ICER for NICE, but the final decision-making ICER was not generally reported for SMC. While all-but-two evaluated NICE submissions included a cost-utility analysis, 14/174 (8%) SMC submissions were primarily assessed on a cost-minimisation basis. There was evidence for differences in willingness-to-pay thresholds: positive outcomes for submissions reporting base-case ICERs <£20,000 per-QALY were 100% for NICE versus 91% for SMC; between £20,000-£30,000 were 100% versus 79%, respectively; and >£30,000, were 80% versus 73%, respectively. High ICERs were more acceptable to both agencies where decision-modifiers such as substantial survival benefit, innovation, or unmet need applied. **CONCLUSIONS:** Differences in NICE and SMC processes can lead to variations in submission outcomes, due to differing assessments of cost-effectiveness and possibly, willingness-to-pay thresholds. More alignment between NICE and SMC or transparency where methods differ could help reduce discrepancies in patient access between jurisdictions.

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DIVERGENCE IN UK HTA RECOMMENDATIONS: NOT ALWAYS A NICE OUTCOME
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OBJECTIVES: England and Scotland have separate health technology assessment (HTA) programs, with process differences sometimes leading to divergent recommendations. The objective of this research was to characterise trends and reasons for differences in National Institute for Health and Care Excellence (NICE) and Scottish Medicines Consortium (SMC) submission outcomes. **METHODS:** All publicly-available technology appraisal advice was extracted from the NICE and SMC websites from January-2010 to January-2018. Superseded, suspended, terminated,