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arrangements and recommendations at both stages were identified extracting automatically from appraisal documents published using a natural language pro-
cessing model. Results: At NICE, 161/211 (79.6%) were not recommended at the appraisal consultation, and of those not recommended 133/161 (82.6%) were recommended in the final appraisal. Of the 133 where the recommendation changed, 109/133 (81.9%) included commercial arrangements. Since 2004 to 2016, the proportion of assessments including commercial arrangements increased to reach a plateau at 2016 where 96/99 (97%) of all recommended decisions included commercial arrangements. For oncology products, all recommended decisions included commercial arrangements from 2015. Conclusions: Results show that initial recommendations at the appraisal consultation can be overturned at NICE. However, this may require greater financial flexibility from the manufacturer. The proportion of final appraisals with commercial arrangements at NICE has dramatically increased since 2004 to 2019. This could be attributed to increased pressure for cost-effectiveness at NICE. Since 2016, commercial arrangements have almost become a requirement to achieve a positive recommendation, particularly for oncology products.

PNS176
IS THE COROR FOR RWE IN BENEFIT ASSESSMENT IN GERMAN HTA NOW OPEN?
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Objectives: GSW, the German law for more safety in drug supply, stipulates that results of practice data can be included in the pre-assessment of drugs and since 2019 the G-BA may ask for their collection to supplement submitted data. The concepts for generation of routine practice data and their use for the benefit assessment have recently been published by IQWiG. The objective of this study was to critically assess these. Methods: We analysed published evidence and engaged in discussions with internal and external experts in the fields of German assessment methodology, RWE, and statistics, on the proposed criteria for routine practice data generation and their potential use for conducting treatment compari-
sions. Results: In A19-43, IQWiG rules out using EMR and claims data for the benefit assessment, due to limited data availability and inconsistent quality. Disease registries are described as the only suitable tool for data collection for benefit assessment. For non-rando-
mised studies, propensity score methods are described as the main acceptable approach to balance treatment groups. In contrast, other HTA bodies (e.g. NICE) allow for more methodological flexibility when generating treatment effect estimates (e.g. multivariate regression analyses). IQWiG concludes that even following the stringent criteria for establishing a registry and guidelines for confounder adjustment, only evidence of ‘low-qualitative certainty’ can be generated. Therefore, our expert panel recommends exploring the use of EMR or claims data, which may fulfull the outlined quality requirements in some cases, in combination with registries. Conclusions: By not following the rules of the available routine practice data, IQWiG overlooks a data source widely accepted by other HTA bodies. However, the door for RWE in German HTA has now been opened. Other analyses based on propensity score methods, e.g. matched adjusted comparisons may become acceptable in the future.

PNS178
DUAL-BRANDING: A PRACTICAL OPTION TO BOLSTER PATIENT ACCESS TO NOVEL MEDICINES?
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Objectives: Optimising patient access to new medicines is a key priority for healthcare systems, who continually seek value-based approaches for reimbursement of innovative therapies. One such approach is dual-branding for a drug with the same active ingredient. Regulators permit dual-branding if the product meets a specific set of qualifying criteria. Although historically there have been challenges associated with this process, there are potential benefits for payers and healthcare systems. This research aims to assess the value and impact of dual branding on patient access in European markets. Method:
- Eight dual-brand case studies were analysed through secondary research. Insights were validated in thirty-minute interviews with three European payer advisors. Results: Analysis of the key drivers for achieving successful regulatory approval of a dual-brand indicates it is a nuanced process determined by pre-defined qualifiers, which have varying levels of importance depending on the agent and therapy area. If regulatory approval is successful, the launch of a second brand has wide-ranging im-
plications on market access. For example, the launch of cabozantinib’s second brand resulted in multiple benefits for patients, notably improved access in Italy and Spain, and faster time to market in France. However, trade-offs also exist with reimbursement of a dual brand, particularly the cost impact for payers, with manufacturers avoiding the price reduction typically associated with the indication expansion of a single-brand - although interestingly this was not always the case. Conclusions: Dual-branding of drugs can provide value to payers and healthcare systems by improving patient access to novel treatments. However, the three traditional interdependent drivers of reim-
bursement: broad access, time to market and therapy cost, are seldom - if ever - achieved together. Payers will therefore need to carefully evaluate and balance the trade-offs when assessing dual-brands as a feasible and practical option to bolster patient access and achieve patient-centricity.

PNS177
IMPACT OF COVID-19 ON HTA BODIES AND PHARMACEUTICAL COMPANY PRICING AND MARKET ACCESS ACTIVITIES
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Objectives: Health technology assessment (HTA) bodies and pharmaceutical com-
panies have been forced to react to an unprecedented level of disruption due to
COVID-19. This study aims to determine the impact of the COVID-19 pandemic on the processes of European HTA bodies (Transparency Committee (TC), France; G-BA, Germany; NICE, England; SMC, Scotland; AIFA, Italy; CIPM, Spain) and activities of pharmaceutical companies. Methods: NICE, SMC, G-BA, AIFA, TC and CIPM guide-
lines were analysed to assess how COVID-19 has affected HTA decision-making in Europe. Additionally, an online survey of pricing and market access (PMA) employees from a range of pharmaceutical and biotech companies, covering the following key topics was conducted:

- Impact of COVID-19 on access to marketed products
- The company and payer vs. HTA challenges for new products
- Factors that would impact future PMA activities Results: Of the HTA agencies in scope, only the G-BA expected no delays in assessments. AIFA, the TC and CIPM expected some impact on PMA decision making. The SMC and NICE, anticipated severe disruptions to their activities. All respondents acknowledged that COVID-19 is having some level of impact on their company: around 60% of respondents believed the impact on the company to be medium or significant. HTA activities are partic-
ularly disrupted, as 100% of respondents with products undergoing assessment were impacted in some way. For already marketed products, 60% of companies are observing an impact on uptake and/or market access, although only 10% experienced an impact on list or net price. 80% of respondents have had their ability to initiate new PMA projects disrupted. Conclusions: In the short term, main challenges are disrupted timelines, launch PMA activity impacting on marketed products. There is anxiety that continued disruption will lead to tighter healthcare budgets, tougher pricing negotiations, price cuts and unpredictable changes to the wider healthcare system.

PNS159
PRESENTATION OF DRUG DATA — A SIGNIFICANT INFLUENCE ON THE ASSESSMENT OF DRUGS?
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Objectives: The aim of this study is to find out whether and how varying the presentation of statistical key data regarding the efficacy of drugs - tabular vs. text and percentage vs. frequency - has an impact on the perceived benefit. Methods: A questionnaire study asking subjects to assess a new drug relative to an appropriate and percentage vs. frequency - has an impact on the perceived bene-
t. Results: 1200 student subjects participated in the questionnaire. The data show a significant improvement in the rating of the new drug once information is presented in tabular form. By contrast, no distinction can be established between
percentage and frequency. However, once we focus on the presentation as tabular, the effect size of the new drug increases significantly. The information is presented using percentages. Conclusions: The study shows that presenting [favourable] data for a new drug in a table rather than in text, leads to a significantly better rating. Obviously, the way the data are presented entails no fundamental infor-
mation about the value of the new drug. Thus, the observed differences not only highlight an apparent framing effect. They also emphasise an important potential bias in evaluations in key statistical information are not presented in a coherent way once official drug assessments are made. Further analyses about relevance are recommended.